* Event/activity requires a separate ticket purchase. A portion of the proceeds will be donated to the Jette Christensen Early Career Professional Grant.

14:00 – 19:00 | Registration Open
Beat the Monday rush and enjoy light welcome refreshments when picking up your materials on Sunday afternoon!

18:30 – 21:30 | PDA Awards Dinner *(Ticket Required - Cocktail Attire)*
New this year – PDA has opened the annual Awards Dinner to all attendees! Purchase your ticket to join in the celebration and recognition of PDA's world-class volunteers. Start your PDA Week with food, fun, and networking!

---

**Monday, 25 March**

07:00 – 19:00

Registration Open

08:00 – 10:00

*Pre-Meeting Hot Topic Breakfast Roundtables (Ticket Required)*
You asked, and PDA listened! Kick-off your Annual Meeting experience with PDA subject matter experts in these brand-new breakfast roundtables. Participation is limited to ensure a robust and engaging discussion. The Roundtables are guaranteed to sell out, so don’t miss your chance to weigh in on these important hot topics!

Learn more

08:00 – 10:00

*Roundtable 1: Speeding Innovation Through Global Regulatory Convergence*
Industry is often asked the ever-important question, “What regulatory changes would help companies speed drug products to the patients that need them and actively prevent drug shortages?”

As the current process requires multiple, repetitive reviews between regulatory authorities (regional or local), significant delays often slow the introduction of novel, lifesaving products and the implementation of manufacturing innovation. Is there a better way to accomplish the scientific review required for new product applications and post-approval changes?

Learn more

**Moderator:** Amanda McFarland MS Senior Consultant *ValSource, Inc.*

**Presenter:** Glenn E. Wright MA President and CEO *PDA*

08:00 – 10:00

*Roundtable 2: Training of the Future*
The world continues to change with the implementation of greater digitalization and automation, as well as a changing workforce with differing learning styles. With all these changes, what will the training of the future look like? This roundtable will explore these questions and will attempt to answer this very elusive question.

Learn more

**Moderator:** Kate Malachowski PhD Associate Director, MS&T *Novavax*

08:00 – 10:00

*Roundtable 3: 503B Compounding Facilities*
It has been just over 10 years since legislation went into effect that provided the U.S. FDA more oversight responsibility for 503B compounding facilities. Much has changed within this part of the industry, from evolving business models to new guidance and evolving expectations.

This roundtable will focus on the challenges 503B compounders are facing today. It is a chance to come together, have open discussions, and learn from one another. The roundtable will start with a 15-20 min presentation on how the industry in this area is evolving to set the stage for the roundtable discussion.

**Moderator:** Susan J. Schniepp  
Distinguished Fellow  
Regulatory Compliance Associates Inc.

08:00 – 10:00

*Roundtable 4: Early and Mid-Career Professional Development*

**Question:** When should early career and mid-career professionals start thinking about their career and the steps they can take to enable and prepare for future opportunities?

**Answer:** Now, and always!

As the saying goes, if you don’t know where you’re going, don’t be surprised if you get lost. Careers can take different paths, some in the way you desire and some in unexpected ways. Preparing early is the best approach and, while it is never too late to act, it is best to begin preparing early in one’s career.

**Moderator:** Divyang Patel  
Senior Specialist, Commissioning, Qualification & Validation (CQN)  
AtkinsRealis

**Presenter:** Ira Mann  
President and Head of Referrals  
IQ Referrals

09:00 – 12:00

*Dendreon Site Visit*

Dendreon’s Seal Beach location houses both an immunotherapy manufacturing facility (IMF) as well as the corporate and commercial headquarters. Their flagship product was the first FDA-approved immunotherapy to harness the innate benefits of personalized cellular treatment made from a patient’s own immune cells. The 180,000+ square foot (16,723+ square meter) cGMP-compliant and FDA approved IMF specializes in autologous and allogeneic cell therapies.

11:00 – 12:00

Group Power Walk (Free for all attendees and guests!)

Join the PDA Local Host Committee to kick off the meeting with a refreshing group walk! Embrace the opportunity to stretch your legs, connect with fellow attendees, and enjoy the crisp morning air as we explore the local surroundings. This leisurely stroll promises to invigorate both body and mind, setting the perfect tone for the exciting days ahead. Don't miss this chance to network, see the local area, and embark on a memorable journey as we start the meeting together. The walking route will be mostly flat and comfortable. Walking shoes are recommended.

13:00 – 15:00

**P1: Connecting Minds, Transforming Possibilities**

Collaboration can bridge gaps in access to care, facilitate early diagnosis, and ensure timely access to treatments, ultimately improving the quality of life for rare disease patients. This opening plenary of the 2024 PDA Annual Meeting will illustrate partnerships are driving positive, patient-centric change in our industry.

Participants will first hear from Rich Horgan, the Founder, President, and CEO of Cure Rare Disease. Recognized by Insider as one of the “30 Leaders Under 40 Transforming Healthcare in 2020” and, most recently, named on the 2021 Forbes “30 Under 30 List,” Mr. Horgan will share the story of his interdisciplinary collaboration vision. By creating a team of world-class researchers and clinicians, his organization has pioneered a novel framework to enable the development and financing of therapies for ultra-rare, genetic diseases.
Next, Takeda’s Pat Gavit will provide insight into how their Los Angeles manufacturing facility, in partnership with the California Department of Public Health, produces a super-orphaned drug once every five years for infants suffering from infant botulism. Mr. Gavit will share how this transformative medicine is manufactured and the challenges Takeda faces to ensure supply continuity to patients.

Moderator: Amanda McFarland MS Senior Consultant ValSource, Inc.

13:00 – 13:30
Welcome from PDA Leadership and Meeting Co-Chairs

Chairperson: Anil Sawant PhD, MSc Senior Vice President, Global Quality Compliance Merck & Co., Inc.
President: Glenn E. Wright MA President and CEO PDA
Co-Chair: Kenneth Paddock Quality Director, Sterility Assurance Baxter Healthcare
Co-Chair: Susan J. Schniepp Distinguished Fellow Regulatory Compliance Associates Inc.

13:30 – 14:10
The Forgotten 10%: The Silent Rare Disease Epidemic

Presenter: Richard Horgan Founder, President, and CEO Cure Rare Disease

14:10 – 14:30
Overcoming Super Orphan Drug Production Challenges to Provide Life Saving Therapies to Patients

Presenter: Patrick Gavit MS Head of Manufacturing Science Takeda

14:30 – 15:00
Q&A

15:00 – 15:30
Networking Break

15:30 – 17:00
A1: The Multiverse of Manufacturing Challenges
The production of biopharmaceuticals presents ever-evolving challenges, ranging from incremental changes to significant leaps over time. The contemporary manufacturing landscape is currently navigating challenges that necessitate simultaneous attention for the establishment of a forward-looking and sustainable manufacturing approach. In this session, the presenters will discuss the intricacies of manufacturing complex products, strategies to alleviate environmental burdens in production, and innovative solutions for formulation manufacturing.

Moderator: Sebastian B. Teitz PhD Director/Principal Consultant Biopharma Excellence

15:30 – 15:50
Advancements and Challenges in Antibody-Drug Conjugate Manufacturing
This presentation provides insights into Antibody-Drug Conjugates (ADCs), addressing manufacturing challenges, facility implications, regulatory
considerations, and the future of ADCs. Ashley Harp will highlight the growing focus on sustainability, adoption of advanced purification technologies, and the need for enhanced safety protocols due to increasing cytotoxicity. Potential strategies to reduce solvent use, such as continuous chromatography technology, are discussed, along with the imperative for improved containment measures as ADC toxicity rises. Innovative purification methods in the R&D space like membrane chromatography and filtration are also explored for potential in minimizing waste and optimizing processing. In summary, the presentation offers a comprehensive exploration of the ADC market. Ashley will highlight case studies and industry data to help the audience understand the intricacies associated with this industry and offers a path forward, promoting safer, more sustainable, and potent therapies.

**Presenter:** Ashley Harp PE Process Engineer CRB

---

A Path Through the Sustainable Manufacturing Forest

The sources of environmental burden from any manufacturing operation are often obscure or even counterintuitive. Mapping the reality requires a comprehensive and science-based approach. Assessments have been published on the burdens produced in the complete life cycle of biomanufacturing facilities, equipment, materials and processes -with variables as manufacturing scale, geographical setting, product type, and manufacturing mode. Novel construction materials, electrification of facilities, recycling, increased manufacturing process efficiency, and use of green energy sources have reduced environmental burdens of facilities. Difficulties in the application of new materials and methods proposed to reduce the environmental footprint arise from such sources as the evolution of biomanufacturing processes, efficiency of proposed initiatives, and hidden trade-offs of all initiatives. There are also difficulties in the overall definitions, scope, and baseline quantification in considering manufacturing environmental sustainability. These include the different ways environmental stress is assessed, other imperatives, such as cost, and the prioritization by the facility, international consortia, and governing organizations. While there is an inherent environmental impact of biopharmaceutical facilities, it is imperative on us as facility designers and builders to implement effective and cost efficient ways to minimize environmental impacts. The presentation will identify design solutions which have shown enhanced returns on investment.

**Presenter:** Ankur K. Shah PE Lead Process Engineer Arcadis DPS Group

---

Challenges and Solutions to Manufacturing of Ultra-High Concentration Antibody Formulations: Downstream Process to Fill-Finish Processing

Challenges in manufacturing of ultra-high concentration antibody formulations have seldom been discussed. These are observed from late downstream operations where antibody gets concentrated to its final concentration, to final fill finish processing and containerization of the product. Present research is focused on challenges practically observed in manufacturing and processing of ultra-high concentration antibody formulations and provides turnkey solutions to these challenges to have consistent and robust manufacturing process. IgG1 has been used as model protein for studying the challenges associated in manufacturing and providing their turnkey solutions. Challenges in late downstream like increased viscosity limiting further concentration can be resolved by used of viscosity modifying agents in the formulation. Replacement of conventionally used ‘A’ screen membranes with ‘D’ screen. Using single pass TFF further provide advantage in targeting higher concentrations for IgG1 with lesser shear and aggregation. Bilayer or asymmetric membrane instead of conventional 0.2µm membrane resulted in better flux while filtration of ultra-high concentration IgG1 formulation. In process holding and maximum idle time during filling operation was optimized to < 60min based on the nozzle drying time for ultra-high concentration IgG1 formulation. Appropriate control strategy of replacing filling nozzles was proposed for fill finish process of ultra-high concentration IgG1 formulation.

**Presenter:** Vaibhav Deokar MTech, PhD Principal Scientist Lupin Limited

---

Q&A

---

15:30 – 17:00

**B1: QRM: The Evolution, Revolution, and Digital Solution**

The pharmaceutical and healthcare industries are constantly changing, adapting, and advancing: the processes, systems, regulatory aspects – and quality risk management (QRM). In this informative session, experts will delve into the development of QRM and its role in risk-based decision-making and patient-focused
learning culture, the current and future state of QRM through the lens of artificial intelligence (AI) and machine learning (ML), and a case study focusing on a new digital framework and its impact on operational and regulatory compliance through continuous improvement and proactive risk management.

**Moderator:** Stephanie N. Lee MBS Operations Manager Amgen Inc.

**15:30 – 15:50**

**QRM Evolution: Unleashing the Learning Culture Advantage in Line with ICH Q9 R1 Innovations**

The pharmaceutical industry is characterized by rapid scientific advancements and changing regulatory landscapes, making continuous learning and knowledge management critical for ensuring high-quality products targeting optimal patient outcomes. An example of changing regulatory landscape is recent revisions to ICH guideline Quality Risk Management Q9(R1) was released in 2023, bringing further clarity to subjectivity, risk-based decision making, how risk impacts supply and product availability, among other changes. The desired outcomes of these changes are expected to help the industry improve QRM practices, however, there is an associated enabler that is not addressed in the guideline - organizational culture. Successful adoption of ICH Q9(R1) will require aspects of behavioral change by most organizations, such as better recognizing subjectivity, and the need to evolve knowledge management practices, among others. This presentation advocates for a patient-focused learning culture, proposing key attributes that, if embraced by organizations, amplify QRM performance outlined in ICH Q9(R1). These attributes include better subjectivity recognition and advanced knowledge management. By implementing such a culture, organizations can mitigate risks and enhance patient safety, catalyzing the intended benefits of the ICH Q9(R1) revision.

**Presenter:** Lorianne Richter Senior Director, GxP Quality Management Systems ALX Oncology

**15:50 – 16:10**

**Revolutionizing QRM: The Impact of AI and ML**

QRM stands as a cornerstone in the pharmaceutical and healthcare sectors, wielding significant influence over decisions crucial to product quality and patient safety. However, the inherent subjectivity in QRM processes often introduces variability and potential biases. In this presentation, we will explore how Artificial Intelligence and Machine Learning techniques can mitigate subjectivity and enhance the objectivity of QRM. By leveraging AI and ML algorithms, organizations can automate risk assessment, streamline data analysis, and unveil hidden patterns, thereby reducing subjectivity in risk evaluation. Furthermore, we will discuss the integration of AI-driven tools to enhance decision support systems and improve risk communication, ultimately empowering organizations to achieve more consistent and data-driven QRM outcomes. These advancements foster a culture of continuous improvement and proactive risk management.

**Presenter:** Ghada N. Haddad PhD Executive Director, Global Quality Transformation Merck & Co., Inc.

**16:10 – 16:30**

**Digital Transition to a Performance-Based QRM: A Case Study**

In this talk, a successful case study of the implementation of a new digital solution for risk management, in tandem with a revamping of key areas in the PQS is presented with a positive impact on the company’s operations and regulatory compliance. A walkthrough will be made of the journey taken for the design and implementation of this solution: From the analysis and regulatory gap assessment of the current QRM process to the definition of new ways of working and Continuous Verification and Monitoring. This presentation will provide a possible framework for QRM that led to a shift of a company's culture towards risk-based decision-making and improved team collaboration and communication supported by a digital platform. Other benefits reported included the increased control of document and knowledge management, compliance with the new regulatory requirements, increased knowledge of QRM-related concepts, and increased value gained from an approach that is fit for purpose.

**Presenter:** Yowvanaraj Gopal Director Professional Services ValGenesis

**16:30 – 17:00**

**Q&A**

---

**C1: Streamlining the Processes to Enhance Product Quality**
Enhancements in product quality and increased efficiency can result from the integration of alternative production processes. Experts will address platform standardization of physical appearance assessments by providing a clear decision table of method selection based on test sample type, implement processes that can impact both product residual and microbial contamination of equipment surfaces further reducing turnaround times, and discuss strategies for controlling particle contamination using ready-to-use containers.

Moderator: Kenneth Paddock Quality Director, Sterility Assurance Baxter Healthcare

15:30 – 15:50
Platform Methodology to Meet the Needs of the “Simply Complicated” Physical Appearance Assessment

Physical appearance (PA) is an attribute to indicate pharmaceutical product quality. PA is routinely included as part of a release and stability panel of testing, included in the regulatory filing. The assessment of PA of a liquid sample typically includes three tests: visible particulates, clarity, and color. Running the assessment is simple yet complicated: several compendial methods are available, but pharmacopeia does not specify the suitable condition(s) for each method. This is more complicated for vaccine products with various turbidity and color, which typically requires input from subject matter expert. Per 21 CFR 211.194(a)(2) of the current GMP regulations in the US, compendial methods must be verified under the actual condition of use. Improper selection of a compendial method(s) during verification will lead to unreliable results and improper specification setting. In this presentation, we proposed a platform method to streamline PA assessment by providing a clear decision table of method selection based on test sample type. We also provided a case study using a vaccine product with yellow-turbid appearance, to show how pharmacopeia method(s) can be suitable or unsuitable for PA assessment, and how specification should be defined.

Presenter: Ying Wan PhD Senior Scientist Merck & Co., Inc.

15:50 – 16:10
The Role of Cleaning and Associated Processes in Microbial Control of Product-Contact Surfaces

There is an understanding of how cleaning processes for pharmaceutical equipment used in aseptic operations are implemented not only for controlling drug product cross-contamination, but also for the initial reduction in bioburden prior to sterilization. There is also an abundance of references considering the requirements for cleaning processes for the removal of product residues and setting of limits for cleaning validation purposes. However, there is limited guidance on bioburden limits for product-contact surfaces of equipment used to manufacture non-sterile products. This lack of information and regulatory requirements prompts questions on whether it is necessary to have a separate sanitization or disinfection step after cleaning of equipment product-contact surfaces for non-aseptic operations. It would be beneficial to implement processes that can address both product residual and microbial contamination of equipment surfaces further reducing turnaround times. Cleaning processes are an important aspect of a facility’s overall contamination control strategy and play an important role in the facility’s ability to be prepared for production schedule challenges.

Presenter: Antonio F. Ortiz Technical Services Manager STERIS Corporation

16:10 – 16:30
Supporting Annex 1 Particle Reduction Requirements with Ready-To-Use Containers

On August 25th, 2023, the EU GMP Annex 1 for the manufacture of sterile medicinal products came into effect. According to Annex 1 and various summaries (such as the PDA letter from November 2022), Quality Risk Management is crucial. Contamination Control Strategy is a significant area that requires a holistic approach to enhance the quality of the product and ensure patient safety. In this section, we will discuss strategies for controlling particle contamination. The incorporation of isolator technology and robotic systems in the fill and finish area has played a substantial role in reducing particle generation in recent years. Many of these lines are flexible filling lines that work with ready-to-use packaging to eliminate glass-to-glass contact throughout the process, which is a considerable benefit. Additionally, suppliers of primary packaging in a ready-to-use configuration can also significantly reduce particle contamination by reducing the risk already at the introduction into the isolator. SCHOTT Pharma has identified multiple crucial areas to support pharma companies to comply with Annex 1, including quality by design in regards to the ready-to-use packaging and others.

Presenter: Dominique Bauert Head of Business Development SCHOTT Pharma

16:30 – 17:00
Q&A
15:30 – 17:00

D1: The Future of Pharmaceutical Drug and Combination Products: Where are We Headed and How Can PDA Help?
This session will look at how PDA has and will continue to support the future of the pharmaceutical industry, the different types of novel drug products, and how combination products will continue to evolve to serve the needs of patients.

**Moderator:** Glenn E. Wright MA President and CEO PDA

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
</table>
| 15:30 – 16:00 | Ready or Not! The Next Wave of Novel Pharmaceutical Drug Product Innovation is Arriving  
**Presenter:** Michael N. Blackton MBA Senior Vice President of Technical Operations Elektrofi |
| 16:00 – 16:30 | The Brave New Future of Combination Products: What it Means for Manufacturing and the Patients That Use Them  
**Presenter:** Maggie Reiff-Bandel MBA Head of R&D Genixus |
| 16:30 – 16:40 | PDA’s Role in Supporting Industry and Innovation  
**Presenter:** Glenn E. Wright MA President and CEO PDA |
| 16:40 – 17:00 | Q&A |

17:00 – 18:30

Happy Hour in the Exhibit Hall

18:30 – 21:00

Opening Reception
The Opening Reception is included with all Full Meeting registrations. Guest tickets are available for purchase for $75.

**Tuesday, 26 March**

06:30 – 07:00

Group Meditation (Free for all attendees and guests!)
Discover tranquility and start your day with a group meditation session. Amidst the hustle and bustle of the meeting, take a moment to center yourself, clear your mind, and foster inner peace. Join the PDA Local Host Committee and like-minded participants in this serene early morning gathering to awaken your senses and
enhance your overall Long Beach experience. Embrace the opportunity to recharge, find balance, and set a positive intention for the day ahead. Don't miss out on this serene and empowering start to your Tuesday. Casual comfortable clothing and a towel or yoga mat are recommended.

07:00 – 18:30
Registration Open

07:00 – 08:00
Continental Breakfast

08:00 – 09:30
P2: AI and Machine Learning

What’s data got to do with it? As an industry, we certainly have a lot of it, but do we use it effectively and efficiently? Can we learn better from other industries? In this session, we will hear from two experts on big data and how to use and model such data to drive business success and positive patient outcomes.

Moderator: Peter J. Makowenskyj MEng Director of Design Consulting G-CON

08:00 – 08:25
Unleashing the Power of AI in CMC

Presenter: Sara Cook PhD President and Founder IliaCook Consulting

08:25 – 08:50
Integrated Artificial Intelligence, Machine Learning, and Complex Systems

Presenter: Ravi Starzl PhD Adjunct Professor, Language Technologies Institute Carnegie Mellon University

08:50 – 09:30
Q&A

09:30 – 10:30
Poster Presentations and Guided Poster Walk in the Exhibit Hall

On the Guided Poster Walk, poster presenters will give a 3-5 minute "Speedy Talk" about their project or research. Once completed, the poster presenters will have an opportunity to talk with attendees throughout the rest of the break.

09:30 – 10:30
An Alternative Approach to Standard Operating Procedures

The classic paradigm of training and executing SOPs in BioPharma- is to Read and Understand, to observe someone else perform the procedure, and then to demonstrate it yourself. Once this initial training phase is complete, you are left solely with a written SOP to reference. This heavy reliance on written instructions can lead to a higher chance of ambiguity and unnoticed or overlooked errors. My proposed solution aims to address this issue by accommodating diverse learning preferences and seamlessly integrating visual aids, such as videos, directly into procedures. To address this challenge, I have embedded QR codes directly within procedures. This approach enables employees to access instructional videos
quickly and conveniently, providing clear guidance, especially for more complex steps, thus reducing errors and preventing confusion during execution.

**Poster Presenter: Max Falcone** Analyst Tunnell Consulting

09:30 – 10:30

**Manufacturing in Miniature: Drug Delivery via Microneedle Array Patches (MAP)**

Microneedle patch technology has progressed to the pre-clinical and early human clinical stage by many developers, but Kindeva is one of the few companies that has made it to Phase 3 clinical studies and has commercial scale equipment. Kindeva Drug Delivery provides recommendations for process development and manufacturing based on its coated microneedle patch drug delivery platform. Manufacturing process scale-up with intention of regulatory submission follows a strategic path. At each stage (lab bench, pilot, and commercial) it’s critical to document data, decisions, and key learnings in support of a design history file and regulatory submission. Documents should be raised at the time of data generation and cover topics including product development decisions, process development milestones, and device development choices. Likewise, methods and specifications mature during development. Data destined for regulatory submissions should be collected consistently over time. If a method changes, comparison data sets utilizing the two methods and same set of samples should be generated to support the change. Specification setting is also evolutionary, with specifications growing more detailed and narrower as the development proceeds. This evolution will be illustrated through Kindeva’s experience in scale up from lab to commercial scale processes for manufacture of coated microneedles.

**Poster Presenter: Andrew Riso** Director of Business Development Kindeva Drug Delivery

09:30 – 10:30

**Evaluating Your Stopper: Proving Stopper Functionality for Real-World Use Cases Through <USP 382>**

With the upcoming implementation of USP < 382> in 2025, there is an increased emphasis on designing clinically representative experiments to prove that the required, optimal container system is achieved regarding piercing performance and resealability. Not only are medical professionals taught varying techniques on how to pierce a stopper, but industry opinions on the best needle and method have led to more questions than answers. To reduce risk to the patient, it is critical to show that one’s stopper will maintain integrity throughout multiple piercings, or multipuncture, applications through demonstrated resealability performance under exaggerated test methods. Early evaluation will provide confidence that your stopper will be able to withstand the various piercing techniques and reduce downstream risk. This poster highlights a comparative study conducted by West on different stoppers using a modified USP < 382> protocol for fragmentation and coring, penetrability, and resealability. Data will be provided showing how the multipuncture performance of stoppers with different formulations, designs, and sizes is affected by stopper sterilization methods (steam versus gamma) and penetration needle gauge (18G versus 21G). Fragments down to the subvisible level were counted in addition to the ≥150µm particles required in the compendia to align with testing for real-world applications.

**Poster Presenter: Todd D. Jasinski** Senior Specialist, Technical Product Development West Pharmaceutical Services, Inc.

09:30 – 10:30

**Exploratory Assessment of an On-Body Delivery System for Large-Volume SC Delivery: Facilitating Rapid Thermal Equilibration to Ambient Temperatures for Immediate Utilization Post-Refrigeration**

In the evolving field of healthcare, ensuring prompt and efficient medication delivery remains a top priority. This study undertakes an exploratory assessment of an on-body delivery system tailored for large volume subcutaneous (SC) delivery. The design is crafted to accelerate thermal equilibration to ambient temperatures, enabling immediate use post-refrigeration. The movement of the drug through the fluid path is central to warming the drug swiftly to near ambient temperatures. Our analysis dives into the performance and efficiency of this system across varied environmental conditions. The data, which will be shared in detail during the presentation, unveils a significant trimming of the time needed to reach ambient temperatures, thereby potentially reducing wait times and enhancing user experience. These preliminary findings highlight the promise of this system and beckon further exploration to ascertain its real-world applicability and advantages, aspiring to advance the sphere of patient-centric medication delivery solutions.

**Poster Presenter: Mehul Desai PharmD, MBA** Vice President, Medical Affairs Enable Injections

09:30 – 10:30

**Quality Culture: From Buzzword to What Works**
Warning letters consistently cite firms for failing to establish a Quality unit with the responsibility and authority to execute its responsibilities across all GMP systems. With the recent focus on quality maturity models and quality metrics to, in part, ensure the continuity of the drug supply, building a sustainable culture of quality is essential for all GMP-regulated facilities. The term “Quality Culture” has been around for years, but few companies have mastered what it means or how to implement and measure a culture of quality in a GMP-regulated environment. This presentation will provide attendees with an overview of the concepts behind quality culture, as well as some strategies for implementation and metrics for measuring performance.

**Poster Presenter: Sean Lloyd MSc Principal Consultant SRL Pharma Ltd**

**09:30 – 10:30**

Using Toxicological Risk Assessment to Minimize Cross-Contamination

Conducting a risk assessment to evaluate the toxicity of a product helps to ensure patients’ safety and prevent unwanted cross-contamination and recalls. Data from both pre-clinical and clinical trials provides insight on safety margins, adverse effects, and pharmacokinetic parameters (i.e., absorption, distribution, metabolism, and excretion). Toxicologist can determine Permitted Daily Exposure (PDE) and/or Accepted Daily Exposure (ADE) across the product lifecycle and use adjustment factors to address both uncertainty and known toxicities associated with a product. Overall toxicological risk characterization for product development, cleaning validation, manufacturing process, and laboratory testing is critical to ensure patient safety. This talk will briefly highlight some of the regulations, risk assessment process, and provide case-studies to determine health-based exposure limits (HBEL).

**Poster Presenter: Wendy Haines PhD, DABT, ASQ CQA Director of Toxicology & Technical Services PharmEng Technology**

**09:30 – 10:30**

In-Line Real-Time Monitoring of Perfusion CHO Cell Culture Critical Process Parameters and Critical Quality attributes using Raman Spectroscopy and Chemometric modelling

Cell culture processes are complex and highly variable and yet only a handful of key parameters such as temperature, pH, and dissolved oxygen (DO) are typically controlled in real time. While measurement and control of these parameters are essential for a robust process, they provide only broad assumptions on the culture’s true state and offer limited insights into the process and cell growth. In contrast, critical process parameters (CPP) such as glucose, lactate, and key performance indicators (KPI) such as total cell density (TCD), viable cell density (VCD), antibody titer, osmolality provide direct indication of the culture’s content and state. These measurements are typically measured offline, however, and do not provide real-time information or effective process control. This presentation describes use of the MilliporeSigma’s ProCellics™ Raman Analyzer with BioicTM PAT Raman Software (also known as Ramant PAT Platform) to perform inline and real-time measurement of TCD, VCD, Antibody titer, Osmolality and the concentration of glucose and lactate a bench-scale bioreactor.

**Poster Presenter: Ushma Mehta MS Regulatory Consultant MilliporeSigma**

**09:30 – 10:30**

Developing Primary Packaging System for Nanosuspensions: Headspace Design Space Case Study

Suspensions with nanometer size drug particles are a unique drug product dosage form which allow high concentrations of water-insoluble small molecules to be parenterally administered into human bodies to treat difficult diseases. They are typically packed in pre-filled syringes (PFS) or glass cartridges with a desired level of container closure integrity (CCI) to protect them from oxygen and microbe ingress. Headspace (HS) is an important attribute that needs to be well controlled during the filling of the nanosuspensions into glass primary containers. This case study highlights two important factors in relation to headspace within a primary pack containing a nanosuspension product: 1) The importance of a maximum allowable headspace given the impact this has on stopper movement and therefore on the primary packaging system's sterility performance; 2) The minimum headspace requirements for nanosuspension products as they need to be well resuspended prior to drug product administration. Thus, the headspace needs to be optimized within a certain window to ensure adequate sterility and achieve the desired dosage. In summary, this case study serves as a good example of a balanced approach on developing challenging primary packaging solutions for this unique parenterally administered nano-suspended drug product dosage form.

**Poster Presenter: Liang Fang PhD Associated Director, Primary Packaging GSK**

**09:30 – 10:30**
Benefits of Single-use for ATMPs in Regards to Annex 1

The presentation will give an overview about technical standards and trends. The presentation highlights regulatory aspects, e.g. EU-GMP Annex one and will also touch the field of aseptic risk reduction and will show how to increase the quality of sterile drug manufacturing. Annex 1 drives technical solutions for ADCs / ATMPs more and more towards:

- Isolators / Containment Isolators - Single-Use and Ready-To-Use components
- Automated or at least semi-Automated processes for better reproducibility

Human interventions are to avoid, to eliminate potential contamination risk factors. Standardized documentation according to latest norms are required. Why does single-use and ready-to-use best possibly comply to EU GMP Annex 1 Why does single-use specially make sense in dealing with new types of medicinal products like ATMPs and ADCs. What are market standards and trends and where is pharma manufacturing moving to.

Posters:

**Poster Presenter: Juergen M. Metzger** Product Specialist/Senior Consultant Final Filling Sartorius North America Inc.

**Poster Presenter: Carolina Gonzalez Gaitan PhD** Parenteral Packaging Scientist Genesis Packaging Technologies

**Poster Presenter: Chad Hafer MEng** Senior Manager Aseptic Operations Kindeva Drug Delivery

**Poster Presenter: Alex J. Kappani** Product Management SKAN AG

**Poster Presenter: Mehul Desai PharmD, MBA** Vice President, Medical Affairs Enable Injections
09:30 – 10:30
System-Based Drug Manufacturing Inspections: An Inspectional Approach to Help Assure Readiness

System-Based cGxP Inspections review the establishment of the quality system used by an organization. Such audits look at a particular system which includes multiple processes and can spread across several employees and departments. This presentation provides an overview of the system-based approach to auditing (and inspections), demonstrating how the main parts of the pharmaceutical or healthcare organization can be divided up into interrelated systems. By assessing performance through the systems approach, the auditor is able to establish: • Is the organization following the established procedures, processes and standards? • Are the personnel involved knowledgeable, and familiar with regulations and all appropriate procedures, processes and standards? • Is documentation available demonstrating training, monitoring, and compliance programs? • Is data from the various parts of the quality system being evaluated to make appropriate risk-based decisions? In terms of the core systems, the six systems represent comprehensive and rational categories in relation to the different standards to which an organization needs to adhere. The systems provide an indication to an auditor as to the overall performance of the organization and across all areas of manufacturing.

Poster Presenter: Mitchell A. Wheeler ASQ CQA, CMDA, CPGP, CMQ/OE Senior Quality Consultant PharmEng Technology

09:30 – 10:30
Developing a Risk Score for Critical Suppliers Using Artificial Intelligence (AI)

The modern economy is familiar with many examples of risk scores, like credit scores, insurance scores, and more. Supply chains are one area where risk scores haven’t yet been fully developed and utilized. In the pharmaceutical industry, where the supply chain has a direct impact on patient safety and health outcomes, supply chain risk scoring is of particular importance, yet as an industry, we have a lot of progress to make. With more data available than ever before, plus the capabilities unlocked by AI and ML, pharmaceutical sponsors can now accurately score the relative risk of all of the organizations upstream from them, like CMOs, API manufacturers, and excipient manufacturers. Takeaways: - Which variables should be used to calculate pharmaceutical supplier risk? - What are some roadblocks to developing a supplier risk score and how can they be overcome? - Entity resolution - you can’t accurately calculate a risk score for a particular entity unless the dataset you’re using has appropriately resolved all of the permutations of the entity name into one profile. - How those variables interact with one another (i.e. how do you score a warning letter and the 483 that preceded it?)

Poster Presenter: Michael de la Torre CEO Redica Systems

09:30 – 10:30
Maintaining Superior Viral Vector Recovery in Cell and Gene Therapy Applications by Using Daikyo Crystal Zenith® Vials

AAV8 and AAV9 were chosen as representative adeno-associated virus (AAV) serotypes, with respective titers in a common buffer formulation, and evaluated in different 2mL vial types: Daikyo Crystal Zenith® (CZ) vial, and two commercially available borosilicate vials. To simulate viral vector recovery in cell and gene therapy applications, the vial combinations were tested across five challenge conditions: 1. 3 months at -80C, recommended condition for long term storage 2. 2 months at 5C, recommended condition for temporary refrigerated storage 3. 3 weeks at 25C, simulating room temp clinical ambient conditions 4. 72 hours of 250RPM agitation, to mimic handling during manufacturing/shipping 5. 5 cycles of Freeze/Thaw, to mimic handling during manufacturing and the potential for structural damage to proteins or DNA In all conditions, the Daikyo CZ vial demonstrated improved viral vector recovery compared to borosilicate glass vials. The data shows that there were no significant changes in product quality due to container storage in the Daikyo CZ vials, and that the CZ vials may comparatively improve viral vector recovery across common storage and handling conditions.

Poster Presenter: Vidya Murthy PhD Director, Strategic Marketing, Advanced Therapies West Pharmaceutical Services, Inc.

09:30 – 10:30
A Model for a Risk-Based Deviation Investigation Process

Deviation investigation process owners often find themselves swamped with investigations, lacking quantitative tools that allow them to discriminate between minor low-risk events and critical high-risk deviations. Additionally, the business processes that support deviation investigations are often not purpose-built to enable the speed and investigational rigor that allow for timely closure and effective corrective action. This talk will present a proven model for building a quantitative risk-based deviation classification system and will discuss assigning investigational tools to assigned deviation risk levels. Supporting business processes will also be discussed, including professionalizing deviation investigators as an expert role within an organization as well as developing daily operational practices and metrics for effective management of the deviation lifecycle: identification,
assessment, investigation, assignment of corrective/preventive actions, and approval/closure.

**Poster Presenter:** Aaron Hubbell Director, Life Sciences Barry-Wehmiller Design Group

---

09:30 – 10:30

Evaluation of New Sterilization Modalities that Enable Terminal Sterilization of Parenteral/Injectable Drug Products Traditionally Filled by Aseptic Manufacturing

Sterile manufacturing of parenteral/injectable drug products is accomplished by either aseptic manufacturing or terminal sterilization, the latter preferred and recommended by regulatory bodies. Product and container closure compatibility with moist heat normally dictates if the product is Aseptically Manufactured or Terminally Sterilized. New technologies and sterilization modalities were evaluated with the goal of broadening the drug product/container closure compatibility assessment. Studies demonstrated new technologies enable conversion of drug products currently Aseptically Manufactured to Terminally Sterilized, thereby reducing manufacturing cost and reducing lack of sterility risks. This presentation will highlight testing of several sterilization modalities, results, and next steps.

**Poster Presenter:** Terrence Hollis Senior Manager, Global Technology and Engineering Pfizer Inc.

---

09:30 – 10:30

The Challenges of Testing Bacterial Spores in Disinfectant Coupon Studies to Meet CCS Compliance

This presentation will cover the complexities of designing a robust and effective disinfectant coupon study. The presentation will present new novel data showing that the testing of bacterial endospores at different time points will always have the presence of the spore stage as well as the vegetative state of the spore forming bacteria. The presentation will cover how to implement an effective disinfectant validation program as part of the contamination control strategy. Risk assessments will be covered as effective methods of determining the coupon surfaces and microorganisms to include in the coupon study. The overall scope of the presentation will cover all key aspects of a well-planned out disinfectant validation study that compliments the contamination control strategy.

**Poster Presenter:** James N. Polarine MA Senior Technical Service Manager STERIS Corporation

---

09:30 – 10:30

Breaking Out of the Human Factors Study Loop, For the Benefit of Patients

Human Factors Engineering (HFE) is a critical component of development and life cycle management for combination drug products. Human factors (HF) studies assess whether combination products are safe and effective and, when properly designed, can eliminate millions of dollars in future life cycle management costs. These studies seek to understand how patients interact with products, what patients expect from products, enable manufacturers to design out risks, and ensure positive patient outcomes and compliance. HFE is never a one-and-done activity. It involves an iterative series of experimentation, testing and qualification. Each HF study yields new observations and options for continuous improvement. This can create a loop which, if not managed properly, can delay the implementation of design improvements and instructions that will benefit patients and users at all stages of a product’s life cycle. This presentation will discuss how principles of Use Related Risk Analysis have been incorporated into autoinjector HF studies ranging from early prototypes to on-market products. It will present a process which balances the iterative process of HF engineering with focus on the end goal, delivering outcomes for patients.

**Poster Presenter:** Amy Lukau Senior Human Factors Lead Kindeva Drug Delivery

---

09:30 – 10:30

Design Verification Testing of Auto-Injectors: Performing All Tests on a Single Unit to Reduce Sample Quantity and Increase Testing Throughput

The development of combination products requires verification of the performance of the devices to meet the design input requirements. For an auto-injector, particularly an auto-injector that was designed by a medical device manufacturer but is being sold as part of a combination product by a drug company, it is important to perform design verification to ensure that the combination product meets the design requirements for the specific combination. While relevant testing must be deduced from a risk-assessment performed on the particular drug-device combination, guidance documents (like ISO 11608-5:2022 Needle-based injection systems for medical use — Requirements and test methods — Part 5: Automated functions) can serve as useful starting points for determining characteristics that require testing. This poster addresses the test methods developed and validated through a Gage R&R study, using devices or surrogates, as needed, for verifying the performance characteristics of an
auto-injector using commercially available force testing equipment with specially designed add-ons that enable the performance of a battery of tests on a single auto-injector, thus generating statistically significant datasets with minimal sample sizes.

**Poster Presenter:** Mike Ulman PhD Technology Manager, Packaging and Delivery Systems *West Pharmaceutical Services, Inc.*

---

**09:30 – 10:30**

Transforming Deviation Management for Expedited Closure and Product Release in Cell and Gene Therapy

This case study, conducted in partnership between a prominent cell and gene therapy manufacturer and a consulting firm, sought to streamline the deviation management process within the organization. The main goals were to define ownership in the process and enhance departmental knowledge and skills resulting in expedited deviation closure, while maintaining a high level of Quality. A detailed examination of the deviation lifecycle included identifying communication gaps, delays resulting from information or decision bottlenecks, and the non-value-added activities in the process. This analysis, enriched by stakeholder involvement, led to the creation of an innovative workflow engineered to promptly resolve low-level deviations within a challenging 24-hour period, or ideally during the same manufacturing shift. To ensure a seamless integration, training sessions were deployed to ensure personnel were aligned with the new workflow and overarching site goal. In the initial weeks following go-live of the new workflow, the data showed a two-thirds reduction in the overall cycle time for low-level deviations. This was a substantial step towards reducing deviation closure time, along with allowing more time to focus resources on critical issues. Importantly, there were additional improvements in the pipeline, which, when implemented, were expected to streamline the process further.

**Poster Presenter:** Christian Spiak Principal Consultant, Human Performance Business Area *CAI*

---

**09:30 – 10:30**

High Yield Sterile Filtration of High Viscosity Pharmaceutical Formulations

Sterilizing pharmaceutical products is essential for patient safety and is typically achieved using terminal sterilization methods. In the case of high viscosity formulations, terminal sterilization is often avoided as it can inadvertently change product attributes. Using commercially available 0.2um sterile filters for viscous formulations remains limited due to significant challenges dictated by the filter design and operating ranges. In this work, a validated high pressure sterile filtration (HPSF) skid is presented as a method to successfully sterilize viscous formulations without compromising patient safety. This system has been used to filter solutions used as medical devices and active pharmaceutical ingredients (API) and is validated in accordance with regulatory guidance. Formulations of sodium hyaluronate (NaHy) with molecular weights of 900 – 2,000 kDa, concentrations as high as 30mg/mL, and viscosities up to 1,000,000 cps were examined. When comparing the filtration yield of a 10mg/mL NaHy solution with 900kDa molecular weight on a commercially available capsule filter to HPSF, the flux with HPSF was three orders of magnitude higher. Additionally, HPSF did not result in concentration differences between unfiltered & filtered solution in contrast to low pressure filtration. HPSF can fast track development and accelerate bringing early phase formulations into the clinic.

**Poster Presenter:** Jack E. Kochevar Process Engineer *Lifecore Biomedical*

---

**09:30 – 10:30**

Supply Chain Verification for API Manufactured by a Third Country

This poster explains the Supply Chain Verification and Risk assessment carried out by Qualified Persons for API imported from a Third Country.

**Poster Presenter:** Farah Nadeem QP Trainee *Paul Palmer Ltd*

---

**09:30 – 10:30**

Data Analysis – Trending and Pattern Recognition for Contamination Control

The regulations are evolving, EMA Annex 1 earlier versions did not mention trends, the current draft version mentions it 23 times. WHO, and FDA also talk about trending, root cause analysis, investigation, and using the data for these purposes. Trending the data is now a regulatory requirement but what trends should we use? This presentation will discuss how often we should trend, what events should trigger trending, root cause analysis, and investigations. Also, which trend tools should we use for the different contamination control processes, cut off method, Control charts (Shewhart, etc..), Quantiles, percentiles, Weibull distribution, scatter plot, regression analysis for slope (upward/downward trends). FYI... Would present as a lightening talk as well.

**Poster Presenter:** Susan B. Cleary EMBA Director of Product Development *Novatek International*
09:30 – 10:30

Behavior of Molded and Tubular Vials During Depyrogenation

Depyrogenation is a key step in the aseptic filling process. Dry heat depyrogenation is the method of choice for glass vials. Most depyrogenation tunnel manufacturers consider the power necessary is proportional to the weight of glass vials. This study shows the reality is different for small vials below 30 ml. An industrial depyrogenation tunnel was used, filled with 100H molded vials and in the center of the conveyor, in the same row two 20R, two 20H and two 20H EasyLyo. The temperature was monitored with thermocouples. The temperature curves for molded and tubular 20ml vials are close and similar. The times recorded to achieve the 3 log reduction were 18 min13s for the tubular vials, 19 min28s for ISO vials and 19 min 37s for EasyLyo vials. The accumulated destruction factors FD for these 2 vials are significantly equivalent. There was no direct correlation between the weight of vials and the energy needed for depyrogenation for glass vials below 30ml. The measured time to achieve a 3 log reduction did not differ by more than 8%, while the weight difference was 70%. This understanding opens new perspectives for drug manufacturers in terms of sustainability and machinability.

Poster Presenter: Jingwei Zhang PhD Group R&D Director SGD Pharma

09:30 – 10:30

High Cell Density Cryopreservation for Upstream Process Intensification Using LN2 Vapor Phase Stored Seed Train Intermediates

Standard seed train operations start by thawing of a single 1 ml vial with cell densities of 10 x 10⁶ VC/ml. For reaching a sufficient absolute cell number for production bioreactor inoculation, several expansion steps, starting with shake flasks, need to be performed. These open cell culture operations result in long ramp up times, high room classifications during the whole process, and are a major source of process variability. High cell density cryopreservation is a method where cells can be frozen in bags with cell densities higher than nowadays standard processes. This leads to the advantage that cell expansion and batch production can be separated. Lower room classification for the cell culture area in GMP manufacturing might be a result due to the reduction of manual handling steps before the main stage bioreactor (closed processing). Furthermore, these intermediates allow global distribution from a central expansion facility to decentralized global production facilities. Currently, we have demonstrated that SU bag assembly was modified to withstand liquid nitrogen vapor phase storage and the process of freeze and thaw was also optimized to maintain cell performance and SU bags integrity after thaw.

Poster Presenter: Ushma Mehta MS Regulatory Consultant MilliporeSigma

09:30 – 10:30

Aseptic Transfer of RTU Containers in the Light of the New Annex 1

The poster will compare the different methods on how to introduce RTU Containers into the aseptic environment with focusing on the operating, sterility and validation principle. Transfer methods as H₂O₂, NTT, Ebeam and pulsed light are being compared. These methods will be put into conclusion with then next Annex 1.

Poster Presenter: Christian Thieme Sales Director - Americas groninger & co. gmbh

09:30 – 10:30

Implementing a Disinfectant Program for Advanced Therapy Medicinal Product Manufacturing

In a fast-paced, rapidly evolving environment like Advanced Therapy Medicinal Product (ATMP) manufacturing, it is easy to overlook critical elements necessary to maintain contamination control. However, despite urgent manufacturing procedures, a sound strategy for contamination control is essential to help ensure microbiological safety and final product integrity. A cleaning and disinfection program must address the unique challenges within ATMP including addressing the special considerations often found within these facilities such as limitations with available resources and critical time-sensitive procedures. Implementing a program that can be adaptable to the unique environment of specialized procedures that incorporates the consideration of smaller processing suites, biosafety cabinets and isolators is key. A well-designed program that is not overly complicated yet focuses on a holistic contamination control approach focused on the challenges in the ATMP environment is essential.

Poster Presenter: Dan A. Klein MA Senior Manager, Technical Services STERIS Corporation
09:30 – 10:30

Cleaning Considerations for Lipid Nanoparticles
The advancements in lipid nanoparticle (LNP) delivery systems have been paramount in the performance, stability, safety, and eventual regulatory approval of novel drugs and vaccines, such as the mRNA COVID-19 vaccine by Moderna, Pfizer/BioNTech, and others. These encapsulated LNPs can deliver drugs using a wide range of sizes based on the LNP components and route of administration. However, the lipophilic nature and complexity of LNPs can present difficulties in the cleaning process. Laboratory cleaning models can be used to efficiently screen cleaning agents and define critical cleaning parameters. The presentation explores the concerns with cleaning drug products utilizing lipid nanoparticle delivery vehicles and provides general cleaning recommendations based on laboratory and field testing. Reference: https://www.pharmtech.com/view/considerations-for-cleaning-lipid-nanoparticles (June, 2022)

Poster Presenter: Paul T. Lopolito Technical Services Director STERIS Corporation

09:30 – 10:30

Fused Quartz Vials: from Glass Science to Drug Containment Solution
Glass is the most used material in pharmaceutical packaging, and borosilicate is currently the most used among those described by the Pharmacopoeia(s). The USP, however, has recently enacted changes to their glass packaging chapter < 660> that enable the introduction of new glass compositions, one of which is fused quartz. While new to the USP chapter, fused quartz has been manufactured for well over one hundred years, valued primarily for its high purity and remarkable properties, including a very low thermal expansion coefficient and excellent chemical durability. This presentation will address the science behind fused quartz vials, with focus on assessing their chemical, physico-chemical and mechanical performances. Although fused quartz is generally considered chemically inert, the selection of any container must always be done taking into consideration the individual drug product and processing requirements. The knowledge of this new glass and of relevant analytical testing can continue to accelerate its adoption as a container for parental preparations and on its classification inside the three main Pharmacopoeia and standard setting organizations like ISO and ASTM. The experts at Stevanato Group and Momentive Technologies are excited to see this “new” glass help solve many of the industry’s most demanding formulation challenges.

Poster Presenter: Serena Panighello EMEA TEC Research Scientist Stevanato Group

09:30 – 10:30

Glass Containers Under-filling: E&L Benchmark of Different Glass Vials
USP < 660> for glass surface chemical durability test prescribes the nominal filling volume as 90% of glass container brimful capacity. Many glass containers for injectable solutions are filled less than this nominal volume which leads to an increased level of E&L, as the surface/volume ratio is increased. We studied the chemical stability of tubular and molded vials in this situation. The study performed a benchmark of E&L levels and pH shift for 3 vials of nominal volume 10ml: tubular, type I molded and type I molded treated with ammonium sulfate. Filled with 10ml and 4ml NaCl 0.9%, the vials went through 1, 2 and 3 cycles of autoclave, followed by extractable analysis by ICP (Inductively Coupled Plasma Atomic Emission Spectrophotometry) and pH measurement. For all types of vials, 4ml under-filling led to a higher pH shift and higher extractable level than nominal filling of 10ml. For the same filling level and autoclave testing, treated molded type I were the most performant in terms of pH stability and E&L levels, followed by type I molded. Tubular vials showed the highest E&L levels and pH shift. Considering the industry practice, type I molded vials is the most relevant choice.

Poster Presenter: Jingwei Zhang PhD Group R&D Director SGD Pharma

09:30 – 10:30

A Holistic, Phase-appropriate Analytical Approach for Establishing Residual Host Cell Protein Specification Throughout the Cell Therapy Drug Product Lifecycle
Residual host cell proteins (HCP) are low-level genomic protein residuals produced from process- or drug-related materials in manufacturing cell therapies. HCP residuals are organic process impurities per the International Conference on Harmonisation (ICH) Q3A/B guidelines (ICH, 2006). These residuals pose a risk to patients’ immunogenic responses while affecting drug efficacy and stability. Drug developers must comply with the United States Pharmacopoeia (USP) < 1086> and < 509> to detect HCP residuals, limiting 0.05% per day of active pharmaceutical ingredients (USP, 2015). Drug release criteria only require HCP results in phase 2 (FDA, 2020). Following phase 2, Biologic License Application filing requires more rigor toward product characterization. To implement a phase-appropriate analytical strategy for cell therapy development, HCP residuals are first identified using a conventional Western size-based assay or a Quadrupole/Time-of-Flight Mass Spectrometer (QTOF-MS). The first method option is far more feasible to execute and collect sufficient data than the latter. Following the 21 Code of Federal Regulations 610.9
(FDA, 2023), multiple QC samples were utilized for method development, validation, and phase 1 sample analysis. We developed a practical and ideal enzyme-linked immunosorbent assay for QC implementation and met the ICH and USP requirements to support phase 2 trials and commercialization.

**Poster Presenter: Michelle Tseng PhD** Senior Director *Azur Group*

<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:30 – 10:30</td>
<td>A New Calibration Technique for Light Obscuration Sensors to Improve Counting Accuracy of Aggregated Proteins</td>
<td>Mark Bumiller, Technology Manager <em>Entegris, Inc.</em></td>
</tr>
<tr>
<td></td>
<td>Identification of Foreign Particulate Matter in Assembled Autoinjectors Through Long-Time Tracking of Individual Particles’ Trajectories</td>
<td>Matthias Kahl, Head of R&amp;D and Lab Services <em>WILCO AG</em></td>
</tr>
<tr>
<td>09:30 – 10:30</td>
<td>Centralized Vaporized Phase Hydrogen Peroxide (VH2O2) as Building Utility</td>
<td>Matt Hofacre, Senior Director, Technical Services <em>STERIS Corporation</em></td>
</tr>
<tr>
<td>09:30 – 10:30</td>
<td>Inert Gas Bleed Valve Location and the Impact on Lyophilization Chamber Pressure</td>
<td></td>
</tr>
</tbody>
</table>
Nitrogen gas bleed valve is an often overlooked variable when transferring a cycle from one dryer to another. The focus of these studies will be on how the location of the gas bleed valve affects the primary drying segment of the lyophilization cycle. The location of the gas bleed valve was varied during these studies and the air temperature at different locations on the shelf and chamber was monitored during primary drying. The air temperature during primary drying was compared by shelf and shelf location to investigate the effects of varying the location of the Nitrogen gas bleed valve. After the air temperature mapping studies were complete, sublimation rate studies were completed using bulk trays and Purified Water USP. The results of these mapping studies revealed differences in air temperature at different locations on the shelf when the Nitrogen gas is introduced at different locations of the lyophilization chamber. Additional sublimation rate studies were completed to compare to the air temperature mapping studies and if warmer temperatures result in higher sublimation rates.

**Poster Presenter:** Jason B. Angstadt MS Scientist III Lyophilization Technology Inc.

---

**C2: Innovations in cGMP Facility Design and Digitization**

This dynamic session will explore the synergistic relationship between cutting-edge technology and intelligent plant maturity assessment for the design and digitization of cGMP facilities. Experts will address how best practices and innovative design tools, like AI, minimize risks, enhance operational efficiency, and reduce construction costs, all while adhering to stringent regulatory requirements. The session will also introduce the BioPhorum Digital Plant Maturity Model (DPMM) 3.0, highlighting its role in assessing plant maturity, developing strategic roadmaps, and influencing the industry’s digital transformation.

**Moderator:** Kate Malachowski PhD Associate Director, MS&T Novavax

**10:30** – **10:50**

**Designing cGMP Facilities with Operations in Mind**

Design of cGMP facilities often takes place prior to assembling the organizational structure, especially those responsible for maintaining compliance with regulatory standards, corporate standards, and industry best practices. In some cases, project stakeholders are unaware of the impact design decisions will have on operations, and designers are not fully aware of the challenges their clients may encounter during operation of a cGMP facility. Oftentimes, regulatory compliance requirements are not fully understood at the time of design, and therefore may not be included in a Basis of Design. Identifying early in the design process how operations personnel will maintain compliance in the facility will help any organization manage risk. In this presentation, our speaker will showcase several examples of facility design elements that he has encountered in his career, and his experience to mitigate risk by implementing additional SOPs, justification through engineering studies, and capital improvements to the facility. With a clear understanding of facility compliance pressure points, both clients and engineers can mitigate facility compliance risk in the design phase with less impact to product safety, operations and future production downtime.

**Presenter:** Jason E. Smith PE, MBA, PMP Director Barry-Wehmiller Design Group

**10:50** – **11:10**

**Leveraging AI for Optimal cGMP Manufacturing Facility Design**

The transformative potential of Artificial Intelligence (AI) in enhancing the design and construction of current Good Manufacturing Practice (cGMP) facilities is yet to be fully realized. The pharmaceutical and biotechnology industries operate within stringent regulatory frameworks, necessitating facilities that meet rigorous standards of safety, quality, and compliance. AI-driven tools and methodological approaches have emerged as indispensable assets in achieving these goals. AI empowers architects and engineers to optimize cGMP manufacturing facility designs by analyzing vast datasets and generating innovative solutions. Through predictive modeling, AI identifies potential bottlenecks, minimizes risks, and maximizes operational efficiency, ultimately reducing construction timelines and costs. Additionally, AI-driven design assists in resource allocation, layout optimization, and energy efficiency, aligning facilities with sustainable and cost-effective practices. This presentation will showcase real-world examples of how AI is revolutionizing cGMP manufacturing facility design, highlighting the advantages of improved compliance, cost-effectiveness, and operational resilience. It will also address potential challenges and ethical considerations, emphasizing the need for responsible AI integration within the pharmaceutical and biotechnology sectors. In summary, AI represents a game-changing tool that can drive innovation, efficiency, and regulatory compliance in the design of cGMP manufacturing facilities, ultimately contributing to safer, more sustainable, and more efficient pharmaceutical production environments.
The BioPhorum DPMM, version 3.0

The BioPhorum Digital Plant Maturity Model (DPMM) was created in 2018 for the biopharmaceutical industry to assess plant maturity, identify capabilities to develop, create strategic plans and roadmaps, influence suppliers, and develop human resource competency and development frameworks. As technology develops, so too must the model, and in October 2023, version 3.0 was released. BioPhorum brought together digital experts from 30 biomanufacturing and contract organizations to refine each of the five levels of maturity (that range from manual paper-based plants, to fully automated ‘adaptive’ plants of the future) and develop the dimensions to reflect the current approach. This presentation aims to explain the changes in the new model and demonstrate its utility to the industry.

**Presenter: James P.M. Colley PhD IT Phorum Director BioPhorum**

11:30 – 12:00

Q&A

10:30 – 12:00

**A2: Accelerating Pharmaceutical Manufacturing**

Join this session to hear about practical implementations, challenges, and successes in the ever-evolving pharmaceutical landscape. This session will examine the power of historical data, platform-based methodologies, and cutting-edge technologies. Participants will hear a case study on transitioning from traditional to agile manufacturing spaces, utilizing off-site solutions as well as the journey of creating a modular vaccine facility.

**Moderator: Ryan Murray MS Senior Consultant ValSource, Inc.**

10:30 – 10:50

**Answering the Call for Flexibility: Adaptive Robotics for ATMP Drug Products**

How do we approach the ever-growing requirements for speed and flexibility in ATMP manufacturing? Is there a way to not only meet the demand of a rapidly evolving marketplace, but to lead the way through volatility with innovation? AST and a CDMO customer partnered together in implementing real-time solutions through robotics and automation for modern therapies requiring highly targeted, small-batch production, while maintaining cGMP and data compliance within a fluctuating, fast-paced contract manufacturing environment. This case study will explore the speed and adaptability necessary to serve the growing customer need, the unique challenges that are posed by modern, targeted therapy applications, and the technical solutions applied that both met the manufacturing challenge of the moment and also provided for future flexibility.

**Presenter: Josh Russell Vice President of Sales and Marketing AST**

10:50 – 11:10

**Accelerating Biopharmaceutical Development Through Data-Driven Strategies, Platforms, and Technology Enablers**

In today's competitive and evolving global landscape, the need for innovative strategies in process development and biomanufacturing is more critical than ever. Pharmaceutical companies are challenged to deliver cutting-edge products to patients with unprecedented speed and agility. This presentation will explore approaches that capitalize on existing data, embrace platform-based methodologies, and harness the potential of various technological accelerators to accelerate drug development.

Historical data and prior knowledge can significantly simplify and expedite the development of new products. Platforms can be powerful enablers in this pursuit, offering expedited pathways for product development and manufacturing efficiency. Their intrinsic advantages in terms of speed and agility make them indispensable tools in staying ahead. Furthermore, strategic application of CMC acceleration levers, such as those recently explored during Covid therapy development and beyond, can further ensure rapid progression from discovery to market. Lastly, new technologies
such as high throughput and automation as well as digital accelerators can further amplify speed of development while cutting down on the cost. This presentation will delve into these concepts and include examples and case studies showcasing the opportunities and challenges associated with practical implementation of such innovative strategies and acceleration techniques in drug product development and commercialization.

Presenter: Nitin Rathore PhD Vice President Amgen Inc.

11:10 – 11:30

A Collaborative Approach to Agile Manufacturing

Over the past several years the biotech has seen a great deal of turbulence with companies’ investment reaching a near all-time high several years ago to the current lull. This has resulted in companies taking a variety of strategies from large scale investments to divesting their legacy manufacturing networks. One strategy that has presented itself extensively within the industry is the departure from traditional purpose-built facilities to those which provide an agile manufacturing space. Off-site manufactured solutions have quickly been identified as a way to deliver more modern facilities by allowing for flexibility, speed to market through parallel construction as well having the ability to address other challenges such as mobile manufacturing and distributed manufacturing. We will present a case study where an off-site manufactured solution was leveraged to deliver a flexible and mobile vaccine facility for our client. Key aspects in design included modular clean rooms housing 25,000+ pound vaccine filling equipment with the capability of being relocated with the equipment intact. Additionally, a large modular utility system was fabricated concurrently and coordination and integration were a challenge that was addressed through an integrated approach.

Presenter: Peter J. Makowenskyj MEng Director of Design Consulting G-CON
Co-Presenter: William L. Mangum Operations Director, Regional Integrated Project Services, LLC

11:30 – 12:00

Q&A

10:30 – 12:00

B2: AI/ML in Pharmaceutical Quality: Advancements and Challenges

This session will cover the latest developments in AI/ML models for improving product quality/supply chain resilience. The presenters will review recently developed guidance documents and propose practical risk-based solutions for compliant implementation of AI/ML, including the importance of data integrity in the quality system. Attendees will gain insights into the latest trends and techniques in AI/ML, associated challenges and uncertainties, and how these advancements can be applied to revolutionize our industry.

Moderator: Malav Parikh ME Director, Global Quality Compliance and Systems Takeda

10:30 – 10:50

Bringing Pharmaceutical Quality Auditing into the Digital Age

When executives are ready to invest in the newest technology, Quality Assurance and Compliance may not be the first department on the company’s list in which to sink money. However, with a careful strategy on how to implement the latest analytics and automation tools, companies can feel confident that their investment will ultimately result in cost savings. The pharmaceutical quality audit has historically been a labor-intensive undertaking for human beings. Auditing is now an area in which current technologies including data analytics and machine learning will enhance the capabilities of expert auditors. Natural language processing (NLP), predictive analysis, and robotic process automation (RPA) can, for example: summarize policies or SOPs and generate audit reports; sample test data, interpret it, and recognize fraudulent data; and determine supplier risk by searching for potential issues including warning letters. Instead of Quality Assurance and Compliance professionals relying on data analytics and visualization tools like Excel, Visio, and PowerPoint, they can use today’s most powerful technology. But, companies will need a plan of attack for their digital evolution. A process beginning with sensible integrations, supported by existing or low-risk systems, provides assurance to the intrepid data science explorers that they are on the right path.

Presenter: Melanie McIntosh ASQ-CQE, CQA, CSSGB Senior Quality Assurance Specialist PharmEng Technology
How AI Can Reveal Enforcement Trends in Data Integrity

With increasing digitalization/digitization throughout the pharmaceutical industry, Data Integrity (DI) is one of the most important parts of the Quality System. It is also a source of a growing amount of enforcement actions from FDA. In fact, DI-related FDA citations have grown significantly over the past five years (2017-2022). As artificial intelligence and machine learning (AI and ML) get increasingly adopted into pharmaceutical business processes, there’s an opportunity to better analyze trends and patterns in various types of datasets, including agency enforcement, which can lead to reduced compliance risk. Improving External Analysis: Once an agency enforcement actions dataset has been appropriately tagged for DI versus the other aspects of the Quality System, as well as for the various sub-categories of DI, like Testing into Compliance, and Original Data, AI and ML can be used to find the most salient trends. For example, what language does FDA use to cite DI issues? (Hint: it is not “data integrity”). What manufacturing processes are most cited for DI-related issues? Etc. This analysis can help pharmaceutical companies evaluate compliance risk from their own sites as well as from the sites operated by manufacturing partners and key suppliers.

Presenter: Michael de la Torre CEO Redica Systems

Compliant Implementation of AI/ML Models in Commercial GMP

AI/ML models in the pharmaceutical industry have recently expanded and provide huge potential in the current fight against drug shortages by improving product quality and supply chain resilience. Currently mostly applied within the pre-commercial phases, they are on the step to support GMP-activities with potential for manufacturing (e.g., visual inspection) and quality management (e.g., NLP). However, the usage of these technologies in the GMP-arena is still lagging due to stakeholder uncertainty, induced by lack of solid regulatory frameworks. Recently developed guidance like the FDA and EMA reflection papers are calling for industry feedback. In this session, we will examine these documents and propose practical solutions for compliant implementation leveraging QRM (ICHQ9) with a patient centric mindset. We will discuss key prerequisites for AI/ML implementation demonstrating how to: i) strengthen data governance programs to support the “all-is-data” nature of AI/ML-solutions. ii) solidify the established QRM framework with risks such as model bias, data drift and overfitting. iii) develop internal AI/ML standards with measures appropriate to the intended use of the solution. Finally, we will navigate case studies and explore examples for risk categorization in drug manufacturing that will include the presentation of a high-level risk assessment framework based on ICHQ9 principles.

Presenter: Ulrich Koellisch PhD Partner GxP-CC GmbH

Q&A

D2: Designing the Products and Processes of Tomorrow

The world keeps changing! This session will look at some of the challenges facing our industry and approaches being developed to overcome the complexity of new formulations, manufacturing floor operations, and quality expectations.

Moderator: Susan J. Schniepp Distinguished Fellow Regulatory Compliance Associates Inc.
Ensuring the Quality of Manufacturing Processes Through the Concepts of a Strong Quality Maturity Management Program

Q&A

Evaluating Your Stopper: Proving Stopper Functionality for Real-World Use Cases Through <USP 382>

With the upcoming implementation of USP <382> in 2025, there is an increased emphasis on designing clinically representative experiments to prove that the required, optimal container system is achieved regarding piercing performance and resealability. Not only are medical professionals taught varying techniques on how to pierce a stopper, but industry opinions on the best needle and method have led to more questions than answers. To reduce risk to the patient, it is critical to show that one’s stopper will maintain integrity throughout multiple piercings, or multipuncture, applications through demonstrated resealability performance under exaggerated test methods. Early evaluation will provide confidence that your stopper will be able to withstand the various piercing techniques and reduce downstream risk. This poster highlights a comparative study conducted by West on different stoppers using a modified USP <382> protocol for fragmentation and coring, penetrability, and resealability. Data will be provided showing how the multipuncture performance of stoppers with different formulations, designs, and sizes is affected by stopper sterilization methods (steam versus gamma) and penetration needle gauge (18G versus 21G). Fragments down to the subvisible level were counted in addition to the ≥150µm particles required in the compendia to align with testing for real-world applications.

Poster Presenter: Todd D. Jasinski Senior Specialist, Technical Product Development West Pharmaceutical Services, Inc.

Transforming Deviation Management for Expedited Closure and Product Release in Cell and Gene Therapy

This case study, conducted in partnership between a prominent cell and gene therapy manufacturer and a consulting firm, sought to streamline the deviation management process within the organization. The main goals were to define ownership in the process and enhance departmental knowledge and skills resulting in expedited deviation closure, while maintaining a high level of Quality. A detailed examination of the deviation lifecycle included identifying communication gaps, redundant meetings, delays resulting from information or decision bottlenecks, and the non-value-added activities in the process. This analysis, enriched by stakeholder involvement, led to the creation of an innovative workflow engineered to promptly resolve low-level deviations within a challenging 24-hour period, or ideally during the same manufacturing shift. To ensure a seamless integration, training sessions were deployed to ensure personnel were aligned with the new workflow and overarching site goal. In the initial weeks following go-live of the new workflow, the data showed a two-thirds reduction in the overall cycle time for low-level deviations. This was a substantial step towards reducing deviation closure time, along with allowing more time to focus resources on critical issues. Importantly, there were additional improvements in the pipeline, which, when implemented, were expected to streamline the process further.

Poster Presenter: Christian Spiak Principal Consultant, Human Performance Business Area CAI

Maintaining Superior Viral Vector Recovery in Cell and Gene Therapy Applications by Using Daikyo Crystal Zenith® Vials

AAV8 and AAV9 were chosen as representative adenov-associated virus (AAV) serotypes, with respective titers in a common buffer formulation, and evaluated in different 2mL vial types: Daikyo Crystal Zenith® (CZ) vial, and two commercially available borosilicate vials. To simulate viral vector recovery in cell and gene therapy applications, the vial combinations were tested across five challenge conditions: 1. 3 months at -80C, recommended condition for long term storage 2. 2 months at 5C, recommended condition for temporary refrigerated storage 3. 3 weeks at 25C, simulating room temp clinical ambient conditions 4. 72 hours of 250RPM agitation, to mimic handling during manufacturing/shipping 5. 5 cycles of Freeze/Thaw, to mimic handling during manufacturing and the potential for structural damage to proteins or DNA In all conditions, the Daikyo CZ vial demonstrated improved viral vector recovery compared to borosilicate glass vials. The data shows that there were no significant changes in
product quality due to container storage in the Daikyo CZ vials, and that the CZ vials may comparatively improve viral vector recovery across common storage and handling conditions.

**Poster Presenter: Eric Kurtz** Manager, Technical Product Development *West Pharmaceutical Services, Inc.*

12:00 – 13:30

**In-Line Real-Time Monitoring of Perfusion CHO Cell Culture Critical Process Parameters and Critical Quality attributes using Raman Spectroscopy and Chemometric modelling**

Cell culture processes are complex and highly variable and yet only a handful of key parameters such as temperature, pH, and dissolved oxygen (DO) are typically controlled in real time. While measurement and control of these parameters are essential for a robust process, they provide only broad assumptions on the culture’s true state and offer limited insights into the process and cell growth. In contrast, critical process parameters (CPP) such as glucose, lactate, and key performance indicators (KPI) such as total cell density (TCD), viable cell density (VCD), antibody titer, osmolality provide direct indication of the culture’s content and state. These measurements are typically measured offline, however, and do not provide real-time information or effective process control. This presentation describes use of the MilliporeSigma’s ProCellics™ Raman Analyzer with Bio4C™ PAT Raman Software (also known as Raman PAT Platform) to perform inline and real-time measurement of TCD, VCD, Antibody titer, Osmolality and the concentration of glucose and lactate a bench-scale bioreactor.

**Poster Presenter: Ushma Mehta MS** Regulatory Consultant *MilliporeSigma*

12:00 – 13:30

**Developing a Risk Score for Critical Suppliers Using Artificial Intelligence (AI)**

The modern economy is familiar with many examples of risk scores, like credit scores, insurance scores, and more. Supply chains are one area where risk scores haven’t yet been fully developed and utilized. In the pharmaceutical industry, where the supply chain has a direct impact on patient safety and health outcomes, supply chain risk scoring is of particular importance, yet as an industry, we have a lot of progress to make. With more data available than ever before, plus the capabilities unlocked by AI and ML, pharmaceutical sponsors can now accurately score the relative risk of all of the organizations upstream from them, like CMOs, API manufacturers, and excipient manufacturers. Takeaways: - Which variables should be used to calculate pharmaceutical supplier risk? - What are some roadblocks to developing a supplier risk score and how can they be overcome? - Entity resolution - you can’t accurately calculate a risk score for a particular entity unless the dataset you’re using has appropriately resolved all of the permutations of the entity name into one profile. - How those variables interact with one another (i.e. how do you score a warning letter and the 483 that preceded it?)

**Poster Presenter: Michael de la Torre** CEO *Redica Systems*

12:00 – 13:30

**An Alternative Approach to Standard Operating Procedures**

The classic paradigm of training and executing SOPs in BioPharma- is to Read and Understand, to observe someone else perform the procedure, and then to demonstrate it yourself. Once this initial training phase is complete, you are left solely with a written SOP to reference. This heavy reliance on written instructions can lead to a higher chance of ambiguity and unnoticed or overlooked errors. My proposed solution aims to address this issue by accommodating diverse learning preferences and seamlessly integrating visual aids, such as videos, directly into procedures. To address this challenge, I have embedded QR codes directly within procedures. This approach enables employees to access instructional videos quickly and conveniently, providing clear guidance, especially for more complex steps, thus reducing errors and preventing confusion during execution.

**Poster Presenter: Max Falcone** Analyst *Tunnell Consulting*

12:00 – 13:30

**A Model for a Risk-Based Deviation Investigation Process**

Deviation investigation process owners often find themselves swamped with investigations, lacking quantitative tools that allow them to discriminate between minor low-risk events and critical high-risk deviations. Additionally, the business processes that support deviation investigations are often not purpose-built to enable the speed and investigational rigor that allow for timely closure and effective corrective action. This talk will present a proven model for building a quantitative risk-based deviation classification system and will discuss assigning investigational tools to assigned
deviation risk levels. Supporting business processes will also be discussed, including professionalizing deviation investigators as an expert role within an organization as well as developing daily operational practices and metrics for effective management of the deviation lifecycle: identification, assessment, investigation, assignment of corrective/preventive actions, and approval/closure.

**Poster Presenter:** Aaron Hubbell  
Director, Life Sciences  
Barry-Wehmiller Design Group

---

12:00 – 13:30

**Fused Quartz Vials: from Glass Science to Drug Containment Solution**

Glass is the most used material in pharmaceutical packaging, and borosilicate is currently the most used among those described by the Pharmacopoeia(s). The USP, however, has recently enacted changes to their glass packaging chapter < 660> that enable the introduction of new glass compositions, one of which is fused quartz. While new to the USP chapter, fused quartz has been manufactured for well over one hundred years, valued primarily for its high purity and remarkable properties, including a very low thermal expansion coefficient and excellent chemical durability. This presentation will address the science behind fused quartz vials, with focus on assessing their chemical, physico-chemical and mechanical performances. Although fused quartz is generally considered chemically inert, the selection of any container must always be done taking into consideration the individual drug product and processing requirements. The knowledge of this new glass and of relevant analytical testing can continue to accelerate its adoption as a container for parenteral preparations and on its classification inside the three main Pharmacopoeia and standard setting organizations like ISO and ASTM. The experts at Stevanato Group and Momentive Technologies are excited to see this “new” glass help solve many of the industry’s most demanding formulation challenges.

**Poster Presenter:** Serena Panighello  
EMEA TEC Research Scientist  
Stevanato Group

---

12:00 – 13:30

**High Cell Density Cryopreservation for Upstream Process Intensification Using LN2 Vapor Phase Stored Seed Train Intermediates**

Standard seed train operations start by thawing of a single 1 ml vial with cell densities of 10 x 10⁶ VC/ml. For reaching a sufficient absolute cell number for production bioreactor inoculation, several expansion steps, starting with shake flasks, need to be performed. These open cell culture operations result in long ramp up times, high room classifications during the whole process, and are a major source of process variability. High cell density cryopreservation is a method where cells can be frozen in bags with cell densities higher than nowadays standard processes. This leads to the advantage that cell expansion and batch production can be separated. Lower room classification for the cell culture area in GMP manufacturing might be a result due to the reduction of manual handling steps before the main stage bioreactor (closed processing). Furthermore, these intermediates allow global distribution from a central expansion facility to decentralized global production facilities. Currently, we have demonstrated that SU bag assembly was modified to withstand liquid nitrogen vapor phase storage and the process of freeze and thaw was also optimized to maintain cell performance and SU bags integrity after thaw.

**Poster Presenter:** Ushma Mehta  
MS Regulatory Consultant  
MilliporeSigma

---

12:00 – 13:30

**Quality Culture: From Buzzword to What Works**

Warning letters consistently cite firms for failing to establish a Quality unit with the responsibility and authority to execute its responsibilities across all GMP systems. With the recent focus on quality maturity models and quality metrics to, in part, ensure the continuity of the drug supply, building a sustainable culture of quality is essential for all GMP-regulated facilities. The term “Quality Culture” has been around for years, but few companies have mastered what it means or how to implement and measure a culture of quality in a GMP-regulated environment. This presentation will provide attendees with an overview of the concepts behind quality culture, as well as some strategies for implementation and metrics for measuring performance.

**Poster Presenter:** Sean Lloyd  
MSc Principal Consultant  
SRL Pharma Ltd

---

12:00 – 13:30

**Implementing a Disinfectant Program for Advanced Therapy Medicinal Product Manufacturing**

In a fast-paced, rapidly evolving environment like Advanced Therapy Medicinal Product (ATMP) manufacturing, it is easy to overlook critical elements necessary to maintain contamination control. However, despite urgent manufacturing procedures, a sound strategy for contamination control...
control is essential to help ensure microbiological safety and final product integrity. A cleaning and disinfection program must address the unique challenges within ATMP including addressing the special considerations often found within these facilities such as limitations with available resources and critical time-sensitive procedures. Implementing a program that can be adaptable to the unique environment of specialized procedures that incorporates the consideration of smaller processing suites, biosafety cabinets and isolators is key. A well-designed program that is not overly complicated yet focuses on a holistic contamination control approach focused on the challenges in the ATMP environment is essential.

**Poster Presenter**: Dan A. Klein MA Senior Manager, Technical Services STERIS Corporation

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Poster Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00 – 13:30</td>
<td>Economic Benefits of an Original Container Closure during Combination Product Development: Expert-Modeled Scenarios Validated by Pharma</td>
<td>Mehul Desai PharmD, MBA Vice President, Medical Affairs Enable Injections</td>
</tr>
<tr>
<td>12:00 – 13:30</td>
<td>Data Analysis ~ Trending and Pattern Recognition for Contamination Control</td>
<td>Susan B. Cleary EMBA Director of Product Development Novatek International</td>
</tr>
<tr>
<td>12:00 – 13:30</td>
<td>System-Based Drug Manufacturing Inspections: An Inspectational Approach to Help Assure Readiness</td>
<td>Mitchell A. Wheeler ASQ CQA, CMDA, CPGP, CMQ/OE Senior Quality Consultant PharmEng Technology</td>
</tr>
<tr>
<td>12:00 – 13:30</td>
<td>Using Toxicological Risk Assessment to Minimize Cross-Contamination</td>
<td>Wendy Haines PhD, DABT, ASQ CQA Director of Toxicology &amp; Technical Services PharmEng Technology</td>
</tr>
</tbody>
</table>
Behavior of Molded and Tubular Vials During Depyrogenation

Depyrogenation is a key step in the aseptic filling process. Dry heat depyrogenation is the method of choice for glass vials. Most depyrogenation tunnel manufacturers consider the power necessary is proportional to the weight of glass vials. This study shows the reality is different for small vials below 30 ml. An industrial depyrogenation tunnel was used, filled with 100H molded vials and in the center of the conveyor, in the same row two 20R, two 20H and two 20H EasyLyo. The temperature was monitored with thermocouples. The temperature curves for molded and tubular 20ml vials are close and similar. The times recorded to achieve the 3 log reduction were 18 min 13s for the tubular vials, 19 min 28s for ISO vials and 19 min 37s for EasyLyo vials. The accumulated destruction factors FD for these 2 vials are significantly equivalent. There was no direct correlation between the weight of vials and the energy needed for depyrogenation for glass vials below 30ml. The measured time to achieve a 3 log reduction did not differ by more than 8%, while the weight difference was 70%. This understanding opens new perspectives for drug manufacturers in terms of sustainability and machinability.

**Poster Presenter:** Jingwei Zhang PhD Group R&D Director SGD Pharma

Breaking Out of the Human Factors Study Loop, For the Benefit of Patients

Human Factors Engineering (HFE) is a critical component of development and life cycle management for combination drug products. Human factors (HF) studies assess whether combination products are safe and effective and, when properly designed, can eliminate millions of dollars in future life cycle management costs. These studies seek to understand how patients interact with products, what patients expect from products, enable manufacturers to design out risks, and ensure positive patient outcomes and compliance. HFE is never a one-and-done activity. It involves an iterative series of experimentation, testing and qualification. Each HF study yields new observations and options for continuous improvement. This can create a loop which, if not managed properly, can delay the implementation of design improvements and instructions that will benefit patients and users at all stages of a product’s life cycle. This presentation will discuss how principles of Use Related Risk Analysis have been incorporated into autoinjector HF studies ranging from early prototypes to on-market products. It will present a process which balances the iterative process of HF engineering with focus on the end goal, delivering outcomes for patients.

**Poster Presenter:** Amy Lukau Senior Human Factors Lead Kindeva Drug Delivery

A New Calibration Technique for Light Obscuration Sensors to Improve Counting Accuracy of Aggregated Proteins

Light obscuration liquid particle counters used for USP <788> and <787> are calibrated using polystyrene latex (PSL) particles with a refractive index (RI) value of 1.58. This calibration approach generates accurate results for large particles with a similar RI value in the critical size ranges of 10 & 25 µm. Various sources have pointed out the inaccuracies in results for protein particles where the RI value of approximately 1.4 is much closer to water, especially at smaller particle sizes. This presentation will describe a new calibration technique for light obscuration/scattering sensors using the new NIST RM 8634 and present results of aggregated proteins with both the historic PSL and the new protein calibration techniques. The calibration procedure used is described in ISO 11171:2020, using the new NIST RM 8634 to create a “protein calibration curve”. Aggregated protein samples were then analyzed by the single particle optical (SPOS) technique using both the historic PSL and new protein calibration curves. Results using the protein calibration curve reported higher particle concentrations at a given size.

**Poster Presenter:** Mark Bumiller Technology Manager Entegris, Inc.

Aseptic Transfer of RTU Containers in the Light of the New Annex 1

The poster will compare the different methods on how to introduce RTU Containers into the aseptic environment with focusing on the operating, sterility and validation principle. Transfer methods as H2O2, NTT, Ebeam and pulsed light are being compared. These methods will be put into conclusion with then new Annex 1.

**Poster Presenter:** Christian Thieme Sales Director - Americas groninger & co. gmbh
Glass Containers Under-filling: E&L Benchmark of Different Glass Vials

USP < 660> for glass surface chemical durability test prescribes the nominal filling volume as 90% of glass container brimful capacity. Many glass containers for injectable solutions are filled less than this nominal volume which leads to an increased level of E&L, as the surface/volume ratio is increased. We studied the chemical stability of tubular and molded vials in this situation. The study performed a benchmark of E&L levels and pH shift for 3 vials of nominal volume 10ml : tubular, type I molded and type I molded treated with ammonium sulfate. Filled with 10ml and 4ml NaCl 0.9%, the vials went through 1, 2 and 3 cycles of autoclave, followed by extractable analysis by ICP (Inductively Coupled Plasma Atomic Emission Spectrophotometry) and pH measurement. For all types of vials, 4ml under-filling led to a higher pH shift and higher extractable level than nominal filling of 10ml. For the same filling level and autoclave testing, treated molded type I were the most performant in terms of pH stability and E&L levels, followed by type I molded. Tubular vials showed the highest E&L levels and pH shift. Considering the industry practice, type I molded vials is the most relevant choice.

**Poster Presenter:** Jingwei Zhang PhD Group R&D Director SGD Pharma

---

The Challenges of Testing Bacterial Spores in Disinfectant Coupon Studies to Meet CCS Compliance

This presentation will cover the complexities of designing a robust and effective disinfectant coupon study. The presentation will present new novel data showing that the testing of bacterial endospores at different time points will always have the presence of the spore stage as well as the vegetative state of the spore forming bacteria. The presentation will cover how to implement an effective disinfectant validation program as part of the contamination control strategy. Risk assessments will be covered as effective methods of determining the coupon surfaces and microorganisms to include in the coupon study. The overall scope of the presentation will cover all key aspects of a well planned out disinfectant validation study that compliments the contamination control strategy.

**Poster Presenter:** James N. Polarine MA Senior Technical Service Manager STERIS Corporation

---

Developing a Method to Learn Capper Settings to Handle Component Variations

Component dimensional variation has been reported as one of the causes for crimping variations. Critical dimensions of components (vial, stopper, cap) can vary within manufacturing tolerances, however these ranges of variation may require adjustments to capper settings to ensure a proper package seal. The settings used to crimp one batch of components may need to be adjusted to crimp another batch. In this work, we developed a way to learn the component variations and then automatically adjust the settings to ensure a proper seal. The possible range for each setting was validated and learning was limited to that range. Data for the learning model was obtained using an in-line machine vision system to continuously monitor component variations and adjust capper settings as required. Throughout the process, a constant compression percentage is monitored, and intervals of finished product tested by Residual Seal Force (RSF) to ensure seal quality.

**Poster Presenter:** Carolina Gonzalez Gaitan PhD Parenteral Packaging Scientist Genesis Packaging Technologies

---

High Yield Sterile Filtration of High Viscosity Pharmaceutical Formulations

Sterilizing pharmaceutical products is essential for patient safety and is typically achieved using terminal sterilization methods. In the case of high viscosity formulations, terminal sterilization is often avoided as it can inadvertently change product attributes. Using commercially available 0.2μm sterile filters for viscous formulations remains limited due to significant challenges dictated by the filter design and operating ranges. In this work, a validated high pressure sterile filtration (HPSF) skid is presented as a method to successfully sterilize viscous formulations without compromising patient safety. This system has been used to filter solutions used as medical devices and active pharmaceutical ingredients (API) and is validated in accordance with regulatory guidance. Formulations of sodium hyaluronate (NaHy) with molecular weights of 900 - 2,000 kDa, concentrations as high as 30mg/mL, and viscosities up to 1,000,000 cps were examined. When comparing the filtration yield of a 10mg/mL NaHy solution with 900kDa molecular weight on a commercially available capsule filter to HPSF, the flux with HPSF was three orders of magnitude higher. Additionally, HPSF did not result in concentration differences between unfiltered & filtered solution in contrast to low pressure filtration. HPSF can fast track development and accelerate bringing early phase formulations into the clinic.

**Poster Presenter:** Jack E. Kochevar Process Engineer Lifecore Biomedical
12:00 – 13:30

Developing Primary Packaging System for Nanosuspensions: Headspace Design Space Case Study

Suspensions with nanometer size drug particles are a unique drug product dosage form which allow high concentrations of water-insoluble small molecules to be parenterally administered into human bodies to treat difficult diseases. They are typically packed in pre-filled syringes (PFS) or glass cartridges with a desired level of container closure integrity (CCI) to protect them from oxygen and microbe ingress. Headspace (HS) is an important attribute that needs to be well controlled during the filling of the nanosuspensions into glass primary containers. This case study highlights two important factors in relation to headspace within a primary pack containing a nanosuspension product: 1) The importance of a maximum allowable headspace given the impact this has on stopper movement and therefore on the primary packaging system’s sterility performance; 2) The minimum headspace requirements for nanosuspension products as they need to be well resuspended prior to drug product administration. Thus, the headspace needs to be optimized within a certain window to ensure adequate sterility and achieve the desired dosage. In summary, this case study serves as a good example of a balanced approach on developing challenging primary packaging solutions for this unique parenterally administered nano-suspended drug product dosage form.

Poster Presenter: Liang Fang PhD Associated Director, Primary Packaging GSK

12:00 – 13:30

Centralized Vaporized Phase Hydrogen Peroxide (VH2O2) as Building Utility

Application of a disinfection and sporicide rotation is a critical component of a contamination control strategy per EU Annex 1. Many current applications deploy a manual process for sporicide application. Automated systems are desirable as they minimize people and equipment required to enter the classified spaces and minimize operating costs and errors as part of the process. These systems provide enhanced coverage in the critical environment areas and are especially critical for ATMP facilities that have strict contamination control requirements. This presentation will explore the use of a centralized, automated system to apply VH2O2 as a biocidal disinfection method in an ATMP facility. A case study will be presented that outlines: • VH2O2 properties and its use as a biocidal disinfection method in biopharmaceutical applications. • VH2O2 integration into the facility HVAC for distribution to clean rooms and RABS. • Equipment integration with the facility building management system (BMS) for control and cycle reporting functions including 21 CFR Part 11 and EU Annex 11 considerations. • Safety considerations for the users and the facility. • Qualification and validation of the process. Users will take away how VH2O2 centralized, automated systems can be implemented for enhanced contamination control strategy practices.

Poster Presenter: Matt Hofacre Senior Director, Technical Services STERIS Corporation

12:00 – 13:30

Exploratory Assessment of an On-Body Delivery System for Large-Volume SC Delivery: Facilitating Rapid Thermal Equilibration to Ambient Temperatures for Immediate Utilization Post-Refrigeration

In the evolving field of healthcare, ensuring prompt and efficient medication delivery remains a top priority. This study undertakes an exploratory assessment of an on-body delivery system tailored for large volume subcutaneous (SC) delivery. The design is crafted to accelerate thermal equilibration to ambient temperatures, enabling immediate use post-refrigeration. The movement of the drug through the fluid path is central to warming the drug swiftly to near ambient temperatures. Our analysis dives into the performance and efficiency of this system across varied environmental conditions. The data, which will be shared in detail during the presentation, unveils a significant trimming of the time needed to reach ambient temperatures, thereby potentially reducing wait times and enhancing user experience. These preliminary findings highlight the promise of this system and beckon further exploration to ascertain its real-world applicability and advantages, aspiring to advance the sphere of patient-centric medication delivery solutions.

Poster Presenter: Mehul Desai PharmD, MBA Vice President, Medical Affairs Enable Injections

12:00 – 13:30

Identification of Foreign Particulate Matter in Assembled Autoinjectors Through Long-Time Tracking of Individual Particles’ Trajectories

Part of the challenge in detecting foreign particles in a liquid parenteral is to discriminate them from bubbles or other intrinsic objects, which do not constitute a defect, but can lead to false rejects. We have implemented an innovative methodology to identify foreign particles in a complex autoinjector device. For this application, we combine a handling adapted to mobilize particles in solution with image processing algorithms for particle tracking. In our test system, the devices circulate in a linear transport system and are turned upside down prior to the image acquisition. In this way, particles which might be stuck on the walls or at the bottom of the device are released in the solution, which facilitates their detection. By
acquiring up to hundreds of images we are able to track the particles’ motion for longer than 1 second, distinguishing whether they tend to move downwards or upwards and identifying them as particles or bubbles, respectively. The strength and novelty of our machine design rely on the fact that the additional time for image analysis is obtained without compromising the speed of the machine.

**Poster Presenter:** Matthias Kahl Head of R&D and Lab Services *WILCO AG*

12:00 – 13:30

**Design Verification Testing of Auto-Injectors: Performing All Tests on a Single Unit to Reduce Sample Quantity and Increase Testing Throughput**

The development of combination products requires verification of the performance of the devices to meet the design input requirements. For an auto-injector, particularly an auto-injector that was designed by a medical device manufacturer but is being sold as part of a combination product by a drug company, it is important to perform design verification to ensure that the combination product meets the design requirements for the specific combination. While relevant testing must be deduced from a risk-assessment performed on the particular drug-device combination, guidance documents (like ISO 11608-5:2022 Needle-based injection systems for medical use — Requirements and test methods — Part 5: Automated functions) can serve as useful starting points for determining characteristics that require testing. This poster addresses the test methods developed and validated through a Gage R&R study, using devices or surrogates, as needed, for verifying the performance characteristics of an auto-injector using commercially available force testing equipment with specially designed add-ons that enable the performance of a battery of tests on a single auto-injector, thus generating statistically significant datasets with minimal sample sizes.

**Poster Presenter:** Mike Ulman PhD Technology Manager, Packaging and Delivery Systems *West Pharmaceutical Services, Inc.*

12:00 – 13:30

**Cleaning Considerations for Lipid Nanoparticles**

The advancements in lipid nanoparticle (LNP) delivery systems have been paramount in the performance, stability, safety, and eventual regulatory approval of novel drugs and vaccines, such as the mRNA COVID-19 vaccine by Moderna, Pfizer/BioNTech, and others. These encapsulated LNPs can deliver drugs using a wide range of sizes based on the LNP components and route of administration. However, the lipophilic nature and complexity of LNPs can present difficulties in the cleaning process. Laboratory cleaning models can be used to efficiently screen cleaning agents and define critical cleaning parameters. The presentation explores the concerns with cleaning drug products utilizing lipid nanoparticle delivery vehicles and provides general cleaning recommendations based on laboratory and field testing. Reference: https://www.pharmtech.com/view/considerations-for-cleaning-lipid-nanoparticles (June, 2022)

**Poster Presenter:** Paul T. Lopolito Technical Services Director *STERIS Corporation*

12:00 – 13:30

**Evaluation of New Sterilization Modalities that Enable Terminal Sterilization of Parenteral/Injectable Drug Products Traditionally Filled by Aseptic Manufacturing**

Sterile manufacturing of parenteral/injectable drug products is accomplished by either aseptic manufacturing or terminal sterilization, the latter preferred and recommended by regulatory bodies. Product and container closure compatibility with moist heat normally dictates if the product is Aseptically Manufactured or Terminal Sterilized. New technologies and sterilization modalities were evaluated with the goal of broadening the drug product/container closure compatibility assessment. Studies demonstrated new technologies enable conversion of drug products currently Aseptically Manufactured to Terminal Sterilized, thereby reducing manufacturing cost and reducing lack of sterility risks. This presentation will highlight testing of several sterilization modalities, results, and next steps.

**Poster Presenter:** Terrence Hollis Senior Manager, Global Technology and Engineering *Pfizer Inc.*

12:00 – 13:30

**A Holistic, Phase-appropriate Analytical Approach for Establishing Residual Host Cell Protein Specification Throughout the Cell Therapy Drug Product Lifecycle**

Residual host cell proteins (HCP) are low-level genomic protein residuals produced from process- or drug-related materials in manufacturing cell therapies. HCP residuals are organic process impurities per the International Conference on Harmonisation (ICH) Q3A/B guidelines (ICH, 2006).
These residuals pose a risk to patients' immunogenic responses while affecting drug efficacy and stability. Drug developers must comply with the United States Pharmacopeia (USP) < 1086> and < 509> to detect HCP residuals, limiting 0.05% per day of active pharmaceutical ingredients (USP, 2015). Drug release criteria only require HCP results in phase 2 (FDA, 2020). Following phase 2, Biologic License Application filing requires more rigors toward product characterization. To implement a phase-appropriate analytical strategy for cell therapy development, HCP residuals are first identified using a conventional Western size-based assay or a Quadrupole/Time-of-Flight Mass Spectrometer (QTOF-MS). The first method option is far more feasible to execute and collect sufficient data than the latter. Following the 21 Code of Federal Regulations §610.9 (FDA, 2023), multiple QC samples were utilized for method development, validation, and phase 1 sample analysis. We developed a practical and ideal enzyme-linked immunosorbent assay for QC implementation and met the ICH and USP requirements to support phase 2 trials and commercialization.

**Poster Presenter:** Michelle Tseng PhD Senior Director Azzur Group

12:00 – 13:30

Isolator/RABS: Risk Minimization Through Correct Glove Management

- Requirements and challenges (Annex 1) - Glove types/ Selection/ Test methods - PDA study published on "How risky are pinholes" - Possible risks that compromise glove integrity - Necessary activities for good glove management - Additional literature for self study

**Poster Presenter:** Alex J. Kappani Product Management SKAN AG

12:00 – 13:30

Benefits of Single-use for ATMPs in Regards to Annex 1

The presentation will give an overview about technical standards and trends. The presentation highlights regulatory aspects, e.g. EU-GMP Annex one and will also touch the field of aseptic risk reduction and will show how to increase the quality of sterile drug manufacturing. Annex 1 drives technical solutions for ADCs / ATMPs more and more towards: - Isolators / Containment Isolators - Single-Use and Ready-To-Use components - Automated or at least semi-Automated processes for better reproducibility Human interventions are to avoid, to eliminate potential contamination risk factors. Standardized documentation according to latest norms are required. Why does single-use and ready-to-use best possibly comply to EU GMP Annex 1 Why does single-use specially make sense in dealing with new types of medicinal products like ATMPs and ADCs. What are market standards and trends and where is pharma manufacturing moving to.

**Poster Presenter:** Juergen M. Metzger Product Specialist/Senior Consultant Final Filling Sartorius North America Inc.

12:00 – 13:30

Inert Gas Bleed Valve Location and the Impact on Lyophilization Chamber Pressure

Nitrogen gas is bled into the lyophilization chamber to control the chamber pressure during primary and secondary drying. The location of the Nitrogen gas bleed valve is an often overlooked variable when transferring a cycle from one dryer to another. The focus of these studies will be how the location of the gas bleed valve effects the primary drying segment of the lyophilization cycle. The location of the gas bleed valve was varied during these studies and the air temperature at different locations on the shelf and chamber was monitored during primary drying. The air temperature during primary drying was compared by shelf and shelf location to investigate the effects of varying the location of the Nitrogen gas bleed valve. After the air temperature mapping studies were complete, sublimation rate studies were completed using bulk trays and Purified Water, USP. The results of these mapping studies revealed differences in air temperature at different locations on the shelf when the Nitrogen gas is introduced at different locations of the lyophilization chamber. Additional sublimation rate studies were completed to compare to the air temperature mapping studies and if warmer temperatures result in higher sublimation rates.

**Poster Presenter:** Jason B. Angstadt MS Scientist III Lyophilization Technology Inc.

12:00 – 13:30

Manufacturing in Miniature: Drug Delivery via Microneedle Array Patches (MAP)

Microneedle patch technology has progressed to the pre-clinical and early human clinical stage by many developers, but Kindeva is one of the few companies that has made it to Phase 3 clinical studies and has commercial scale equipment. Kindeva Drug Delivery provides recommendations for process development and manufacturing based on its coated microneedle patch drug delivery platform. Manufacturing process scale-up with intention of regulatory submission follows a strategic path. At each stage (lab bench, pilot, and commercial) it’s critical to document data, decisions,
and key learnings in support of a design history file and regulatory submission. Documents should be raised at the time of data generation and cover topics including product development decisions, process development milestones, and device development choices. Likewise, methods and specifications mature during development. Data destined for regulatory submissions should be collected consistently over time. If a method changes, comparison data sets utilizing the two methods and same set of samples should be generated to support the change. Specification setting is also evolutionary, with specifications growing more detailed and narrower as the development proceeds. This evolution will be illustrated through Kindeva’s experience in scale up from lab to commercial scale processes for manufacture of coated microneedles.

**Poster Presenter:** Andrew Riso Director of Business Development Kindeva Drug Delivery

12:00 – 13:30

Supply Chain Verification for API Manufactured by a Third Country

This poster explains the Supply Chain Verification and Risk assessment carried out by Qualified Persons for API imported from a Third Country.

**Poster Presenter:** Farah Nadeem QP Trainee Paul Palmer Ltd

12:00 – 13:30

Applying Holistic Sterile Manufacturing Design Principles to Build an Agile Combination Product Contract Manufacturing Facility Which Anticipates the Over the Horizon Compliance Requirements

There is an incredible level of complexity, investment and risk with building a sterile manufacturing facility. When the facility will serve the global needs of a diverse contract manufacturing customer base, it must be built for agility, efficiency, scalable and most importantly for global compliance-known today and what’s over the horizon. Examples of holistic design utilized in Kindeva’s new aseptic manufacturing facility; • Levo-magnetic drive motors reducing wear and particulate generation • Disposable bagging systems in formulation tanks reducing cross-contamination risk and establishing more efficient change overs • Automated PUPSIIT systems integrated into the filling process providing continuous filter integrity. • Filling machines utilize isolators eliminating the need for traditional gowning and aseptic training, reducing grade A areas to the isolator interiors, and reducing time to qualify operators. • Modular filling suites operating independently eliminating facility wide shutdowns • In-process fill check technology tracks individual drug containers allowing for automatic removal of individual containers not meeting quality parameters. Product quality, operational efficiency and compliance isn’t determined by any single process or design element. These are only achieved and maintained through holistic design principles that collectively meet the need of the market and regulators tomorrow and over the horizon.

**Poster Presenter:** Chad Hafer MEng Senior Manager Aseptic Operations Kindeva Drug Delivery

12:00 – 13:30

Networking Lunch and Tech Talks in the Exhibit Hall

13:30 – 14:15

IG01: Data Governance, Management, Integrity, and Digitalization

**Interest Group Leader:** Kir F. Henrici Chief Executive Officer The Henrici Group

**Interest Group Leader:** Ulrich Koellisch PhD Partner GxP-CC GmbH

13:30 – 14:15

IG02: Annex 1 Implementation and Quality Risk Management

**Interest Group Leader:** Marcia C. Baroni MBA Vice President Enterprise GxP Compliance & Systems Emergent BioSolutions

**Interest Group Leader:** Gabriele Gori SVP Global Quality Head and Chief Quality Officer Biogen
**Interest Group Leader:** Stephen E. Langille PhD Senior Microbiology Consultant ValSource, Inc.

**Interest Group Leader:** Amanda McFarland MS Senior Consultant ValSource, Inc.

**Interest Group Leader:** Malav Parikh ME Director, Global Quality Compliance and Systems Takeda

---

**13:30 – 15:00**

**Mini Training Course: Cleaning and Disinfection (Ticket Required)**

PDA’s Technical Report No. 70 (TR70): Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities provides insight into current industry trends and regulatory expectations concerning cleaning and disinfection of an aseptic facility. This mini training course, presented by one of the authors of TR70, will highlight different aspects of the technical report as it relates to the warehouse to the filling line, focusing on the aseptic processing area.

**Presenter:** Brent Watkins SCMD Technical Manager Veltek Associates, Inc.

---

**13:30 – 14:15**

**Lightning Presentations: Session 1**

Join PDA’s first ever lightning Presentations session! These exciting presentations will use the Pecha Kucha presentation method which calls for telling a story using images rather than reading text from slides during a PowerPoint presentation. The Lightning Presentations will have 20 slides set to automatically advance after only 20 seconds of commentary per slide for a total presentation time of just 6 minutes and 40 seconds.

**Moderator:** Kenneth Paddock Quality Director, Sterility Assurance Baxter Healthcare

<table>
<thead>
<tr>
<th>Time</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>13:30</td>
<td>Quality Management Systems: Accelerated Pathways for Developing, Scale-up, and Optimization</td>
</tr>
<tr>
<td>13:37</td>
<td>Delivering Value Through Quality External Engagement</td>
</tr>
</tbody>
</table>

**Presenters:**

- Mandy Gervasio MS Vice President, QA & Compliance Comanche Biopharma
- Cindy Capeloto Head of Quality External Engagement Takeda

---

**13:44 – 13:51**

**Is It a Quality Issue or a Manufacturing Defect? Fundamentals of Operations Partnership**

Join me to explore a few tips and approaches to improve the enduring narrative of our real work relationships between Quality and Manufacturing. We'll quickly explore problem-solving to achieve the best results. With a little bit of humor, you can be inspired to be “besties” with your...
counterparts, and we’ll acknowledge the importance of supporting quality standards in a manufacturing. Don’t miss this lightning talk – it’s the insight you need today!

**Presenter:** Cheryl Norder  Vice President Global Quality Phillips-Medisize, A Molex Company

---

13:51 – 13:58

**Cessation of In Vivo Lot Release Testing**

Lot Release Testing (LRT) is required prior to the commercial release of lots, or batches, to ensure product quality. For tests such as purity and potency, in vivo tests are still industry standard for therapies such as biologics. Though hurdles to end in vivo testing exist such as fear of lot rejection from the FDA and industry norms, there is more than ample valid reasoning to end this testing for approved biologics. In vitro alternatives exist (or can exist) that would align with reasons to support the cessation of in vivo LRT that include animal welfare concerns, business considerations, human ethical considerations, lack of in vivo equivalence to humans, and the push by industry, regulatory bodies, and the general public to reduce animal use in testing.

**Presenter:** Stephanie P. Kurtz MS  Strategic Account Executive SQA Services

---

13:58 – 14:05

**Pre-Filled Syringe Considerations for VHP Sterilization**

Vaporized Hydrogen Peroxide (VHP) is a growing option for sterilizing pre-filled syringes that contain an aseptically filled biological product. The sterilization of the syringe, packaging, and associated components allows for a sterile presentation to the patient reducing the risk of infection. The recent ISO 22441 standard defines the development, validation, and controls for VHP sterilization, however, there are several steps to consider as part of the feasibility process for pre-filled syringe products. This tech talk will focus on the key areas to consider for pre-filled syringe designs used in a VHP sterilization process. Items discussed will include best design practices for vacuum tolerance, materials, and flow path considerations.

**Presenter:** Juha P. Mattila MEng  Director, Sterilization Technologies STERIS Corporation

---

14:05 – 14:12

**Q&A**

---

13:30 – 14:15

**IG03: Visual Inspection of Parenterals**

- **Interest Group Leader:** John G. Shabushnig PhD  Principal Consultant Insight Pharma Consulting, LLC
- **Interest Group Leader:** Rick J. Watson  Director, Sterile and Validation Center of Excellence Merck & Co., Inc.

14:15 – 14:30

**Transition to Next IG**

14:30 – 15:15

**IG05: Packaging Science**

- **Interest Group Leader:** Anthony A. Perry  Regional Director of Quality SCHOTT
- **Interest Group Leader:** Xu Song MS  Senior Director/CMC Lead AstraZeneca
14:30 – 15:15

IG06: Vaccines

**Interest Group Leader:** Jane L. Halpern PhD Executive Director IAVI

**Interest Group Leader:** Sabrina Restrepo PhD Director, Vaccines - Technical Product Leadership Merck & Co., Inc.

14:30 – 15:15

IG07: Process Validation

**Interest Group Leader:** Robert Dream Managing Director HDR Company LLC

14:30 – 15:15

Lightning Presentations: Session 2

PDA’s Lightning Presentations will use the Pecha Kucha presentation method which calls for telling a story using images rather than reading text from slides during a PowerPoint presentation. Each presentation will have 20 slides set to automatically advance after only 20 seconds of commentary per slide for a total talk time of just 6 minutes and 40 seconds.

**Moderator:** Lisa Bennett MForSc Senior GMP Consultant and Trainer SeerPharma

14:30 – 14:37

Sterility Testing of Cell and Gene Therapies

As the pharmaceutical industry continually evolves, so do the products produced. Viral Vectors, Cellular Therapies, and Viral Vaccines are increasingly predominant as they are a naturally sourced treatment of illness and disease. However, these treatments can present challenges to pharmaceutical developers because of their unique make-up, as these products are made for specific, individual patients, sometimes originating from a patient’s own body. Client’s face the challenge of outsourcing materials and products, and working with third party laboratories providing release testing to monitor the quality and integrity of their products. Most of these products are integral, requiring short testing timelines, as they may be needed as soon as possible for critically ill patients. Most compendial methods aren’t conducive to these tight timelines. The individuality of these products leads to small differences in products targeting similar conditions. The proper information and planning throughout the clinical experience is key to the eventual release and administration of these products. In this presentation, Eurofins Lancaster Laboratories will dive into some of the key information needed as a third party testing facility, expand on how to deal with issues, troubleshooting, as well as new technology for rapid and streamlined methods to explore when performing release testing.

**Presenter:** Zachary Beck Senior Microbiologist, Group Leader III Eurofins BPT

14:37 – 14:44

Digitizing Process Specifications to Expedite Tech Transfers

Manufacturing or process specification information is typically disseminated in multiple applications (ELNs, spreadsheets, ERPs, etc.). The data is usually unstructured, and terminology is not aligned across different users and through the product lifecycle. Lacking standardization, not having a consistent model, and the lower level of digitalization have a negative impact on tech transfers as manual translation/transfer tasks are needed. While digitizing the process definition has benefits, it is as important to have a solid design framework that allows the development of process specifications via reusable standard objects that facilitate change management and simplify the introduction of process variations across different production sites. Digitizing the process definition and using a digital collaboration platform not only increase standardization and reduce data integrity problem but also expedite the process tech transfer process internally or externally.

**Presenter:** Sergio Diaz Product Marketing Manager Emerson
14:44 – 14:51
Trends Driving Container Closure Integrity Testing and Positive Controls

Review of global trends in CCIT, with an emphasis on deterministic leak detection and state of the art laser micro-drilling of positive controls. - Global regulatory changes (Annex 1, FDA USP 1207) are driving manufacturers to deterministic leak detection technologies. - Proper use of these technologies requires higher repeatability to produce statistically significant data. - These requirements are driving a renewed focus on CCIT, and the implementation of CCIT in Package Design and Package Validation. - CCIT is therefore driving the need for positive controls with smaller drilled defects, including appropriate documentation (metrology, COCs)


14:51 – 14:58
Analysis of a Robotic Airborne Disinfection System Utilizing Hydrogen Peroxide for Disinfecting Clean Rooms

Airborne Surface Disinfection (ASD) entails eradicating bioburden from surfaces by employing a combination of a specialized device and disinfectant. The effectiveness of this approach is contingent on factors such as the ASD device's capabilities, the chosen disinfectant, the characteristics of the target location (including its complexity and occupancy), and environmental elements like relative humidity, temperature, and the materials present in the area being treated. The intricacy of the target area may necessitate the use of multiple ASDs or longer ASD timeframes. This study involved three separate trials conducted in two distinct complex target locations. The robotic ASD device utilized 7.4% H2O2 as the disinfectant, accompanied by chemical, biological, and enzyme indicators, along with data loggers capturing relative humidity and temperature. The results from all indicators demonstrated a satisfactory >4-log reduction. Notably, the total ASD duration was significantly reduced, totalling 120 minutes as compared to >180 minutes, thereby saving both the need for additional devices and the overall cycle time. Integrating the ASD device into a robotic platform holds promise for mitigating the need for multiple devices, thereby reducing the overall ASD duration without compromising its effectiveness.

Presenter: Prasanna K. Sistla Technical Director VM Sciences

14:58 – 15:05
Improved Identification of Pharmaceutical Ingredients and Contaminants Using Artificial Intelligence and Machine Learning

Traditional methods of identifying particulate ingredients and contaminants in parenteral drugs using image analysis (Static or Dynamic) typically use a simple binary thresholding method to detect the presence of a particle in an image. Subsequent steps for classification of the particles identified can be performed by calculating the morphological properties of the derived particle image including properties such as size, circularity, convexity, and aspect ratio, and using them to create classification sets. The boundaries of these classes are often arbitrarily drawn when defined by the operator, leading to the misclassification of similar looking particles in a formulation especially when performing compositional analysis. The integration of Artificial Intelligence (supervised and unsupervised) and Machine Learning into the detection and classification of particles in an image set can significantly improve the identification and classification of discrete particle sets by considering the total complexity of the particle images and all derived parameters in a single algorithm, creating a reductive classification of all ingredients including APIs, excipients, and contaminants. This work will discuss the application of AI/ML to static image analysis processing of parenteral drug formulation images and highlight the value of the technology for detection and identification of ingredients and contaminants.

Presenter: Matthew J. McGann MSc Director, Products and Markets ImageProVision

15:05 – 15:12
Q&A

14:44 – 15:15
IG04: Advanced Manufacturing and Applied Process Digitalization

Interest Group Leader: Peter J. Makowenskyj MEng Director of Design Consulting G-CON
### Poster Presentations in the Exhibit Hall

**15:00 – 16:00**

**A Holistic, Phase-appropriate Analytical Approach for Establishing Residual Host Cell Protein Specification Throughout the Cell Therapy Drug Product Lifecycle**

Residual host cell proteins (HCP) are low-level genomic protein residuals produced from process- or drug-related materials in manufacturing cell therapies. HCP residuals are organic process impurities per the International Conference on Harmonisation (ICH) Q3A/B guidelines (ICH, 2006). These residuals pose a risk to patients' immunogenic responses while affecting drug efficacy and stability. Drug developers must comply with the United States Pharmacopeia (USP) &lt;1086&gt; and &lt;509&gt; to detect HCP residuals, limiting 0.05% per day of active pharmaceutical ingredients (USP, 2015). Drug release criteria only require HCP results in phase 2 (FDA, 2020). Following phase 2, Biologic License Application filing requires more rigors toward product characterization. To implement a phase-appropriate analytical strategy for cell therapy development, HCP residuals are first identified using a conventional Western size-based assay or a Quadrupole/Time-of-Flight Mass Spectrometer (QTOF-MS). The first method option is far more feasible to execute and collect sufficient data than the latter. Following the 21 Code of Federal Regulations §610.9 (FDA, 2023), multiple QC samples were utilized for method development, validation, and phase 1 sample analysis. We developed a practical and ideal enzyme-linked immunosorbent assay for QC implementation and met the ICH and USP requirements to support phase 2 trials and commercialization.

**Poster Presenter:** Michelle Tseng PhD Senior Director Azzur Group

**15:00 – 16:00**

**A New Calibration Technique for Light Obscuration Sensors to Improve Counting Accuracy of Aggregated Proteins**

Light obscuration liquid particle counters used for USP &lt;788&gt; and &lt;787&gt; are calibrated using polystyrene latex (PSL) particles with a refractive index (RI) value of 1.58. This calibration approach generates accurate results for large particles with a similar RI value in the critical size ranges of 10 &amp; 25 µm. Various sources have pointed out the inaccuracies in results for protein particles where the RI value of approximately 1.4 is much closer to water, especially at smaller particle sizes. This presentation will describe a new calibration technique for light obscuration/scattering sensors using the new NIST RM 8634 and present results of aggregated proteins with both the historic PSL and the new protein calibration techniques. The calibration procedure used is described in ISO 11171:2020, using the new NIST RM 8634 to create a “protein calibration curve”. Aggregated protein samples were then analyzed by the single particle optical (SPOS) technique using both the historic PSL and new protein calibration curves. Results using the protein calibration curve reported higher particle concentrations at a given size.

**Poster Presenter:** Mark Bumiller Technology Manager Entegris, Inc.

**15:00 – 16:00**

**Transforming Deviation Management for Expedited Closure and Product Release in Cell and Gene Therapy**

This case study, conducted in partnership between a prominent cell and gene therapy manufacturer and a consulting firm, sought to streamline the deviation management process within the organization. The main goals were to define ownership in the process and enhance departmental knowledge and skills resulting in expedited deviation closure, while maintaining a high level of Quality. A detailed examination of the deviation lifecycle included identifying communication gaps, redundant meetings, delays resulting from information or decision bottlenecks, and the non-value-added activities in the process. This analysis, enriched by stakeholder involvement, led to the creation of an innovative workflow engineered to promptly resolve low-level deviations within a challenging 24-hour period, or ideally during the same manufacturing shift. To ensure a seamless integration, training sessions were deployed to ensure personnel were aligned with the new workflow and overarching site goal. In the initial weeks following go-live of the new workflow, the data showed a two-thirds reduction in the overall cycle time for low-level deviations. This was a substantial step towards reducing deviation closure time, along with allowing more time to focus resources on critical issues. Importantly, there were additional improvements in the pipeline, which, when implemented, were expected to streamline the process further.
Applying Holistic Sterile Manufacturing Design Principles to Build an Agile Combination Product Contract Manufacturing Facility Which Anticipates the Over the Horizon Compliance Requirements

There is an incredible level of complexity, investment and risk with building a sterile manufacturing facility. When the facility will serve the global needs of a diverse contract manufacturing customer base, it must be built for agility, efficiency, scalable and most importantly for global compliance-known today and what’s over the horizon. Examples of holistic design utilized in Kindeva’s new aseptic manufacturing facility; • Levo-magnetic drive motors- reducing wear and particulate generation • Disposable bagging systems in formulation tanks reducing cross-contamination risk and establishing more efficient change overs • Automated PUPSIT systems integrated into the filling process providing continuous filter integrity • Filling machines utilize isolators eliminating the need for traditional gowning and aseptic training, reducing grade A areas to the isolator interiors, and reducing time to qualify operators. • Modular filling suites- operating independently eliminating facility wide shutdowns • In-process fill check technology tracks individual drug containers allowing for automatic removal of individual containers not meeting quality parameters. Product quality, operational efficiency and compliance isn’t determined by any single process or design element. These are only achieved and maintained through holistic design principles that collectively meet the need of the market and regulators tomorrow and over the horizon.

Fused Quartz Vials: from Glass Science to Drug Containment Solution

Glass is the most used material in pharmaceutical packaging, and borosilicate is currently the most used among those described by the Pharmacopeia(s). The USP, however, has recently enacted changes to their glass packaging chapter < 660> that enable the introduction of new glass compositions, one of which is fused quartz. While new to the USP chapter, fused quartz has been manufactured for well over one hundred years, valued primarily for its high purity and remarkable properties, including a very low thermal expansion coefficient and excellent chemical durability. This presentation will address the science behind fused quartz vials, with focus on assessing their chemical, physico-chemical and mechanical performances. Although fused quartz is generally considered chemically inert, the selection of any container must always be done taking into consideration the individual drug product and processing requirements. The knowledge of this new glass and of relevant analytical testing can continue to accelerate its adoption as a container for parenteral preparations and on its classification inside the three main Pharmacopoeia and standard setting organizations like ISO and ASTM. The experts at Stevanato Group and Momentive Technologies are excited to see this “new” glass help solve many of the industry’s most demanding formulation challenges.

Quality Culture: From Buzzword to What Works

Warning letters consistently cite firms for failing to establish a Quality unit with the responsibility and authority to execute its responsibilities across all GMP settings. With the recent focus on quality maturity models and quality metrics to, in part, ensure the continuity of the drug supply, building a sustainable culture of quality is essential for all GMP-regulated facilities. The term “Quality Culture” has been around for years, but few companies have mastered what it means or how to implement and measure a culture of quality in a GMP-regulated environment. This presentation will provide attendees with an overview of the concepts behind quality culture, as well as some strategies for implementation and metrics for measuring performance.

System-Based Drug Manufacturing Inspections: An Inspectional Approach to Help Assure Readiness

System-Based cGxP Inspections review the establishment of the quality system used by an organization. Such audits look at a particular system which includes multiple processes and can spread across several employees and departments. This presentation provides an overview of the system-based approach to auditing (and inspections), demonstrating how the main parts of the pharmaceutical or healthcare organization can be divided up into interrelated systems. By assessing performance through the systems approach, the auditor is able to establish: • Is the organization following the established procedures, processes and standards? • Are the personnel involved knowledgeable, and familiar with regulations and all...
### Agenda

**2024 PDA Annual Meeting**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
</table>
| 15:00 – 16:00 | **Manufacturing in Miniature: Drug Delivery via Microneedle Array Patches (MAP)**  
Microneedle patch technology has progressed to the pre-clinical and early human clinical stage by many developers, but Kindeva is one of the few companies that has made it to Phase 3 clinical studies and has commercial scale equipment. Kindeva Drug Delivery provides recommendations for process development and manufacturing based on its coated microneedle patch drug delivery platform. Manufacturing process scale-up with intention of regulatory submission follows a strategic path. At each stage (lab bench, pilot, and commercial) it’s critical to document data, decisions, and key learnings in support of a design history file and regulatory submission. Documents should be raised at the time of data generation and cover topics including product development decisions, process development milestones, and device development choices. Likewise, methods and specifications mature during development. Data destined for regulatory submissions should be collected consistently over time. If a method changes, comparison data sets utilizing the two methods and same set of samples should be generated to support the change. Specification setting is also evolutionary, with specifications growing more detailed and narrower as the development proceeds. This evolution will be illustrated through Kindeva’s experience in scale up from lab to commercial scale processes for manufacture of coated microneedles.  
**Poster Presenter:** Andrew Riso Director of Business Development Kindeva Drug Delivery |
| 15:00 – 16:00 | **Centralized Vaporized Phase Hydrogen Peroxide (VH2O2) as Building Utility**  
Application of a disinfection and sporicide rotation is a critical component of a contamination control strategy per EU Annex 1. Many current applications deploy a manual process for sporicide application. Automated systems are desirable as they minimize people and equipment required to enter the classified spaces and minimize operating costs and errors as part of the process. These systems provide enhanced coverage in the critical environment areas and are especially critical for ATMP facilities that have strict contamination control requirements. This presentation will explore the use of a centralized, automated system to apply VH2O2 as a biodecontamination method in an ATMP facility. A case study will be presented that outlines: • VH2O2 properties and its use as a biodecontamination method in biopharmaceutical applications. • VH2O2 integration into the facility HVAC for distribution to clean rooms and RABS. • Equipment integration with the facility building management system (BMS) for control and cycle reporting functions including 21 CFR Part 11 and EU Annex 11 considerations. • Safety considerations for the users and the facility. • Qualification and validation of the process. Users will take away how VH2O2 centralized, automated systems can be implemented for enhanced contamination control strategy practices.  
**Poster Presenter:** Matt Hofacre Senior Director, Technical Services STERIS Corporation |
| 15:00 – 16:00 | **An Alternative Approach to Standard Operating Procedures**  
The classic paradigm of training and executing SOPs in BioPharma- is to Read and Understand, to observe someone else perform the procedure, and then to demonstrate it yourself. Once this initial training phase is complete, you are left solely with a written SOP to reference. This heavy reliance on written instructions can lead to a higher chance of ambiguity and unnoticed or overlooked errors. My proposed solution aims to address this issue by accommodating diverse learning preferences and seamlessly integrating visual aids, such as videos, directly into procedures. To address this challenge, I have embedded QR codes directly within procedures. This approach enables employees to access instructional videos quickly and conveniently, providing clear guidance, especially for more complex steps, thus reducing errors and preventing confusion during execution.  
**Poster Presenter:** Max Falcone Analyst Tunnell Consulting |
| 15:00 – 16:00 | **Evaluating Your Stopper: Proving Stopper Functionality for Real-World Use Cases Through <USP 382>** |

**Appropriate procedures, processes and standards? • Is documentation available demonstrating training, monitoring, and compliance programs? • Is data from the various parts of the quality system being evaluated to make appropriate risk-based decisions? In terms of the core systems, the six systems represent comprehensive and rational categories in relation to the different standards to which an organization needs to adhere. The systems provide an indication to an auditor as to the overall performance of the organization and across all areas of manufacturing.**
With the upcoming implementation of USP < 382> in 2025, there is an increased emphasis on designing clinically representative experiments to prove that the required, optimal container system is achieved regarding piercing performance and resealability. Not only are medical professionals taught varying techniques on how to pierce a stopper, but industry opinions on the best needle and method have led to more questions than answers. To reduce risk to the patient, it is critical to show that one’s stopper will maintain integrity throughout multiple piercings, or multipuncture, applications through demonstrated resealability performance under exaggerated test methods. Early evaluation will provide confidence that your stopper will be able to withstand the various piercing techniques and reduce downstream risk. This poster highlights a comparative study conducted by West on different stoppers using a modified USP < 382> protocol for fragmentation and coring, penetrability, and resealability. Data will be provided showing how the multipuncture performance of stoppers with different formulations, designs, and sizes is affected by stopper sterilization methods (steam versus gamma) and penetration needle gauge (18G versus 21G). Fragments down to the subvisible level were counted in addition to the ≥150µm particles required in the compendia to align with testing for real-world applications.

**Poster Presenter:** Todd D. Jasinski Senior Specialist, Technical Product Development *West Pharmaceutical Services, Inc.*

---

**Inert Gas Bleed Valve Location and the Impact on Lyophilization Chamber Pressure**

Nitrogen gas is bled into the lyophilization chamber to control the chamber pressure during primary and secondary drying. The location of the Nitrogen gas bleed valve is an often overlooked variable when transferring a cycle from one dryer to another. The focus of these studies will be how the location of the gas bleed valve affects the primary drying segment of the lyophilization cycle. The location of the gas bleed valve was varied during these studies and the air temperature at different locations on the shelf and chamber was monitored during primary drying. The air temperature during primary drying was compared by shelf and shelf location to investigate the effects of varying the location of the Nitrogen gas bleed valve. After the air temperature mapping studies were complete, sublimation rate studies were completed using bulk trays and Purified Water, USP. The results of these mapping studies revealed differences in air temperature at different locations on the shelf when the Nitrogen gas is introduced at different locations of the lyophilization chamber. Additional sublimation rate studies were completed to compare to the air temperature mapping studies and if warmer temperatures result in higher sublimation rates.

**Poster Presenter:** Jason B. Angstadt MS Scientist III *Lyophilization Technology Inc.*

---

**Supply Chain Verification for API Manufactured by a Third Country**

This poster explains the Supply Chain Verification and Risk assessment carried out by Qualified Persons for API imported from a Third Country.

**Poster Presenter:** Farah Nadeem QP Trainee *Paul Palmer Ltd*

---

**Using Toxicological Risk Assessment to Minimize Cross-Contamination**

Conducting a risk assessment to evaluate the toxicity of a product helps to ensure patients' safety and prevent unwanted cross-contamination and recalls. Data from both pre-clinical and clinical trials provides insight on safety margins, adverse effects, and pharmacokinetic parameters (i.e., absorption, distribution, metabolism, and excretion). Toxicologist can determine Permitted Daily Exposure (PDE) and/or Accepted Daily Exposure (ADE) across the product lifecycle and use adjustment factors to address both uncertainty and known toxicities associated with a product. Overall toxicological risk characterization for product development, cleaning validation, manufacturing process, and laboratory testing is critical to ensure patient safety. This talk will briefly highlight some of the regulations, risk assessment process, and provide case-studies to determine health-based exposure limits (HBEL).

**Poster Presenter:** Wendy Haines PhD, DABT, ASQ CQA Director of Toxicology & Technical Services *PharmEng Technology*

---

**Identification of Foreign Particulate Matter in Assembled Autoinjectors Through Long-Time Tracking of Individual Particles’ Trajectories**

Part of the challenge in detecting foreign particles in a liquid parenteral is to discriminate them from bubbles or other intrinsic objects, which do not constitute a defect, but can lead to false rejects. We have implemented an innovative methodology to identify foreign particles in a complex autoinjector device. For this application, we combine a handling adapted to mobilize particles in solution with image processing algorithms for...
Particle tracking. In our test system, the devices circulate in a linear transport system and are turned upside down prior to the image acquisition. In this way, particles which might be stuck on the walls or at the bottom of the device are released in the solution, which facilitates their detection. By acquiring up to hundreds of images we are able to track the particles’ motion for longer than 1 second, distinguishing whether they tend to move downwards or upwards and identifying them as particles or bubbles, respectively. The strength and novelty of our machine design rely on the fact that the additional time for image analysis is obtained without compromising the speed of the machine.

Poster Presenter: Matthias Kahl Head of R&D and Lab Services WILCO AG

15:00 – 16:00

Behavior of Molded and Tubular Vials During Depyrogenation

Depyrogenation is a key step in the aseptic filling process. Dry heat depyrogenation is the method of choice for glass vials. Most depyrogenation tunnel manufacturers consider the power necessary is proportional to the weight of glass vials. This study shows the reality is different for small vials below 30 ml. An industrial depyrogenation tunnel was used, filled with 100 H molded vials and in the center of the conveyor, in the same row two 20R, two 20H and two 20H EasyLyo. The temperature was monitored with thermocouples. The temperature curves for molded and tubular 20ml vials are close and similar. The times recorded to achieve the 3 log reduction were 18 min 13s for the tubular vials, 19 min 28s for ISO vials and 19 min 37s for EasyLyo vials. The accumulated destruction factors FD for these 2 vials are significantly equivalent. There was no direct correlation between the weight of vials and the energy needed for depyrogenation for glass vials below 30ml. The measured time to achieve a 3 log reduction did not differ by more than 8%, while the weight difference was 70%. This understanding opens new perspectives for drug manufacturers in terms of sustainability and machinability.

Poster Presenter: Jingwei Zhang PhD Group R&D Director SGD Pharma

15:00 – 16:00

Developing a Risk Score for Critical Suppliers Using Artificial Intelligence (AI)

The modern economy is familiar with many examples of risk scores, like credit scores, insurance scores, and more. Supply chains are one area where risk scores haven’t yet been fully developed and utilized. In the pharmaceutical industry, where the supply chain has a direct impact on patient safety and health outcomes, supply chain risk scoring is of particular importance, yet as an industry, we have a lot of progress to make. With more data available than ever before, plus the capabilities unlocked by AI and ML, pharmaceutical sponsors can now accurately score the relative risk of all of the organizations upstream from them, like CMOs, API manufacturers, and excipient manufacturers. Takeaways: - Which variables should be used to calculate pharmaceutical supplier risk? - What are some roadblocks to developing a supplier risk score and how can they be overcome? - Entity resolution - you can’t accurately calculate a risk score for a particular entity unless the dataset you’re using has appropriately resolved all of the permutations of the entity name into one profile. - How those variables interact with one another (i.e. how do you score a warning letter and the 483 that preceded it)?

Poster Presenter: Michael de la Torre CEO Redica Systems

15:00 – 16:00

Cleaning Considerations for Lipid Nanoparticles

The advancements in lipid nanoparticle (LNP) delivery systems have been paramount in the performance, stability, safety, and eventual regulatory approval of novel drugs and vaccines, such as the mRNA COVID-19 vaccine by Moderna, Pfizer/BioNTech, and others. These encapsulated LNPs can deliver drugs using a wide range of sizes based on the LNP components and route of administration. However, the lipophilic nature and complexity of LNPs can present difficulties in the cleaning process. Laboratory cleaning models can be used to efficiently screen cleaning agents and define critical cleaning parameters. The presentation explores the concerns with cleaning drug products utilizing lipid nanoparticle delivery vehicles and provides general cleaning recommendations based on laboratory and field testing. Reference: https://www.pharmtech.com/view/considerations-for-cleaning-lipid-nanoparticles (June, 2022)

Poster Presenter: Paul T. Lopolito Technical Services Director STERIS Corporation

15:00 – 16:00

Exploratory Assessment of an On-Body Delivery System for Large-Volume SC Delivery: Facilitating Rapid Thermal Equilibration to Ambient Temperatures for Immediate Utilization Post-Refrigeration
In the evolving field of healthcare, ensuring prompt and efficient medication delivery remains a top priority. This study undertakes an exploratory assessment of an on-body delivery system tailored for large volume subcutaneous (SC) delivery. The design is crafted to accelerate thermal equilibration to ambient temperatures, enabling immediate use post-refrigeration. The movement of the drug through the fluid path is central to warming the drug swiftly to near ambient temperatures. Our analysis dives into the performance and efficiency of this system across varied environmental conditions. The data, which will be shared in detail during the presentation, unveils a significant trimming of the time needed to reach ambient temperatures, thereby potentially reducing wait times and enhancing user experience. These preliminary findings highlight the promise of this system and beckon further exploration to ascertain its real-world applicability and advantages, aspiring to advance the sphere of patient-centric medication delivery solutions.

**Poster Presenter:** Mehul Desai PharmD, MBA Vice President, Medical Affairs Enable Injections

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>15:00</td>
<td>Isolator/RABS: Risk Minimization Through Correct Glove Management</td>
</tr>
<tr>
<td>15:00</td>
<td>Evaluation of New Sterilization Modalities that Enable Terminal Sterilization of Parenteral/Injectable Drug Products Traditionally Filled by Aseptic Manufacturing</td>
</tr>
<tr>
<td>15:00</td>
<td>Data Analysis ~ Trending and Pattern Recognition for Contamination Control</td>
</tr>
<tr>
<td>15:00</td>
<td>Benefits of Single-use for ATMPs in Regards to Annex 1</td>
</tr>
</tbody>
</table>

**Poster Presenter:** Alex J. Kappani Product Management SKAN AG

**Poster Presenter:** Terrence Hollis Senior Manager, Global Technology and Engineering Pfizer Inc.

**Poster Presenter:** Susan B. Cleary EMBA Director of Product Development Novatek International

**Poster Presenter:** Mehul Desai PharmD, MBA Vice President, Medical Affairs Enable Injections

**Poster Presenter:** Alex J. Kappani Product Management SKAN AG

**Poster Presenter:** Terrence Hollis Senior Manager, Global Technology and Engineering Pfizer Inc.

**Poster Presenter:** Susan B. Cleary EMBA Director of Product Development Novatek International

**Poster Presenter:** Mehul Desai PharmD, MBA Vice President, Medical Affairs Enable Injections
**Poster Presenter: Juergen M. Metzger** Product Specialist/Senior Consultant Final Filling Sartorius North America Inc.

15:00 – 16:00

In-Line Real-Time Monitoring of Perfusion CHO Cell Culture Critical Process Parameters and Critical Quality attributes using Raman Spectroscopy and Chemometric modelling

Cell culture processes are complex and highly variable and yet only a handful of key parameters such as temperature, pH, and dissolved oxygen (DO) are typically controlled in real time. While measurement and control of these parameters are essential for a robust process, they provide only broad assumptions on the culture’s true state and offer limited insights into the process and cell growth. In contrast, critical process parameters (CPP) such as glucose, lactate, and key performance indicators (KPI) such as total cell density (TCD), viable cell density (VCD), antibody titer, osmolality provide direct indication of the culture’s content and state. These measurements are typically measured offline, however, and do not provide real-time information or effective process control. This presentation describes use of the MilliporeSigma’s ProCellics™ Raman Analyzer with Bio4C™ PAT Raman Software (also known as Raman PAT Platform) to perform inline and real-time measurement of TCD, VCD, Antibody titer, Osmolality and the concentration of glucose and lactate a bench-scale bioreactor.

**Poster Presenter: Ushma Mehta MS** Regulatory Consultant MilliporeSigma

15:00 – 16:00

Aseptic Transfer of RTU Containers in the Light of the New Annex 1

The poster will compare the different methods on how to introduce RTU Containers into the aseptic environment with focusing on the operating, sterility and validation principle. Transfer methods as H2O2, NTT, Ebeam and pulsed light are being compared. These methods will be put into conclusion with then new Annex 1.

**Poster Presenter: Christian Thieme** Sales Director - Americas groninger & co. gmbh

15:00 – 16:00

Implementing a Disinfectant Program for Advanced Therapy Medicinal Product Manufacturing

In a fast-paced, rapidly evolving environment like Advanced Therapy Medicinal Product (ATMP) manufacturing, it is easy to overlook critical elements necessary to maintain contamination control. However, despite urgent manufacturing procedures, a sound strategy for contamination control is essential to help ensure microbiological safety and final product integrity. A cleaning and disinfection program must address the unique challenges within ATMP including addressing the special considerations often found within these facilities such as limitations with available resources and critical time-sensitive procedures. Implementing a program that can be adaptable to the unique environment of specialized procedures that incorporates the consideration of smaller processing suites, biosafety cabinets and isolators is key. A well-designed program that is not overly complicated yet focuses on a holistic contamination control approach focused on the challenges in the ATMP environment is essential.

**Poster Presenter: Dan A. Klein MA** Senior Manager, Technical Services STERIS Corporation

15:00 – 16:00

Glass Containers Under-filling: E&L Benchmark of Different Glass Vials

USP <660> for glass surface chemical durability test prescribes the nominal filling volume as 90% of glass container brimful capacity. Many glass containers for injectable solutions are filled less than this nominal volume which leads to an increased level of E&L, as the surface/volume ratio is increased. We studied the chemical stability of tubular and molded vials in this situation. The study performed a benchmark of E&L levels and pH shift for 3 vials of nominal volume 10ml : tubular, type I molded and type I molded treated with ammonium sulfate. Filled with 10ml and 4ml NaCl 0,9%, the vials went through 1, 2 and 3 cycles of autoclave, followed by extractable analysis by ICP (Inductively Coupled Plasma Atomic Emission Spectrophotometry) and pH measurement. For all types of vials, 4ml under-filling led to a higher pH shift and higher extractable level than nominal filling of 10ml. For the same filling level and autoclave testing, treated molded type I were the most performant in terms of pH stability and E&L levels, followed by type I molded. Tubular vials showed the highest E&L levels and pH shift. Considering the industry practice, type I molded vials is the most relevant choice.

**Poster Presenter: Jingwei Zhang PhD** Group R&D Director SGD Pharma
15:00 – 16:00

High Cell Density Cryopreservation for Upstream Process Intensification Using LN2 Vapor Phase Stored Seed Train Intermediates

Standard seed train operations start by thawing of a single 1 ml vial with cell densities of 10 x 106 VC/ml. For reaching a sufficient absolute cell number for production bioreactor inoculation, several expansion steps, starting with shake flasks, need to be performed. These open cell culture operations result in long ramp up times, high room classifications during the whole process, and are a major source of process variability. High cell density cryopreservation is a method where cells can be frozen in bags with cell densities higher than nowadays standard processes. This leads to the advantage that cell expansion and batch production can be separated. Lower room classification for the cell culture area in GMP manufacturing might be a result due to the reduction of manual handling steps before the main stage bioreactor (closed processing). Furthermore, these intermediates allow global distribution from a central expansion facility to decentralized global production facilities. Currently, we have demonstrated that SU bag assembly was modified to withstand liquid nitrogen vapor phase storage and the process of freeze and thaw was also optimized to maintain cell performance and SU bags integrity after thaw.

Poster Presenter: Ushma Mehta MS Regulatory Consultant MilliporeSigma

15:00 – 16:00

Maintaining Superior Viral Vector Recovery in Cell and Gene Therapy Applications by Using Daikyo Crystal Zenith® Vials

AAV8 and AAV9 were chosen as representative adeno-associated virus (AAV) serotypes, with respective titers in a common buffer formulation, and evaluated in different 2 mL vial types: Daikyo Crystal Zenith® (CZ) vial, and two commercially available borosilicate vials. To simulate viral vector recovery in cell and gene therapy applications, the vial combinations were tested across five challenge conditions: 1. 3 months at -80°C, recommended condition for long term storage 2. 2 months at 5°C, recommended condition for temporary refrigerated storage 3. 3 weeks at 25°C, simulating room temp clinical ambient conditions 4. 72 hours of 250RPM agitation, to mimic handling during manufacturing/shipping 5. 5 cycles of Freeze/Thaw, to mimic handling during manufacturing and the potential for structural damage to proteins or DNA In all conditions, the Daikyo CZ vial demonstrated improved viral vector recovery compared to borosilicate glass vials. The data shows that there were no significant changes in product quality due to container storage in the Daikyo CZ vials, and that the CZ vials may comparatively improve viral vector recovery across common storage and handling conditions.

Poster Presenter: Eric Kurtz Manager, Technical Product Development West Pharmaceutical Services, Inc.

15:00 – 16:00

Developing a Method to Learn Capper Settings to Handle Component Variations

Component dimensional variation has been reported as one of the causes for crimping variations. Critical dimensions of components (vial, stopper, cap) can vary within manufacturing tolerances, however these ranges of variation may require adjustments to capper settings to ensure a proper package seal. The settings used to crimp one batch of components may need to be adjusted to crimp another batch. In this work, we developed a way to learn the component variations and then automatically adjust the settings to ensure a proper seal. The possible range for each setting was validated and learning was limited to that range. Data for the learning model was obtained using an in-line machine vision system to continuously monitor component variations and adjust capper settings as required. Throughout the process, a constant compression percentage is monitored, and intervals of finished product tested by Residual Seal Force (RSF) to ensure seal quality.

Poster Presenter: Carolina Gonzalez Gaitan PhD Parenteral Packaging Scientist Genesis Packaging Technologies

15:00 – 16:00

Breaking Out of the Human Factors Study Loop, For the Benefit of Patients

Human Factors Engineering (HFE) is a critical component of development and life cycle management for combination drug products. Human factors (HF) studies assess whether combination products are safe and effective and, when properly designed, can eliminate millions of dollars in future life cycle management costs. These studies seek to understand how patients interact with products, what patients expect from products, enable manufacturers to design out risks, and ensure positive patient outcomes and compliance. HFE is never a one-and-done activity. It involves an iterative series of experimentation, testing and qualification. Each HF study yields new observations and options for continuous improvement. This can create a loop which, if not managed properly, can delay the implementation of design improvements and instructions that will benefit patients and users at all stages of a product’s life cycle. This presentation will discuss how principles of Use Related Risk Analysis have been incorporated into autoinjector HF studies ranging from early prototypes to on-market products. It will present a process which balances the iterative process of HF engineering with focus on the end goal, delivering outcomes for patients.
<table>
<thead>
<tr>
<th>Time</th>
<th>Poster Presenter</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>15:00 – 16:00</td>
<td><strong>Amy Lukau</strong> Senior Human Factors Lead, Kindeva Drug Delivery</td>
<td><em>The Challenges of Testing Bacterial Spores in Disinfectant Coupon Studies to Meet CCS Compliance</em></td>
</tr>
<tr>
<td>15:00 – 16:00</td>
<td><strong>James N. Polarine MA</strong> Senior Technical Service Manager, STERIS Corporation</td>
<td><em>Design Verification Testing of Auto-Injectors: Performing All Tests on a Single Unit to Reduce Sample Quantity and Increase Testing Throughput</em></td>
</tr>
<tr>
<td>15:00 – 16:00</td>
<td><strong>Mike Ulman PhD</strong> Technology Manager, Packaging and Delivery Systems, West Pharmaceutical Services, Inc.</td>
<td><em>High Yield Sterile Filtration of High Viscosity Pharmaceutical Formulations</em></td>
</tr>
<tr>
<td>15:00 – 16:00</td>
<td><strong>Jack E. Kochevar</strong> Process Engineer, Lifecore Biomedical</td>
<td><em>A Model for a Risk-Based Deviation Investigation Process</em></td>
</tr>
</tbody>
</table>

**Poster Presenter: Amy Lukau** Senior Human Factors Lead, Kindeva Drug Delivery

The Challenges of Testing Bacterial Spores in Disinfectant Coupon Studies to Meet CCS Compliance

This presentation will cover the complexities of designing a robust and effective disinfectant coupon study. The presentation will present new novel data showing that the testing of bacterial endosporas at different time points will always have the presence of the spore stage as well as the vegetative state of the spore forming bacteria. The presentation will cover how to implement an effective disinfectant validation program as part of the contamination control strategy. Risk assessments will be covered as effective methods of determining the coupon surfaces and microorganisms to include in the coupon study. The overall scope of the presentation will cover all key aspects of a well planned out disinfectant validation study that compliments the contamination control strategy.  

**Poster Presenter: James N. Polarine MA** Senior Technical Service Manager, STERIS Corporation

Design Verification Testing of Auto-Injectors: Performing All Tests on a Single Unit to Reduce Sample Quantity and Increase Testing Throughput

The development of combination products requires verification of the performance of the devices to meet the design input requirements. For an auto-injector, particularly an auto-injector that was designed by a medical device manufacturer but is being sold as part of a combination product by a drug company, it is important to perform design verification to ensure that the combination product meets the design requirements for the specific combination. While relevant testing must be deduced from a risk-assessment performed on the particular drug-device combination, guidance documents (like ISO 11608-5:2022 Needle-based injection systems for medical use — Requirements and test methods — Part 5: Automated functions) can serve as useful starting points for determining characteristics that require testing. This poster addresses the test methods developed and validated through a Gage R&R study, using devices or surrogates, as needed, for verifying the performance characteristics of an auto-injector using commercially available force testing equipment with specially designed add-ons that enable the performance of a battery of tests on a single auto-injector, thus generating statistically significant datasets with minimal sample sizes.

**Poster Presenter: Mike Ulman PhD** Technology Manager, Packaging and Delivery Systems, West Pharmaceutical Services, Inc.

High Yield Sterile Filtration of High Viscosity Pharmaceutical Formulations

Sterilizing pharmaceutical products is essential for patient safety and is typically achieved using terminal sterilization methods. In the case of high viscosity formulations, terminal sterilization is often avoided as it can inadvertently change product attributes. Using commercially available 0.2um sterile filters for viscous formulations remains limited due to significant challenges dictated by the filter design and operating ranges. In this work, a validated high pressure sterile filtration (HPSF) skid is presented as a method to successfully sterileize viscous formulations without compromising patient safety. This system has been used to filter solutions used as medical devices and active pharmaceutical ingredients (API) and is validated in accordance with regulatory guidance. Formulations of sodium hyaluronate (NaHy) with molecular weights of 900 – 2,000 kDa, concentrations as high as 30mg/mL, and viscosities up to 1,000,000 cps were examined. When comparing the filtration yield of a 10mg/mL NaHy solution with 900kDa molecular weight on a commercially available capsule filter to HPSF, the flux with HPSF was three orders of magnitude higher. Additionally, HPSF did not result in concentration differences between unfiltered & filtered solution in contrast to low pressure filtration. HPSF can fast track development and accelerate bringing early phase formulations into the clinic.

**Poster Presenter: Jack E. Kochevar** Process Engineer, Lifecore Biomedical

A Model for a Risk-Based Deviation Investigation Process

Deviation investigation process owners often find themselves swamped with investigations, lacking quantitative tools that allow them to discriminate between minor low-risk events and critical high-risk deviations. Additionally, the business processes that support deviation investigations are often not purpose-built to enable the speed and investigational rigor that allow for timely closure and effective corrective action. This talk will present a proven model for building a quantitative risk-based deviation classification system and will discuss assigning investigational tools to assigned deviation risk levels. Supporting business processes will also be discussed, including professionalizing deviation investigators as an expert role within...
an organization as well as developing daily operational practices and metrics for effective management of the deviation lifecycle: identification, assessment, investigation, assignment of corrective/preventive actions, and approval/closure.

**Poster Presenter:** Aaron Hubbell  
*Director, Life Sciences Barry-Wehmiller Design Group*

---

15:00 – 16:00

**Developing Primary Packaging System for Nanosuspensions: Headspace Design Space Case Study**

Suspensions with nanometer size drug particles are a unique drug product dosage form which allow high concentrations of water-insoluble small molecules to be parenterally administered into human bodies to treat difficult diseases. They are typically packed in pre-filled syringes (PPS) or glass cartridges with a desired level of container closure integrity (CCI) to protect them from oxygen and microbe ingress. Headspace (HS) is an important attribute that needs to be well controlled during the filling of the nanosuspensions into glass primary containers. This case study highlights two important factors in relation to headspace within a primary pack containing a nanosuspension product: 1) The importance of a maximum allowable headspace given the impact this has on stopper movement and therefore on the primary packaging system's sterility performance; 2) The minimum headspace requirements for nanosuspension products as they need to be well resuspended prior to drug product administration. Thus, the headspace needs to be optimized within a certain window to ensure adequate sterility and achieve the desired dosage. In summary, this case study serves as a good example of a balanced approach on developing challenging primary packaging solutions for this unique parenterally administered nano-suspended drug product dosage form.

**Poster Presenter:** Liang Fang PhD  
*Associated Director, Primary Packaging GSK*

---

15:00 – 16:00

**Economic Benefits of an Original Container Closure during Combination Product Development: Expert-Modeled Scenarios Validated by Pharma**

**Poster Presenter:** Mehul Desai PharmD, MBA  
*Vice President, Medical Affairs Enable Injections*

---

16:00 – 17:30

**D3: The Case for Disruption: Challenging the Status Quo to Ensure a Viable Future**

Back by popular demand! This session will be an opportunity to discuss what needs to change in our industry and ideas for doing so, regardless of what, or how long, it would take to get there. The floor is open to topics including improvements to aseptic processing, updating regulatory requirements, and navigating post-approval changes (PAC) to next-generation technologies, and defining the ultimate desired state for sterile product manufacturing. A brief presentation will set the stage for an open forum to hear your views and ideas.

**Moderator:** Josh Eaton MS  
*Senior Director, Scientific and Regulatory Affairs PDA*

---

16:00 – 17:30

**Panel Discussion**

- **Panelist:** Hal Baseman MBA  
  *Chief Operating Officer ValSource, Inc.*

- **Panelist:** Gabriele Gori  
  *SVP Global Quality Head and Chief Quality Officer Biogen*

---

16:00 – 17:30

**C3: Navigating the Future of Pharma: Patient-Focused, Tech-Enabled, and Intensely Efficient**

Join this session to learn about the coming together of patient-centric innovations, operational excellence through technology, and process intensification strategies, collectively shaping the future of pharmaceutical manufacturing. The presenters will highlight three distinct perspectives, each addressing pivotal aspects of innovation
Unlock the Potential: Integrated Development of High-Volume Drug/Device Combination Products

The pharmaceutical market is undergoing a groundbreaking transformation, driven by the increasing demand for large volume delivery devices for subcutaneous (SC) administration of parenteral formulations. This method has gained popularity for the treatment of chronic diseases, offering longer dosing intervals compared to intravenous applications. Ready-to-use delivery devices are the future, designed to simplify administration for the end-user. Patients can self-administer in the comfort of their own homes, or healthcare professionals can administer in office settings. The benefits are numerous, including decreased treatment burden, enhanced convenience, improved adherence, significant cost savings, and fewer capacity bottlenecks.

The presentation will delve into the key challenges faced in the development of high volume combination products for SC administration. We will explore the crucial considerations in selecting the most suitable device, taking into account both user/patient needs and drug product development perspectives. From product compatibility to regulatory aspects, we will navigate the complexities of drug product development, all while choosing clinical phase-appropriate approaches. It will become clear that an integrated, holistic drug product/device development approach is essential for the success of combination products.

Presenter: Adithya Balasubramanian Director ten23 health AG

Embracing Innovation to Drive Operational Excellence

Making medicine with safety first and quality always is integral to meeting patient needs. Increasingly, operational excellence in pharmaceutical manufacturing operations has benefitted from the application of technology and best practices. A wide array of technologies is available to reduce human error, reduce friction in processes, improve response through robust process monitoring and real-time alerts/process status, and improve training effectiveness. These technologies can also generate data that is used for ongoing process improvement, root cause analysis, and feedback, coaching and training needs. These transformational capabilities enable a continuous learning and improvement culture and organization. In this session, we will share a variety of applications of technology being leveraged to increase operational excellence related to aseptic practices in parenteral manufacturing. The session will include examples of virtual reality, augmented reality, video learning, biometric treadmill experiences, and wearable technology to reduce process friction. Use of an Apple Watch algorithm that provides real-time feedback on operator movement will be highlighted. Cloud-based movement analytics may be used to assist with continuous improvement and aseptic operator coaching.

Presenter: Scot Lindsey Senior Vice President & Information Officer, M&Q Eli Lilly and Company

Lifecycle Management PAT Implementation for Process Intensification

In this talk, we will present a case study developed in process intensification of tableting processed for oral dosage forms. Use cases will be presented where the strategy for process intensification was achieved by the implementation of PAT tools for real time process control and quality decision making as well as RTR of the final product. Structured approaches were followed encompassing end-to-end process mapping, principles of quality risk management, the execution of feasibility studies using different spectroscopic methods, and DoE studies for spectroscopic calibration and validation of multivariate predictive models of tablets’ CQAs. Pathways to overcome practical regulatory considerations and technical challenges will be presented as well as the benefits achieved in cycle time and cost reduction and well as overall OEE.

Presenter: Rui Cesar Silva PhD Senior Product Lifecycle Consultant ValGenesis

Q&A
16:00 – 17:30

B3: Revolutionizing Manufacturing: Patient Focus, Tech Excellence, and Intensified Processes
Embark on a comprehensive exploration of key challenges in biopharmaceutical development, spanning three pivotal areas, and the patient-centric strategies shaping the next era of pharmaceutical manufacturing. The session will present a holistic perspective on navigating the convergence of knowledge, validation, and quality management for optimal outcomes.

Moderator: Catriona Murphy MSc Senior Advisor QA/Qualified Person Eli Lilly and Company

16:00 – 16:20
Knowledge Management Best Practices for Preserving Biologic CQA Information
During technology transfer of a biologic process between product development and product scale up, loss of information can cause adverse impacts on CQAs, and therefore, adverse impacts to product strength, identity, safety, quality, and potency. This presentation defines some common biologic CQAs and critical information (data, documents, knowledge, risk assessments, etc.) used for development and support/monitoring of those CQAs. Building upon existing literature (e.g. ISPE’s Good Practice Guide for Knowledge Management in the Pharmaceutical Industry), this presentation defines how and when that CQA-related information is commonly lost during the product development and scale up windows and provides methods for prevention of loss of information related to those CQAs.

Presenter: Beth Fulton MS Consultant ValSource, Inc.

16:20 – 16:40
The Integration of CSA into the CSV Projects
To ensure that computer systems used in the manufacturing of medicine are reliable, it is essential to have a process in place that assesses and reports on the quality and performance of every stage of the system lifecycle. This gives both regulated users and the competent authorities confidence that the controlled computer system(s) and their associated processes are operating with integrity within their prescribed environments (PIC/S PI 011-3, September 2007). In September 2022, the US FDA released a draft guidance called CSA, which proposes a risk-based approach for ensuring that medical device software is suitable for its intended use. This approach considers potential risks to the device's safety and quality if the software fails to function as expected. These risks determine the level of assurance effort and activities required to establish trust in the software. This guideline is crucial for validating computer systems used in medical devices. This same concept can be applied to the manufacturing of medicine. This approach considers potential risks to patient safety and product quality if the software fails to function as expected. The presentation will outline a sample method for scaling SLC documentation and the validation process approach based on the risk to the requirements.

Presenter: Orlando Lopez Data Warehouse Records Quality SME Independent Consultant

16:40 – 17:00
Methods for Measuring the Quality Management Maturity of a Manufacturing Network
Over ten years ago, the FDA released their first Federal Register Notice on Quality Metrics (QM). The Agency has recently expanded their thinking on QM by linking it to Quality Management Maturity (QMM). Industry engagement on both topics has been robust and included pilots and numerous Agency presentations. While much of the recent engagement has centered on quality culture assessments, and the FDA states that QM ≠ QMM, QMs have been included under the QMM umbrella with other factors such as quality culture and risk management. These components work together to fulfill the QMM end goal: preventing drug shortages. The first objective will be to discuss how the usage of both a qualitative approach (e.g., the PDA Quality Culture Maturity Model) and a quantitative approach (e.g., a holistic compliance risk model) is needed to implement a full scale QMM program. The second objective is to share the evolution of QM that are used to review the compliance posture of a site from the industry-standard metric-by-metric review (“stoplight” charts) to developing a more holistic risk model that aims to be automated and predictive. Finally, the presentation will conclude with common challenges in implementing both approaches within an organization.

Presenter: Adam M. Caruso MBA Associate Director, Strategic Programs and Regulatory Intelligence Merck & Co., Inc.

17:00 – 17:30
Q&A
A3: Biopharmaceutical Evolution: Stability, Contamination Solutions, and mRNA Triumphs

After delving into the critical realm of combination product stability with a comprehensive two-stage approach, the first presentation will emphasize the need for additional stability data to support post-market activities and underscore the importance of regulatory approval for shelf-life modifications. Next, a case study will show one company’s comprehensive approach to interpreting and implementing the Annex 1 contamination control strategy requirements. The final presentation will uncover the analytical tools driving the quality and consistency of mRNA-based vaccines and therapeutics and share insights into the progress made in building consensus on quality attributes and test methods.

Moderator: Jennifer Cheung MS Vice President, Quality Assurance and Regulatory Affairs WuXi Advanced Therapies

16:00 – 16:20

Ensuring Robustness in Combination Product Stability

This Combination Product Stability proposal encompasses a two-stage approach delving into the critical realm of combination product stability (shelf-life) challenges associated with parenteral drugs and the associated delivery devices. These two stages are:

- **Stage 1:** The first stage covers device verification of essential performance requirements to evaluate functionality during planned shelf-life post-assembly and storage. Accelerated and real-time aging studies are conducted to confirm device functionality over shelf life, ensuring representative conditions by means of preconditioning and testing.
- **Stage 2:** The second stage evaluates device functionality and drug product quality post-extrusion, focusing on stability of assembled and stored combination product lots. Combination product stability data packages vary due to commercial readiness timelines. As such, the use of combination product stability data generated from commercially representative material may be obtained from various points in the development lifecycle to enable optimal filing strategies. This discussion also includes topics speaking to the identified need for additional stability data to support post-market activities of the combination product, emphasizing the importance of regulatory approval for shelf-life modifications.

Presenter: Luis Montes MS Product Quality Principal Lead Amgen Inc.

16:20 – 16:40

Case Study on the Global Implementation of a Risk-Based Contamination Control Strategy

Recent revisions to EU Annex 1 heavily emphasize the importance of a contamination control strategy (CCS) for manufacturers, and the requirements and guidance are numerous and cover many topics. This presentation will describe the basic principles and applicability of contamination control, as well as regulatory requirements and industry best practices for CCS (including the use of risk assessments). Additionally, this presentation will provide an overview of one company’s approach for interpreting and implementing the Annex 1 CCS requirements, including updating existing CCS global guidance and implementing tools such as a template for sites to create local CCS and global contamination risk assessment with recommended risk questions, appropriate risk assessment tools/methods for each risk question, and guidance on how to group risk assessments for efficient management.

Presenter: Elizabeth Brockson MPH, VPH Aseptic Processing and Sterility Assurance Lead Takeda

16:40 – 17:00

Analytical Tools to Support Quality and Consistency of mRNA Vaccines and Therapeutics

The development and approval of mRNA-based vaccines for COVID-19 revealed the potential of this platform for both preventative and therapeutic purposes and has led to an explosion of mRNA-based products in development. Compared to traditional biotherapeutics, mRNA products have advantages in terms of flexibility and speed, but also introduce a new paradigm for testing due to the use of novel raw materials and delivery systems as well as unique product quality attributes and impurities. The cell-free manufacturing process utilizes a number of raw materials, such as capping reagents, nucleosides, enzymes, plasmid, and LNP components, for which quality and consistency need to be assessed and ensured. One of the advantages of the mRNA modality is that mRNA-based products share common physiochemical properties, making them amenable to platform analytical methods. This presentation will focus on analytical approaches that support quality of mRNA-based products at two levels: 1) qualification of raw materials and 2) platform methods for testing drug substance and drug product and will share progress in building consensus on quality attributes and test methods for this new therapeutic modality.

Presenter: Kevin L Carrick PhD Senior Director USP
17:00 – 17:30
Q&A

16:00 – 17:30
*Mini Training Course: Environmental Monitoring Sampling – Isolator/RABS Gloves (Ticket Required)

Environmental surveillance is a tool utilized to evaluate the effect of controls on the manufacturing environment. A process to assess the cleanroom and other controlled environments of a pharmaceutical facility can serve as an adjunct to the sterility assurance program for the microbial quality of drugs. This mini training course will review the methods to environmental monitoring sample isolator/RABS gloves.

Presenter: Marc Glogovsk MS Business Unit Manager/Senior Consultant - Microbiology ValSource, Inc.

18:00 – 21:00
*Evening Activities (Ticket Required)

- Tuesday Night Trivia at Beachwood Brewing | 18:00 – 20:30
- Evening Dinner Cruise | 18:30 – 21:00
- Paint and Sip Soirée | 19:00 – 21:00

19:00 – 22:00
*Documentary Deep Dive: Of Medicine and Miracles

Join PDA in their first-ever “documentary deep dive” session! A special guest from the documentary team will be there in person to introduce the film and facilitate the post-screening discussion. Tickets include the film, discussion, and light refreshments.

At the age of six, Emily Whitehead was diagnosed with leukemia and the lives of her and her parents were suddenly thrust into uncertainty. Through bracingly honest interviews and home videos, Of Medicine and Miracles details her family’s experience bouncing from hospital to hospital, trying to stay hopeful amidst hopelessness, and their fateful correspondence with a doctor whose research could hold the key to her survival. But time is of the essence.

A stunning feat of non-fiction filmmaking, Of Medicine and Miracles applies an acutely personal perspective to a highly publicized case, allowing Emily’s parents to speak candidly about the American healthcare system, experimental cancer treatments, and their overwhelming love for their daughter. Academy Award winner Ross Kauffman’s new documentary is a tear-jerking, heart-racing record of medical history that honors its subjects and their trauma while empowering future generations to attempt the impossible. – Cara Casamano

Moderator: Kenneth Paddock Quality Director, Sterility Assurance Baxter Healthcare

---

**Wednesday, 27 March**

07:00 – 16:00
Registration Open

07:00 – 08:00
Group Yoga (Free for all attendees and guests!)
Energize, rejuvenate, and embrace the day with a refreshing yoga session in the company of the PDA Local Host Committee and your fellow attendees. Whether you’re a seasoned yogi or a beginner, this class offers a perfect opportunity to enhance your physical and mental well-being. Start your day with balance and positivity, ensuring you make the most of the conference ahead. Join us for this invigorating yoga experience, and greet Wednesday with a fresh, focused mindset. Casual comfortable clothing and a towel or yoga mat are recommended.

08:00 – 09:00
Continental Breakfast

08:30 – 10:30
*Mini Breakfast Training Course: Points to Consider No. 1: Aseptic Processing (Revised 2023) (Ticket Required)
PDA will conduct a special two-hour course on its recently published, comprehensive Points to Consider for Aseptic Processing. In the past, PDA published what have become quite important Points to Consider in anticipation of changes to or clarification of regulatory positions on aseptic processing. The 2003 version preceded the US FDA’s Aseptic Processing Guidance, and the 2015/2016 parts 1 and 2 versions preceded the EMA/PIC/S revision to Annex 1. The latter Points to Consider versions contained timely topics and questions that revealed industry and regulatory authority concerns and what we perceived to be, areas of debate, as communicated by PDA members and others during meetings, workshops, and discussions. These topics and the resulting recommendations and rationale, as developed by industry experts, helped PDA form its science and risk-based response to the Annex 1 revision. While many of our points appear to be reflected in the final August 2022 version of Annex 1, some required further exploration and clarifications. For that reason, in 2023, the PDA published another revision to the Points to Consider for Aseptic Processing. These points include such topics as clarification of facility design and environmental monitoring expectations, positions on the use of Isolators, RABS, BFS, and lyophilization technologies, new approaches to personnel qualification, positions on the use and evaluation of aseptic process simulations, and more. You should attend this course because, while PDA Technical Reports and training are excellent sources of information on how to perform established operations, PDA Points to Consider delve deeper into the issues and topics that remain in discussion and may be pain points that you are or will be facing. This course will provide you with an opportunity to discuss these points with industry experts and your peers, and help you use that knowledge to form your own positions.

Presenter: Hal Baseman MBA Chief Operating Officer ValSource, Inc.

09:00 – 10:30
B4: Navigating AI, Data Integrity, and Regulatory Challenges
This transformative session will explore the evolving landscape of AI and the pressing need for regulation as data integrity challenges loom. Experts will look at the pitfalls of overregulation stifling innovation with a call for a genuine and fast dialogue to drive breakthrough changes in innovation, quality management systems (QMS), and inspections. The biologics and gene therapy sectors as well the critical role of contract manufacturing organizations (CMOs) will also be discussed.

Moderator: Ryan Murray MS Senior Consultant ValSource, Inc.

09:00 – 09:20
AI, DI, and Overregulation: Impact on QMS
Artificial Intelligence has been around for some time. Only recently, have we woken up to its dangers and as is usually the case, far too late industry and regulators are begging for regulation. No one questions the need for regulation, the question is how much and…how? Data Integrity (strangely, one subset of the AI riddle) has overtaken the Pharma industry to a level where it is questionable if any company could pass a rigorous, focussed multi-person inspection on the topic. Over regulation stymies innovation. Our QMS is dysfunctional as we slap yet another plaster over the last inspector’s personal opinion (sometimes covering sometimes removing the one before). We need holistic systems. The deviations CONTINUE to recur despite metrics, KPIIS etc. The solution of yet another SOP has failed. Pharma is scared to innovate. The cost is too high. A genuine, frank and fast dialog is needed with PDA leading the charge and resulting in a concept paper for breakthrough change in industry and regulatory approach to: innovation, QMS, inspection. More of the same is simply making the drug shortage worse

Presenter: Karen Taylor MSc Owner PCI Pharmaceutical Consulting Israel Ltd

09:20 – 09:40
Assessing the Quality Management Maturity of an ATMP CMO

The growth of Biologics and Gene Therapy sectors of pharma are expected to double over the next five years. CMOs are gearing up to support this growth, as manufacturing space is needed to support this growth. Recent FDA Warning Letters for firms utilizing CMOs may now include a section on “Use of Contract Manufacturers”. These warning letters go on to state the firm is “responsible for the quality of your drugs regardless of agreements in place with your contract facilities”. Having a process for selecting the right CMO goes beyond the traditional GMP audit process and should include an assessment of the overall Quality Management Maturity (QMM) of the firm. QMM assesses additional processes, controls and measures the CMO has in place during everyday operations and not just for the audit. This session will explore several QMM elements to review in your CMO assessments.

Presenter: Londa Ritchey MS, MBA Quality Director & Principal Consultant PharmaLex

09:40 – 10:00

Ensuring Patient Access to Medicines Through RAPID Root Cause Analysis

Takeda Pharmaceuticals is a global company with a diverse landscape of internal and external manufacturing delivering over $30B in revenue. Takeda initiates a global RAPID investigation team when a deviation/event occurs that is sufficient in scope to put patient supply at risk. The pandemic forced Takeda’s global RAPID investigation team to capitalize on a variety of technologies and systems to achieve accurate root cause analysis in 14 days or less while working remotely in a global setting. This talk will discuss the structure of the RAPID investigation team, how technologies and systems were integrated to facilitate the RCA process, and the process to creating investigational products meeting investigational quality standards (IQS).

Presenter: Paul Hanson PhD Vice President, Head of Lifecycle Management, Innovation, and Strategy Takeda

10:00 – 10:30

Q&A

09:00 – 10:30

D4: What is PDA Working On?

We have the answers, and it is exciting! Join us for an inside look at PDA activities and initiatives with our Technical Advisory Boards (ABs), Interest Group (IGs) Leaders, the PDA Training and Education Team, and PDA’s Chapter Presidents.

Moderator: Josh Eaton MS Senior Director, Scientific and Regulatory Affairs PDA

09:00 – 09:20

PDA AB Overview and Updates: What are They, How Do They Work, and On What are They Focused?

09:20 – 09:30

PDA IG Overview and Updates: What They Are, What Makes a Successful IG Meeting, and How You Can Get Involved

Presenter: Amanda McFarland MS Senior Consultant ValSource, Inc.

09:30 – 09:50

PDA Training and Education Overview: What PDA is Doing in This Space, Future Plans, and How You Can Get Involved

Presenter: David B Talmage MBA Vice President, Education PDA
## Agenda

### 09:50 – 10:00

**PDA Chapters Overview: The Who, What, Why, and How to Get Involved in One of the 24 Chapters**

**Presenter:** Trevor Swan Senior Director, Membership and Chapters *PDA*

### 10:00 – 10:30

**Q&A**

### 09:00 – 10:30


The field of gene therapy is rapidly developing and expanding, with many new and innovative therapies to treat disease. Experts in this session will share insights into techniques for manufacturing, testing, and qualification of adeno-associated virus (AAV) products. Additionally, best practices and strategies for navigating ATMP regulatory submissions, the importance of interpreting and applying multimodal CMC data, and its analyses for the advancement of ATMP-related manufacturing will be presented.

**Moderator:** Stephanie N. Lee MBS Operations Manager *Amgen Inc.*

### 09:00 – 09:20

**Analytical Tools to Support the Production and Characterization of AAV Therapeutics**

The rapidly emerging field of gene therapy is being led by the development of adeno-associated virus (AAV) products, which have emerged as the most common delivery system. However, the complexity of AAV particles makes production and characterization challenging. Production efficiency is impacted by the quality of various starting materials, such as plasmids, enzymes, and expression cells. As with other biologic therapeutics, multiple analytical methods are necessary to test critical quality attributes. Analysis of full to empty particles has proven to be a particular challenge. To assess this ratio, a thorough characterization of capsid proteins and the DNA transgene is required, but the vast selection of capsid serotypes and endless number of transgenes compounds the complexity of this process. Currently, there is no consensus on the appropriate method to analyze empty:full capsids and, with at least 7 commonly used methods, analyses with multiple methods can utilize valuable resources while yielding conflicting results. A better understanding of different analytical techniques and the development of AAV standards will help elucidate some of these challenges. This presentation will outline best practices for manufacturing and testing of AAV therapeutics, with particular focus on the qualification of raw materials and assessment of empty vs full capsids.

**Presenter:** Anthony Blaszczzyk PhD Senior Scientist *USP*

### 09:20 – 09:40

**Developing an ATMP Regulatory Submission Strategy: Concepts That Work**

With only limited regulatory guidance on advanced therapeutic medicinal products (ATMPs), the industry is struggling to develop a strategy for chemistry, manufacturing, and control (CMC) submissions that will be acceptable by regulatory agencies. This session will present conceptual approaches based on a Contract Testing, Development and Manufacturing Organization (CTDMO) perspective. You will learn best practices on leveraging available guidance on aseptic processing and science-based risk assessments to develop a sound approach. The foundation of all proposals is based on the most up-to-date regulatory guidance for risk assessments (ICH Q9), justifications, quality by design (ICH Q8), and product lifecycle management (ICH Q12) to deal with the challenges and changes that occur during product development, especially for ATMPs. Details regarding completion of specific CMC sections in module 3 of the Common Technical Document (CTD) for drug substance and product will also be highlighted, keeping lifecycle management in mind. Case studies showing the implementation of these concepts to overcome challenges of submitting specific analytical potency assay and comparability protocol details in an initial IND regulatory submission will be presented.

**Presenter:** Janmeet S. Anant PhD Senior Regulatory Consultant *MilliporeSigma*

### 09:40 – 10:00

**Analytical Tools to Support the Production and Characterization of AAV Therapeutics**

The rapidly emerging field of gene therapy is being led by the development of adeno-associated virus (AAV) products, which have emerged as the most common delivery system. However, the complexity of AAV particles makes production and characterization challenging. Production efficiency is impacted by the quality of various starting materials, such as plasmids, enzymes, and expression cells. As with other biologic therapeutics, multiple analytical methods are necessary to test critical quality attributes. Analysis of full to empty particles has proven to be a particular challenge. To assess this ratio, a thorough characterization of capsid proteins and the DNA transgene is required, but the vast selection of capsid serotypes and endless number of transgenes compounds the complexity of this process. Currently, there is no consensus on the appropriate method to analyze empty:full capsids and, with at least 7 commonly used methods, analyses with multiple methods can utilize valuable resources while yielding conflicting results. A better understanding of different analytical techniques and the development of AAV standards will help elucidate some of these challenges. This presentation will outline best practices for manufacturing and testing of AAV therapeutics, with particular focus on the qualification of raw materials and assessment of empty vs full capsids.

**Presenter:** Anthony Blaszczzyk PhD Senior Scientist *USP*
What New Therapeutic Modality CMC Challenges Tell Us About Facility Design

**Presenter:** Jeff Odum  
**Co-Presenter:** Paul Fleming

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:00 – 10:30</td>
<td>Q&amp;A</td>
</tr>
</tbody>
</table>

09:00 – 10:30

**C4: Automation, Innovation, & Robotics for Annex 1 & CCS Compliance**

This spirited session will explore how advances in robotics and automation can support compliance with Annex 1 and contamination control strategy (CCS). Experts will discuss innovations in aseptic environments, including filling processes, equipment, and isolator work cells. Participants will also be able to engage in discussions regarding the potential transition from injectable pharmaceuticals to microneedle array patch (MAP) technologies.

**Moderator:** Divyang Patel  
**Presenter:** Brent Lieffers

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00 – 09:20</td>
<td>Embracing Innovation to Meet the Requirements of Annex 1</td>
</tr>
<tr>
<td>09:20 – 09:40</td>
<td>Robotics and Automation: Enabling Higher Quality and Annex 1 CCS Compliance</td>
</tr>
<tr>
<td>09:40 – 10:00</td>
<td>The End of an Era: Injectable Pharmaceuticals as a Relic of the Past</td>
</tr>
</tbody>
</table>

09:00 – 10:00

**The End of an Era: Injectable Pharmaceuticals as a Relic of the Past**

The pharmaceutical industry has been dominated by the development of novel sterile injectable drugs and biologics for decades. While there has always been interest in topical and transdermal drug delivery systems, the skin is a robust natural barrier and very few molecules were good candidates for topical delivery. The issue of residual potent drugs remaining after application further decreased the interest in a topical route of delivery. Today’s session will explore how advances in robotics and automation can support compliance with Annex 1 and contamination control strategy (CCS). Experts will discuss innovations in aseptic environments, including filling processes, equipment, and isolator work cells. Participants will also be able to engage in discussions regarding the potential transition from injectable pharmaceuticals to microneedle array patch (MAP) technologies.
administration. However, the recent advances in microneedle array patch (MAPs) technologies as a method for drug and biological product delivery has resulted in a rapidly advancing field with several products undergoing Phase 3 clinical trials and a robust pipeline. While the clinical data is promising, there are several scientific and regulatory challenges that remain in this emerging field. Once these challenges are overcome, the use of MAP platforms has the potential to completely revolutionize the drug delivery process. The main advantages for MAPs include a painless application for patient compliance, ease of application without a trained healthcare provider, extended storage times and temperatures, and reduction in medical waste.

**Presenter: Jessica Chiaruttini PhD** Senior Microbiology Consultant *ValSource, Inc.*

10:00 – 10:30

Q&A

10:30 – 11:30

**Poster Presentations in the Exhibit Hall**

10:30 – 11:30

**Exploratory Assessment of an On-Body Delivery System for Large-Volume SC Delivery: Facilitating Rapid Thermal Equilibration to Ambient Temperatures for Immediate Utilization Post-Refrigeration**

In the evolving field of healthcare, ensuring prompt and efficient medication delivery remains a top priority. This study undertakes an exploratory assessment of an on-body delivery system tailored for large volume subcutaneous (SC) delivery. The design is crafted to accelerate thermal equilibration to ambient temperatures, enabling immediate use post-refrigeration. The movement of the drug through the fluid path is central to warming the drug swiftly to near ambient temperatures. Our analysis dives into the performance and efficiency of this system across varied environmental conditions. The data, which will be shared in detail during the presentation, unveils a significant trimming of the time needed to reach ambient temperatures, thereby potentially reducing wait times and enhancing user experience. These preliminary findings highlight the promise of this system and beckon further exploration to ascertain its real-world applicability and advantages, aspiring to advance the sphere of patient-centric medication delivery solutions.

**Poster Presenter: Mehul Desai PharmD, MBA** Vice President, Medical Affairs *Enable Injections*

10:30 – 11:30

**Maintaining Superior Viral Vector Recovery in Cell and Gene Therapy Applications by Using Daikyo Crystal Zenith® Vials**

AAV8 and AAV9 were chosen as representative adeno-associated virus (AAV) serotypes, with respective titers in a common buffer formulation, and evaluated in different 2mL vial types: Daikyo Crystal Zenith® (CZ) vial, and two commercially available borosilicate vials. To simulate viral vector recovery in cell and gene therapy applications, the vial combinations were tested across five challenge conditions: 1. 3 months at -80°C, recommended condition for long term storage 2. 2 months at 5°C, recommended condition for temporary refrigerated storage 3. 3 weeks at 25°C, simulating room temp clinical ambient conditions 4. 72 hours of 250RPM agitation, to mimic handling during manufacturing/shipping 5. 5 cycles of Freeze/Thaw, to mimic handling during manufacturing and the potential for structural damage to proteins or DNA In all conditions, the Daikyo CZ vial demonstrated improved viral vector recovery compared to borosilicate glass vials. The data shows that there were no significant changes in product quality due to container storage in the Daikyo CZ vials, and that the CZ vials may comparatively improve viral vector recovery across common storage and handling conditions.

**Poster Presenter: Eric Kurtz** Manager, Technical Product Development *West Pharmaceutical Services, Inc.*

10:30 – 11:30

**Economic Benefits of an Original Container Closure during Combination Product Development: Expert-Modeled Scenarios Validated by Pharma**

**Poster Presenter: Mehul Desai PharmD, MBA** Vice President, Medical Affairs *Enable Injections*
### 10:30 – 11:30

**High Cell Density Cryopreservation for Upstream Process Intensification Using LN2 Vapor Phase Stored Seed Train Intermediates**

Standard seed train operations start by thawing of a single 1 ml vial with cell densities of 10 x 106 VC/ml. For reaching a sufficient absolute cell number for production bioreactor inoculation, several expansion steps, starting with shake flasks, need to be performed. These open cell culture operations result in long ramp up times, high room classifications during the whole process, and are a major source of process variability. High cell density cryopreservation is a method where cells can be frozen in bags with cell densities higher than nowadays standard processes. This leads to the advantage that cell expansion and batch production can be separated. Lower room classification for the cell culture area in GMP manufacturing might be a result due to the reduction of manual handling steps before the main stage bioreactor (closed processing). Furthermore, these intermediates allow global distribution from a central expansion facility to decentralized global production facilities. Currently, we have demonstrated that SU bag assembly was modified to withstand liquid nitrogen vapor phase storage and the process of freeze and thaw was also optimized to maintain cell performance and SU bags integrity after thaw.

**Poster Presenter: Ushma Mehta MS Regulatory Consultant MilliporeSigma**

### 10:30 – 11:30

**Identification of Foreign Particulate Matter in Assembled Autoinjectors Through Long-Time Tracking of Individual Particles’ Trajectories**

Part of the challenge in detecting foreign particles in a liquid parenteral is to discriminate them from bubbles or other intrinsic objects, which do not constitute a defect, but can lead to false rejects. We have implemented an innovative methodology to identify foreign particles in a complex autoinjector device. For this application, we combine a handling adapted to mobilize particles in solution with image processing algorithms for particle tracking. In our test system, the devices circulate in a linear transport system and are turned upside down prior to the image acquisition. In this way, particles which might be stuck on the walls or at the bottom of the device are released in the solution, which facilitates their detection. By acquiring up to hundreds of images we are able to track the particles’ motion for longer than 1 second, distinguishing whether they tend to move downwards or upwards and identifying them as particles or bubbles, respectively. The strength and novelty of our machine design rely on the fact that the additional time for image analysis is obtained without compromising the speed of the machine.

**Poster Presenter: Matthias Kahl Head of R&D and Lab Services WILCO AG**

### 10:30 – 11:30

**Manufacturing in Miniature: Drug Delivery via Microneedle Array Patches (MAP)**

Microneedle patch technology has progressed to the pre-clinical and early human clinical stage by many developers, but Kindeva is one of the few companies that has made it to Phase 3 clinical studies and has commercial scale equipment. Kindeva Drug Delivery provides recommendations for process development and manufacturing based on its coated microneedle patch drug delivery platform. Manufacturing process scale-up with intention of regulatory submission follows a strategic path. At each stage (lab bench, pilot, and commercial) it’s critical to document data, decisions, and key learnings in support of a design history file and regulatory submission. Documents should be raised at the time of data generation and cover topics including product development decisions, process development milestones, and device development choices. Likewise, methods and specifications mature during development. Data destined for regulatory submissions should be collected consistently over time. If a method changes, comparison data sets utilizing the two methods and same set of samples should be generated to support the change. Specification setting is also evolutionary, with specifications growing more detailed and narrower as the development proceeds. This evolution will be illustrated through Kindeva’s experience in scale up from lab to commercial scale processes for manufacture of coated microneedles.

**Poster Presenter: Andrew Riso Director of Business Development Kindeva Drug Delivery**

### 10:30 – 11:30

**An Alternative Approach to Standard Operating Procedures**

The classic paradigm of training and executing SOPs in BioPharma- is to Read and Understand, to observe someone else perform the procedure, and then to demonstrate it yourself. Once this initial training phase is complete, you are left solely with a written SOP to reference. This heavy reliance on written instructions can lead to a higher chance of ambiguity and unnoticed or overlooked errors. My proposed solution aims to address this issue by accommodating diverse learning preferences and seamlessly integrating visual aids, such as videos, directly into procedures. To address this challenge, I have embedded QR codes directly within procedures. This approach enables employees to access instructional videos...
quickly and conveniently, providing clear guidance, especially for more complex steps, thus reducing errors and preventing confusion during execution.

**Poster Presenter: Max Falcone** Analyst Tunnell Consulting

10:30 – 11:30

Centralized Vaporized Phase Hydrogen Peroxide (VH2O2) as Building Utility

Application of a disinfection and sporicide rotation is a critical component of a contamination control strategy per EU Annex 1. Many current applications deploy a manual process for sporicide application. Automated systems are desirable as they minimize people and equipment required to enter the classified spaces and minimize operating costs and errors as part of the process. These systems provide enhanced coverage in the critical environment areas and are especially critical for ATMP facilities that have strict contamination control requirements. This presentation will explore the use of a centralized, automated system to apply VH2O2 as a biodecontamination method in an ATMP facility. A case study will be presented that outlines: • VH2O2 properties and its use as a biodecontamination method in biopharmaceutical applications. • VH2O2 integration into the facility HVAC for distribution to clean rooms and RABS. • Equipment integration with the facility building management system (BMS) for control and cycle reporting functions including 21 CFR Part 11 and EU Annex 11 considerations. • Safety considerations for the users and the facility. • Qualification and validation of the process. Users will take away how VH2O2 centralized, automated systems can be implemented for enhanced contamination control strategy practices.

**Poster Presenter: Matt Hofacre** Senior Director, Technical Services STERIS Corporation

10:30 – 11:30

Isolator/RABS: Risk Minimization Through Correct Glove Management

- Requirements and challenges (Annex 1) - Glove types/ Selection/ Test methods - PDA study published on "How risky are pinholes" - Possible risks that compromise glove integrity - Necessary activities for good gloves management. - Additional literature for self study

**Poster Presenter: Alex J. Kappani** Product Management SKAN AG

10:30 – 11:30

A New Calibration Technique for Light Obscuration Sensors to Improve Counting Accuracy of Aggregated Proteins

Light obscuration liquid particle counters used for USP < 788> and < 787> are calibrated using polystyrene latex (PSL) particles with a refractive index (RI) value of 1.58. This calibration approach generates accurate results for large particles with a similar RI value in the critical size range of 10 & 25 µm. Various sources have pointed out the inaccuracies in results for protein particles where the RI value of approximately 1.4 is much closer to water, especially at smaller particle sizes. This presentation will describe a new calibration technique for light obscuration/scattering sensors using the new NIST RM 8634 and present results of aggregated proteins with both the historic PSL and the new protein calibration techniques. The calibration procedure used is described in ISO 11171:2020, using the new NIST RM 8634 to create a "protein calibration curve". Aggregated protein samples were then analyzed by the single particle optical (SPOS) technique using both the historic PSL and new protein calibration curves. Results using the protein calibration curve reported higher particle concentrations at a given size.

**Poster Presenter: Mark Bumiller** Technology Manager Entegris, Inc.

10:30 – 11:30

Developing Primary Packaging System for Nanosuspensions: Headspace Design Space Case Study

Suspensions with nanometer size drug particles are a unique drug product dosage form which allow high concentrations of water-insoluble small molecules to be parenterally administered into human bodies to treat difficult diseases. They are typically packed in pre-filled syringes (PFS) or glass cartridges with a desired level of container closure integrity (CCI) to protect them from oxygen and microbe ingress. Headspace (HS) is an important attribute that needs to be well controlled during the filling of the nanosuspensions into glass primary containers. This case study highlights two important factors in relation to headspace within a primary pack containing a nanosuspension product: 1) The importance of a maximum allowable headspace given the impact this has on stopper movement and therefore on the primary packaging system's sterility performance; 2) The minimum headspace requirements for nanosuspension products as they need to be well resuspended prior to drug product administration. Thus, the headspace needs to be optimized within a certain window to ensure adequate sterility and achieve the desired dosage. In summary, this case study serves as a good example of a balanced approach on developing challenging primary packaging solutions for this unique parenterally administered...
nano-suspended drug product dosage form.

**Poster Presenter: Liang Fang PhD** Associated Director, Primary Packaging GSK

### 10:30 – 11:30

**Implementing a Disinfectant Program for Advanced Therapy Medicinal Product Manufacturing**

In a fast-paced, rapidly evolving environment like Advanced Therapy Medicinal Product (ATMP) manufacturing, it is easy to overlook critical elements necessary to maintain contamination control. However, despite urgent manufacturing procedures, a sound strategy for contamination control is essential to help ensure microbiological safety and final product integrity. A cleaning and disinfection program must address the unique challenges within ATMP including addressing the special considerations often found within these facilities such as limitations with available resources and critical time-sensitive procedures. Implementing a program that can be adaptable to the unique environment of specialized procedures that incorporates the consideration of smaller processing suites, biosafety cabinets and isolators is key. A well-designed program that is not overly complicated yet focuses on a holistic contamination control approach focused on the challenges in the ATMP environment is essential.

**Poster Presenter: Dan A. Klein MA** Senior Manager, Technical Services STERIS Corporation

### 10:30 – 11:30

**Transforming Deviation Management for Expedited Closure and Product Release in Cell and Gene Therapy**

This case study, conducted in partnership between a prominent cell and gene therapy manufacturer and a consulting firm, sought to streamline the deviation management process within the organization. The main goals were to define ownership in the process and enhance departmental knowledge and skills resulting in expedited deviation closure, while maintaining a high level of Quality. A detailed examination of the deviation lifecycle included identifying communication gaps, redundant meetings, delays resulting from information or decision bottlenecks, and the non-value-added activities in the process. This analysis, enriched by stakeholder involvement, led to the creation of an innovative workflow engineered to promptly resolve low-level deviations within a challenging 24-hour period, or ideally during the same manufacturing shift. To ensure a seamless integration, training sessions were deployed to ensure personnel were aligned with the new workflow and overarching site goal. In the initial weeks following go-live of the new workflow, the data showed a two-thirds reduction in the overall cycle time for low-level deviations. This was a substantial step towards reducing deviation closure time, along with allowing more time to focus resources on critical issues. Importantly, there were additional improvements in the pipeline, which, when implemented, were expected to streamline the process further.

**Poster Presenter: Christian Spiak** Principal Consultant, Human Performance Business Area CAI

### 10:30 – 11:30

**Using Toxicological Risk Assessment to Minimize Cross-Contamination**

Conducting a risk assessment to evaluate the toxicity of a product helps to ensure patients' safety and prevent unwanted cross-contamination and recalls. Data from both pre-clinical and clinical trials provides insight on safety margins, adverse effects, and pharmacokinetic parameters (i.e., absorption, distribution, metabolism, and excretion). Toxicologist can determine Permitted Daily Exposure (PDE) and/or Accepted Daily Exposure (ADE) across the product lifecycle and use adjustment factors to address both uncertainty and known toxicities associated with a product. Overall toxicological risk characterization for product development, cleaning validation, manufacturing process, and laboratory testing is critical to ensure patient safety. This talk will briefly highlight some of the regulations, risk assessment process, and provide case-studies to determine health-based exposure limits (HBEL).

**Poster Presenter: Wendy Haines PhD, DABT, ASQ CQA** Director of Toxicology & Technical Services PharmEng Technology

### 10:30 – 11:30

**Applying Holistic Sterile Manufacturing Design Principles to Build an Agile Combination Product Contract Manufacturing Facility Which Anticipates the Over the Horizon Compliance Requirements**

There is an incredible level of complexity, investment and risk with building a sterile manufacturing facility. When the facility will serve the global needs of a diverse contract manufacturing customer base, it must be built for agility, efficiency, scalable and most importantly for global compliance-known today and what’s over the horizon. Examples of holistic design utilized in Kindeva’s new aseptic manufacturing facility; • Levo-magnetic drive motors- reducing wear and particulate generation • Disposable bagging systems in formulation tanks reducing cross-contamination risk and establishing more efficient change overs • Automated PUPSIT systems integrated into the filling process providing continuous filter integrity. •
Filling machines utilize isolators eliminating the need for traditional gowning and aseptic training, reducing grade A areas to the isolator interiors, and reducing time to qualify operators. • Modular filling suites operating independently eliminating facility wide shutdowns • In-process fill check technology tracks individual drug containers allowing for automatic removal of individual containers not meeting quality parameters. Product quality, operational efficiency and compliance isn’t determined by any single process or design element. These are only achieved and maintained through holistic design principles that collectively meet the need of the market and regulators tomorrow and over the horizon.

Poster Presenter: Chad Hafer MEng Senior Manager Aseptic Operations Kindeva Drug Delivery

10:30 – 11:30

Fused Quartz Vials: from Glass Science to Drug Containment Solution

Glass is the most used material in pharmaceutical packaging, and borosilicate is currently the most used among those described by the Pharmacopoeia(s). The USP, however, has recently enacted changes to their glass packaging chapter <660> that enable the introduction of new glass compositions, one of which is fused quartz. While new to the USP chapter, fused quartz has been manufactured for over one hundred years, valued primarily for its high purity and remarkable properties, including a very low thermal expansion coefficient and excellent chemical durability. This presentation will address the science behind fused quartz vials, with focus on assessing their chemical, physico-chemical and mechanical performances. Although fused quartz is generally considered chemically inert, the selection of any container must always be done taking into consideration the individual drug product and processing requirements. The knowledge of this new glass and of relevant analytical testing can continue to accelerate its adoption as a container for parenteral preparations and on its classification inside the three main Pharmacopoeias and standard setting organizations like ISO and ASTM. The experts at Stevanato Group and Momentive Technologies are excited to see this “new” glass help solve many of the industry’s most demanding formulation challenges.

Poster Presenter: Serena Panighello EMEA TEC Research Scientist Stevanato Group

10:30 – 11:30

Breaking Out of the Human Factors Study Loop, For the Benefit of Patients

Human Factors Engineering (HFE) is a critical component of development and life cycle management for combination drug products. Human factors (HF) studies assess whether combination products are safe and effective and, when properly designed, can eliminate millions of dollars in future life cycle management costs. These studies seek to understand how patients interact with products, what patients expect from products, enable manufacturers to design out risks, and ensure positive patient outcomes and compliance. HFE is never a one-and-done activity. It involves an iterative series of experimentation, testing and qualification. Each HF study yields new observations and options for continuous improvement. This can create a loop which, if not managed properly, can delay the implementation of design improvements and instructions that will benefit patients and users at all stages of the product’s life cycle. This presentation will discuss how principles of Use Related Risk Analysis have been incorporated into autoinjector HF studies ranging from early prototypes to on-market products. It will present a process which balances the iterative process of HFE engineering with focus on the end goal, delivering outcomes for patients.

Poster Presenter: Amy Lukau Senior Human Factors Lead Kindeva Drug Delivery

10:30 – 11:30

A Model for a Risk-Based Deviation Investigation Process

Deviation investigation process owners often find themselves swamped with investigations, lacking quantitative tools that allow them to discriminate between minor low-risk events and critical high-risk deviations. Additionally, the business processes that support deviation investigations are often not purpose-built to enable the speed and investigational rigor that allow for timely closure and effective corrective action. This talk will present a proven model for building a quantitative risk-based deviation classification system and will discuss assigning investigational tools to assigned deviation risk levels. Supporting business processes will also be discussed, including professionalizing deviation investigators as an expert role within an organization as well as developing daily operational practices and metrics for effective management of the deviation lifecycle: identification, assessment, investigation, assignment of corrective/preventive actions, and approval/closure.

Poster Presenter: Aaron Hubbell Director, Life Sciences Barry-Wehmiller Design Group

10:30 – 11:30

Data Analysis ~ Trending and Pattern Recognition for Contamination Control
The regulations are evolving, EMA Annex 1 earlier versions did not mention trends, the current draft version mentions it 23 times. WHO, and FDA also talk about trending, root cause analysis, investigation, and using the data for these purposes. Trending the data is now a regulatory requirement but what trends should we use? This presentation will discuss how often we should trend, what events should trigger trending, root cause analysis, and investigations. Also, which trend tools should we use for the different contamination control processes, cut off method, Control charts (Shewhart, etc.). Quantiles, percentiles, Weibull distribution, scatter plot, regression analysis for slope (upward/downward trends). FYI... Would present as a lightening talk as well

Poster Presenter: Susan B. Cleary EMBA Director of Product Development Novatek International

10:30 – 11:30
Behavior of Molded and Tubular Vials During Depyrogenation

Depyrogenation is a key step in the aseptic filling process. Dry heat depyrogenation is the method of choice for glass vials. Most depyrogenation tunnel manufacturers consider the power necessary is proportional to the weight of glass vials. This study shows the reality is different for small vials below 30 ml. An industrial depyrogenation tunnel was used, filled with 100H molded vials and in the center of the conveyor, in the same row two 20R, two 20H and two 20H EasyLyo. The temperature was monitored with thermocouples. The temperature curves for molded and tubular 20ml vials are close and similar. The times recorded to achieve the 3 log reduction were 18 min13s for the tubular vials, 19 min28s for ISO vials and 19 min 37s for EasyLyo vials. The accumulated destruction factors FD for these 2 vials are significantly equivalent. There was no direct correlation between the weight of vials and the energy needed for depyrogenation for glass vials below 30ml. The measured time to achieve a 3 log reduction did not differ by more than 8%, while the weight difference was 70%. This understanding opens new perspectives for drug manufacturers in terms of sustainability and machinability.

Poster Presenter: Jingwei Zhang PhD Group R&D Director SGD Pharma

10:30 – 11:30
Supply Chain Verification for API Manufactured by a Third Country

This poster explains the Supply Chain Verification and Risk assessment carried out by Qualified Persons for API imported from a Third Country.

Poster Presenter: Farah Nadeem QP Trainee Paul Palmer Ltd

10:30 – 11:30
Evaluation of New Sterilization Modalities that Enable Terminal Sterilization of Parenteral/Injectable Drug Products Traditionally Filled by Aseptic Manufacturing

Sterile manufacturing of parenteral/ injectable drug products is accomplished by either aseptic manufacturing or terminal sterilization, the latter preferred and recommended by regulatory bodies. Product and container closure compatibility with moist heat normally dictates if the product is Aseptically Manufactured or Termi nally Sterilized. New technologies and sterilization modalities were evaluated with the goal of broadening the drug product/container closure compatibility assessment. Studies demonstrated new technologies enable conversion of drug products currently Aseptically Manufactured to Terminal sterilization, thereby reducing manufacturing cost and reducing lack of sterility risks. This presentation will highlight testing of several sterilization modalities, results, and next steps.

Poster Presenter: Terrence Hollis Senior Manager, Global Technology and Engineering Pfizer Inc.

10:30 – 11:30
A Holistic, Phase-appropriate Analytical Approach for Establishing Residual Host Cell Protein Specification Throughout the Cell Therapy Drug Product Lifecycle

Residual host cell proteins (HCP) are low-level genomic protein residuals produced from process- or drug-related materials in manufacturing cell therapies. HCP residuals are organic process impurities per the International Conference on Harmonisation (ICH) Q3A/B guidelines (ICH, 2006). These residuals pose a risk to patients' immunogenic responses while affecting drug efficacy and stability. Drug developers must comply with the United States Pharmacopoeia (USP) < 1086> and < 599> to detect HCP residuals, limiting 0.05% per day of active pharmaceutical ingredients (USP, 2015). Drug release criteria only require HCP results in phase 2 (FDA, 2020). Following phase 2, Biologic License Application filing requires more rigor toward product characterization. To implement a phase-appropriate analytical strategy for cell therapy development, HCP
residuals are first identified using a conventional Western size-based assay or a Quadrupole/Time-of-Flight Mass Spectrometer (QTOF-MS). The first method option is far more feasible to execute and collect sufficient data than the latter. Following the 21 Code of Federal Regulations §610.9 (FDA, 2023), multiple QC samples were utilized for method development, validation, and phase 1 sample analysis. We developed a practical and ideal enzyme-linked immunosorbent assay for QC implementation and met the ICH and USP requirements to support phase 2 trials and commercialization.

Poster Presenter: Michelle Tseng PhD Senior Director Azuur Group

10:30 – 11:30

Inert Gas Bleed Valve Location and the Impact on Lyophilization Chamber Pressure

Nitrogen gas is bled into the lyophilization chamber to control the chamber pressure during primary and secondary drying. The location of the Nitrogen gas bleed valve is an often overlooked variable when transferring a cycle from one dryer to another. The focus of these studies will be how the location of the gas bleed valve effects the primary drying segment of the lyophilization cycle. The location of the gas bleed valve was varied during these studies and the air temperature at different locations on the shelf and chamber was monitored during primary drying. The air temperature during primary drying was compared by shelf and shelf location to investigate the effects of varying the location of the Nitrogen gas bleed valve. After the air temperature mapping studies were complete, sublimation rate studies were completed using bulk trays and Purified Water, USP. The results of these mapping studies revealed differences in air temperature at different locations on the shelf when the Nitrogen gas is introduced at different locations of the lyophilization chamber. Additional sublimation rate studies were completed to compare to the air temperature mapping studies and if warmer temperatures result in higher sublimation rates.

Poster Presenter: Jason B. Angstadt MS Scientist III Lyophilization Technology Inc.

10:30 – 11:30

Developing a Risk Score for Critical Suppliers Using Artificial Intelligence (AI)

The modern economy is familiar with many examples of risk scores, like credit scores, insurance scores, and more. Supply chains are one area where risk scores haven’t yet been fully developed and utilized. In the pharmaceutical industry, where the supply chain has a direct impact on patient safety and health outcomes, supply chain risk scoring is of particular importance, yet as an industry, we have a lot of progress to make. With more data available than ever before, plus the capabilities unlocked by AI and ML, pharmaceutical sponsors can now accurately score the relative risk of all of the organizations upstream from them, like CMOs, API manufacturers, and excipient manufacturers. Takeaways: - Which variables should be used to calculate pharmaceutical supplier risk? - What are some roadblocks to developing a supplier risk score and how can they be overcome? - Entity resolution - you can’t accurately calculate a risk score for a particular entity unless the dataset you’re using has appropriately resolved all of the permutations of the entity name into one profile. - How those variables interact with one another (i.e. how do you score a warning letter and the 483 that preceded it?)

Poster Presenter: Michael de la Torre CEO Redica Systems

10:30 – 11:30

Benefits of Single-use for ATMPs in Regards to Annex 1

The presentation will give an overview about technical standards and trends. The presentation highlights regulatory aspects, e.g. EU-GMP Annex one and will also touch the field of aseptic risk reduction and will show how to increase the quality of sterile drug manufacturing. Annex 1 drives technical solutions for ADCs / ATMPs more and more towards: - Isolators / Containment Isolators - Single-Use and Ready-To-Use components - Automated or at least semi-Automated processes for better reproducibility. Human interventions are to avoid, to eliminate potential contamination risk factors. Standardized documentation according to latest norms are required. Why does single-use and ready-to-use best possibly comply to EU GMP Annex 1. Why does single-use specially make sense in dealing with new types of medicinal products like ATMPs and ADCs. What are market standards and trends and where is pharma manufacturing moving to.

Poster Presenter: Juergen M. Metzger Product Specialist/Senior Consultant Final Filling Sartorius North America Inc.

10:30 – 11:30

Quality Culture: From Buzzword to What Works

Warning letters consistently cite firms for failing to establish a Quality unit with the responsibility and authority to execute its responsibilities across all
### Agenda

**2024 PDA Annual Meeting**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:30 – 11:30</td>
<td>Evaluating Your Stopper: Proving Stopper Functionality for Real-World Use Cases Through &lt;USP 382&gt;</td>
</tr>
<tr>
<td></td>
<td>With the upcoming implementation of USP &lt; 382&gt; in 2025, there is an increased emphasis on designing clinically representative experiments to prove that the required, optimal container system is achieved regarding piercing performance and resealability. Not only are medical professionals taught varying techniques on how to pierce a stopper, but industry opinions on the best needle and method have led to more questions than answers. To reduce risk to the patient, it is critical to show that one’s stopper will maintain integrity throughout multiple piercings, or multipuncture, applications through demonstrated resealability performance under exaggerated test methods. Early evaluation will provide confidence that your stopper will be able to withstand the various piercing techniques and reduce downstream risk. This poster highlights a comparative study conducted by West on different stoppers using a modified USP &lt; 382&gt; protocol for fragmentation and coring, penetrability, and resealability. Data will be provided showing how the multipuncture performance of stoppers with different formulations, designs, and sizes is affected by stopper sterilization methods (steam versus gamma) and penetration needle gauge (18G versus 21G). Fragments down to the subvisible level were counted in addition to the ≥150µm particles required in the compendia to align with testing for real-world applications.</td>
</tr>
<tr>
<td></td>
<td><strong>Poster Presenter:</strong> Todd D. Jasinski Senior Specialist, Technical Product Development West Pharmaceutical Services, Inc.</td>
</tr>
<tr>
<td>10:30 – 11:30</td>
<td>System-Based Drug Manufacturing Inspections: An Inspectional Approach to Help Assure Readiness</td>
</tr>
<tr>
<td></td>
<td>System-Based cGDP Inspections review the establishment of the quality system used by an organization. Such audits look at a particular system which includes multiple processes and can spread across several employees and departments. This presentation provides an overview of the system-based approach to auditing (and inspections), demonstrating how the main parts of the pharmaceutical or healthcare organization can be divided up into interrelated systems. By assessing performance through the systems approach, the auditor is able to establish: • Is the organization following the established procedures, processes and standards? • Are the personnel involved knowledgeable, and familiar with regulations and all appropriate procedures, processes and standards? • Is documentation available demonstrating training, monitoring, and compliance programs? • Is data from the various parts of the quality system being evaluated to make appropriate risk-based decisions? In terms of the core systems, the six systems represent comprehensive and rational categories in relation to the different standards to which an organization needs to adhere. The systems provide an indication to an auditor as to the overall performance of the organization and across all areas of manufacturing.</td>
</tr>
<tr>
<td></td>
<td><strong>Poster Presenter:</strong> Mitchell A. Wheeler ASQ CQA, CMDA, CPGP, CMQ/OE Senior Quality Consultant PharmEng Technology</td>
</tr>
<tr>
<td>10:30 – 11:30</td>
<td>Developing a Method to Learn Capper Settings to Handle Component Variations</td>
</tr>
<tr>
<td></td>
<td>Component dimensional variation has been reported as one of the causes for crimping variations. Critical dimensions of components (vial, stopper, cap) can vary within manufacturing tolerances, however these ranges of variation may require adjustments to capper settings to ensure a proper package seal. The settings used to crimp one batch of components may need to be adjusted to crimp another batch. In this work, we developed a way to learn the component variations and then automatically adjust the settings to ensure a proper seal. The possible range for each setting was validated and learning was limited to that range. Data for the learning model was obtained using an in-line machine vision system to continuously monitor component variations and adjust capper settings as required. Throughout the process, a constant compression percentage is monitored, and intervals of finished product tested by Residual Seal Force (RSF) to ensure seal quality.</td>
</tr>
<tr>
<td></td>
<td><strong>Poster Presenter:</strong> Carolina Gonzalez Gaitan PhD Parenteral Packaging Scientist Genesis Packaging Technologies</td>
</tr>
<tr>
<td>10:30 – 11:30</td>
<td>The Challenges of Testing Bacterial Spores in Disinfectant Coupon Studies to Meet CCS Compliance</td>
</tr>
</tbody>
</table>

GMP systems. With the recent focus on quality maturity models and quality metrics to, in part, ensure the continuity of the drug supply, building a sustainable culture of quality is essential for all GMP-regulated facilities. The term “Quality Culture” has been around for years, but few companies have mastered what it means or how to implement and measure a culture of quality in a GMP-regulated environment. This presentation will provide attendees with an overview of the concepts behind quality culture, as well as some strategies for implementation and metrics for measuring performance.

**Poster Presenter:** Sean Lloyd MSc Principal Consultant SRL Pharma Ltd
This presentation will cover the complexities of designing a robust and effective disinfectant coupon study. The presentation will present new novel data showing that the testing of bacterial endospores at different time points will always have the presence of the spore stage as well as the vegetative state of the spore forming bacteria. The presentation will cover how to implement an effective disinfectant validation program as part of the contamination control strategy. Risk assessments will be covered as effective methods of determining the coupon surfaces and microorganisms to include in the coupon study. The overall scope of the presentation will cover all key aspects of a well planned out disinfectant validation study that compliments the contamination control strategy.

**Poster Presenter:** James N. Polarine MA Senior Technical Service Manager STERIS Corporation

10:30 – 11:30

**Glass Containers Under-filling: E&L Benchmark of Different Glass Vials**

USP < 660> for glass surface chemical durability test prescribes the nominal filling volume as 90% of glass container brimful capacity. Many glass containers for injectable solutions are filled less than this nominal volume which leads to an increased level of E&L, as the surface/volume ratio is increased. We studied the chemical stability of tubular and molded vials in this situation. The study performed a benchmark of E&L levels and pH shift for 3 vials of nominal volume 10ml : tubular, type I molded and type I molded treated with ammonium sulfate. Filled with 10ml and 4ml NaCl 0.9%, the vials went through 1, 2 and 3 cycles of autoclave, followed by extractable analysis by ICP (Inductively Coupled Plasma Atomic Emission Spectrophotometry) and pH measurement. For all types of vials, 4ml under-filling led to a higher pH shift and higher extractable level than nominal filling of 10ml. For the same filling level and autoclave testing, treated molded type I were the most performant in terms of pH stability and E&L levels, followed by type I molded. Tubular vials showed the highest E&L levels and pH shift. Considering the industry practice, type I molded vials is the most relevant choice.

**Poster Presenter:** Jingwei Zhang PhD Group R&D Director SGD Pharma

10:30 – 11:30

**Cleaning Considerations for Lipid Nanoparticles**

The advancements in lipid nanoparticle (LNP) delivery systems have been paramount in the performance, stability, safety, and eventual regulatory approval of novel drugs and vaccines, such as the mRNA COVID-19 vaccine by Moderna, Pfizer/BioNTech, and others. These encapsulated LNPs can deliver drugs using a wide range of sizes based on the LNP components and route of administration. However, the lipophilic nature and complexity of LNPs can present difficulties in the cleaning process. Laboratory cleaning models can be used to efficiently screen cleaning agents and define critical cleaning parameters. The presentation explores the concerns with cleaning drug products utilizing lipid nanoparticle delivery vehicles and provides general cleaning recommendations based on laboratory and field testing. Reference: https://www.pharmtech.com/view/considerations-for-cleaning-lipid-nanoparticles (June, 2022)

**Poster Presenter:** Paul T. Lopolito Technical Services Director STERIS Corporation

10:30 – 11:30

**High Yield Sterile Filtration of High Viscosity Pharmaceutical Formulations**

Sterilizing pharmaceutical products is essential for patient safety and is typically achieved using terminal sterilization methods. In the case of high viscosity formulations, terminal sterilization is often avoided as it can inadvertently change product attributes. Using commercially available 0.2um sterile filters for viscous formulations remains limited due to significant challenges dictated by the filter design and operating ranges. In this work, a validated high pressure sterile filtration (HPSF) skid is presented as a method to successfully sterilize viscous formulations without compromising patient safety. This system has been used to filter solutions used as medical devices and active pharmaceutical ingredients (API) and is validated in accordance with regulatory guidance. Formulations of sodium hyaluronate (NaHy) with molecular weights of 900 - 2,000 kDa, concentrations as high as 30mg/mL, and viscosities up to 1,000,000 cps were examined. When comparing the filtration yield of a 10mg/mL NaHy solution with 900kDa molecular weight on a commercially available capsule filter to HPSF, the flux with HPSF was three orders of magnitude higher. Additionally, HPSF did not result in concentration differences between unfiltered & filtered solution in contrast to low pressure filtration. HPSF can fast track development and accelerate bringing early phase formulations into the clinic.

**Poster Presenter:** Jack E. Kochevar Process Engineer Lifecore Biomedical

10:30 – 11:30

**Design Verification Testing of Auto-Injectors: Performing All Tests on a Single Unit to Reduce Sample Quantity and Increase**
Testing Throughput

The development of combination products requires verification of the performance of the devices to meet the design input requirements. For an auto-injector, particularly an auto-injector that was designed by a medical device manufacturer but is being sold as part of a combination product by a drug company, it is important to perform design verification to ensure that the combination product meets the design requirements for the specific combination. While relevant testing must be deduced from a risk-assessment performed on the particular drug-device combination, guidance documents (like ISO 11608-5:2022 Needle-based injection systems for medical use — Requirements and test methods — Part 5: Automated functions) can serve as useful starting points for determining characteristics that require testing. This poster addresses the test methods developed and validated through a Gage R&R study, using devices or surrogates, as needed, for verifying the performance characteristics of an auto-injector using commercially available force testing equipment with specially designed add-ons that enable the performance of a battery of tests on a single auto-injector, thus generating statistically significant datasets with minimal sample sizes.

Poster Presenter: Mike Ulman PhD Technology Manager, Packaging and Delivery Systems West Pharmaceutical Services, Inc.
Nitrogen gas is bled into the lyophilization chamber to control the chamber pressure during primary and secondary drying. The location of the Nitrogen gas bleed valve is an often overlooked variable when transferring a cycle from one dryer to another. The focus of these studies will be to determine how the location of the gas bleed valve affects the primary drying segment of the lyophilization cycle. The location of the gas bleed valve was varied during these studies and the air temperature at different locations on the shelf and chamber was monitored during primary drying. The air temperature during primary drying was compared by shelf and shelf location to investigate the effects of varying the location of the Nitrogen gas bleed valve. After the air temperature mapping studies were complete, sublimation rate studies were completed using bulk trays and Purified Water, USP. The results of these mapping studies revealed differences in air temperature at different locations on the shelf when the Nitrogen gas is introduced at different locations of the lyophilization chamber. Additional sublimation rate studies were completed to compare to the air temperature mapping studies and if warmer temperatures result in higher sublimation rates.
Cleaning Considerations for Lipid Nanoparticles

The advancements in lipid nanoparticle (LNP) delivery systems have been paramount in the performance, stability, safety, and eventual regulatory approval of novel drugs and vaccines, such as the mRNA COVID-19 vaccine by Moderna, Pfizer/BioNTech, and others. These encapsulated LNPs can deliver drugs using a wide range of sizes based on the LNP components and route of administration. However, the lipophilic nature and complexity of LNPs can present difficulties in the cleaning process. Laboratory cleaning models can be used to efficiently screen cleaning agents and define critical cleaning parameters. The presentation explores the concerns with cleaning drug products utilizing lipid nanoparticle delivery vehicles and provides general cleaning recommendations based on laboratory and field testing. Reference: https://www.pharmtech.com/view/considerations-for-cleaning-lipid-nanoparticles (June, 2022)

Developing a Method to Learn Capper Settings to Handle Component Variations

Component dimensional variation has been reported as one of the causes for crimping variations. Critical dimensions of components (vial, stopper, cap) can vary within manufacturing tolerances, however these ranges of variation may require adjustments to capper settings to ensure a proper package seal. The settings used to crimp one batch of components may need to be adjusted to crimp another batch. In this work, we developed a way to learn the component variations and then automatically adjust the settings to ensure a proper seal. The possible range for each setting was validated and learning was limited to that range. Data for the learning model was obtained using an in-line machine vision system to continuously monitor component variations and adjust capper settings as required. Throughout the process, a constant compression percentage is monitored, and intervals of finished product tested by Residual Seal Force (RSF) to ensure seal quality.

A Holistic, Phase-appropriate Analytical Approach for Establishing Residual Host Cell Protein Specification Throughout the Cell Therapy Drug Product Lifecycle

Residual host cell proteins (HCP) are low-level genomic protein residuals produced from process- or drug-related materials in manufacturing cell therapies. HCP residuals are organic process impurities per the International Conference on Harmonisation (ICH) Q3A/B guidelines (ICH, 2006). These residuals pose a risk to patients’ immunogenic responses while affecting drug efficacy and stability. Drug developers must comply with the United States Pharmacopeia (USP) <1086> and <509> to detect HCP residuals, limiting 0.05% per day of active pharmaceutical ingredients (USP, 2015). Drug release criteria only require HCP results in phase 2 (FDA, 2020). Following phase 2, Biologic License Application filing requires more rigors toward product characterization. To implement a phase-appropriate analytical strategy for cell therapy development, HCP residuals are first identified using a conventional Western size-based assay or a Quadrupole/Time-of-Flight Mass Spectrometer (QTOF-MS). The first method option is far more feasible to execute and collect sufficient data than the latter. Following the 21 Code of Federal Regulations 8610.9 (FDA, 2023), multiple QC samples were utilized for method development, validation, and phase 1 sample analysis. We developed a practical and ideal enzyme-linked immunosorbent assay for QC implementation and met the ICH and USP requirements to support phase 2 trials and commercialization.

Implementing a Disinfectant Program for Advanced Therapy Medicinal Product Manufacturing

In a fast-paced, rapidly evolving environment like Advanced Therapy Medicinal Product (ATMP) manufacturing, it is easy to overlook critical elements necessary to maintain contamination control. However, despite urgent manufacturing procedures, a sound strategy for contamination control is essential to help ensure microbiological safety and final product integrity. A cleaning and disinfection program must address the unique challenges within ATMP including addressing the special considerations often found within these facilities such as limitations with available resources and critical time-sensitive procedures. Implementing a program that can be adaptable to the unique environment of specialized procedures that
incorporates the consideration of smaller processing suites, biosafety cabinets and isolators is key. A well-designed program that is not overly complicated yet focuses on a holistic contamination control approach focused on the challenges in the ATMP environment is essential.

**Poster Presenter: Dan A. Klein MA Senior Manager, Technical Services STERIS Corporation**

<table>
<thead>
<tr>
<th>12:15 – 13:45</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Design Verification Testing of Auto-Injectors: Performing All Tests on a Single Unit to Reduce Sample Quantity and Increase Testing Throughput</strong></td>
</tr>
</tbody>
</table>

The development of combination products requires verification of the performance of the devices to meet the design input requirements. For an auto-injector, particularly an auto-injector that was designed by a medical device manufacturer but is being sold as part of a combination product by a drug company, it is important to perform design verification to ensure that the combination product meets the design requirements for the specific combination. While relevant testing must be deduced from a risk-assessment performed on the particular drug-device combination, guidance documents (like ISO 11608-5:2022 Needle-based injection systems for medical use — Requirements and test methods — Part 5: Automated functions) can serve as useful starting points for determining characteristics that require testing. This poster addresses the test methods developed and validated through a Gage R&R study, using devices or surrogates, as needed, for verifying the performance characteristics of an auto-injector using commercially available force testing equipment with specially designed add-ons that enable the performance of a battery of tests on a single auto-injector, thus generating statistically significant datasets with minimal sample sizes.

**Poster Presenter: Mike Ulman PhD Technology Manager, Packaging and Delivery Systems West Pharmaceutical Services, Inc.**

<table>
<thead>
<tr>
<th>12:15 – 13:45</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fused Quartz Vials: from Glass Science to Drug Containment Solution</strong></td>
</tr>
</tbody>
</table>

Glass is the most used material in pharmaceutical packaging, and borosilicate is currently the most used among those described by the Pharmacopoeia(s). The USP, however, has recently enacted changes to their glass packaging chapter < 660> that enable the introduction of new glass compositions, one of which is fused quartz. While new to the USP chapter, fused quartz has been manufactured for well over one hundred years, valued primarily for its high purity and remarkable properties, including a very low thermal expansion coefficient and excellent chemical durability. This presentation will address the science behind fused quartz vials, with focus on assessing their chemical, physico-chemical and mechanical performances. Although fused quartz is generally considered chemically inert, the selection of any container must always be done taking into consideration the individual drug product and processing requirements. The knowledge of this new glass and of relevant analytical testing can continue to accelerate its adoption as a container for parenteral preparations and on its classification inside the three main Pharmacopoeia and standard setting organizations like ISO and ASTM. The experts at Stevanato Group and Momentive Technologies are excited to see this “new” glass help solve many of the industry’s most demanding formulation challenges.

**Poster Presenter: Serena Panighello EMEA TEC Research Scientist Stevanato Group**

<table>
<thead>
<tr>
<th>12:15 – 13:45</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Evaluation of New Sterilization Modalities that Enable Terminal Sterilization of Parenteral/Injectable Drug Products Traditionally Filled by Aseptic Manufacturing</strong></td>
</tr>
</tbody>
</table>

Sterile manufacturing of parenteral/injectable drug products is accomplished by either aseptic manufacturing or terminal sterilization, the latter preferred and recommended by regulatory bodies. Product and container closure compatibility with moist heat normally dictates if the product is Aseptically Manufactured or Terminally Sterilized. New technologies and sterilization modalities were evaluated with the goal of broadening the drug product/container closure compatibility assessment. Studies demonstrated new technologies enable conversion of drug products currently Aseptically Manufactured to Terminally Sterilized, thereby reducing manufacturing cost and reducing lack of sterility risks. This presentation will highlight testing of several sterilization modalities, results, and next steps.

**Poster Presenter: Terrence Hollis Senior Manager, Global Technology and Engineering Pfizer Inc.**

<table>
<thead>
<tr>
<th>12:15 – 13:45</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Developing Primary Packaging System for Nanosuspensions: Headspace Design Space Case Study</strong></td>
</tr>
</tbody>
</table>

Suspensions with nanometer size drug particles are a unique drug product dosage form which allow high concentrations of water-insoluble small molecules to be parenterally administered into human bodies to treat difficult diseases. They are typically packed in pre-filled syringes (PFS) or
glass cartridges with a desired level of container closure integrity (CCI) to protect them from oxygen and microbe ingress. Headspace (HS) is an important attribute that needs to be well controlled during the filling of the nanosuspensions into glass primary containers. This case study highlights two important factors in relation to headspace within a primary pack containing a nanosuspension product: 1) The importance of a maximum allowable headspace given the impact this has on stopper movement and therefore on the primary packaging system's sterility performance; 2) The minimum headspace requirements for nanosuspension products as they need to be well resuspended prior to drug product administration. Thus, the headspace needs to be optimized within a certain window to ensure adequate sterility and achieve the desired dosage. In summary, this case study serves as a good example of a balanced approach on developing challenging primary packaging solutions for this unique parenterally administered nano-suspended drug product dosage form.

Poster Presenter: Liang Fang PhD Associated Director, Primary Packaging GSK

12:15 – 13:45

Economic Benefits of an Original Container Closure during Combination Product Development: Expert-Modeled Scenarios Validated by Pharma

Poster Presenter: Mehul Desai PharmD, MBA Vice President, Medical Affairs Enable Injections

12:15 – 13:45

The Challenges of Testing Bacterial Spores in Disinfectant Coupon Studies to Meet CCS Compliance

This presentation will cover the complexities of designing a robust and effective disinfectant coupon study. The presentation will present new novel data showing that the testing of bacterial endospores at different time points will always have the presence of the spore stage as well as the vegetative state of the spore forming bacteria. The presentation will cover how to implement an effective disinfectant validation program as part of the contamination control strategy. Risk assessments will be covered as effective methods of determining the coupon surfaces and microorganisms to include in the coupon study. The overall scope of the presentation will cover all key aspects of a well planned out disinfectant validation study that compliments the contamination control strategy.

Poster Presenter: James N. Polarine MA Senior Technical Service Manager STERIS Corporation

12:15 – 13:45

Glass Containers Under-filling: E&L Benchmark of Different Glass Vials

USP < 660> for glass surface chemical durability test prescribes the nominal filling volume as 90% of glass container brimful capacity. Many glass containers for injectable solutions are filled less than this nominal volume which leads to an increased level of E&L, as the surface/volume ratio is increased. We studied the chemical stability of tubular and molded vials in this situation. The study performed a benchmark of E&L levels and pH shift for 3 vials of nominal volume 10ml : tubular, type I molded and type I molded treated with ammonium sulfate. Filled with 10ml and 4ml NaCl 0.9%, the vials went through 1, 2 and 3 cycles of autoclave, followed by extractable analysis by ICP (Inductively Coupled Plasma Atomic Emission Spectrophotometry) and pH measurement. For all types of vials, 4ml under-filling led to a higher pH shift and higher extractable level than nominal filling of 10ml. For the same filling level and autoclave testing, treated molded type I were the most performant in terms of pH stability and E&L levels, followed by type I molded. Tubular vials showed the highest E&L levels and pH shift. Considering the industry practice, type I molded vials is the most relevant choice.

Poster Presenter: Jingwei Zhang PhD Group R&D Director SGD Pharma

12:15 – 13:45

High Yield Sterile Filtration of High Viscosity Pharmaceutical Formulations

Sterilizing pharmaceutical products is essential for patient safety and is typically achieved using terminal sterilization methods. In the case of high viscosity formulations, terminal sterilization is often avoided as it can inadvertently change product attributes. Using commercially available 0.2um sterile filters for viscous formulations remains limited due to significant challenges dictated by the filter design and operating ranges. In this work, a validated high pressure sterile filtration (HPSF) skid is presented as a method to successfully sterilize viscous formulations without compromising patient safety. This system has been used to filter solutions used as medical devices and active pharmaceutical ingredients (API) and is validated in accordance with regulatory guidance. Formulations of sodium hyaluronate (NaHy) with molecular weights of 900 – 2,000 kDa, concentrations as high as 30mg/mL, and viscosities up to 1,000,000 cps were examined. When comparing the filtration yield of a 10mg/mL NaHy solution with
900kDa molecular weight on a commercially available capsule filter to HPSF, the flux with HPSF was three orders of magnitude higher. Additionally, HPSF did not result in concentration differences between unfiltered & filtered solution in contrast to low pressure filtration. HPSF can fast track development and accelerate bringing early phase formulations into the clinic.

**Poster Presenter: Jack E. Kochevar Process Engineer Lifecore Biomedical**

### 12:15 – 13:45

**Applying Holistic Sterile Manufacturing Design Principles to Build an Agile Combination Product Contract Manufacturing Facility Which Anticipates the Over the Horizon Compliance Requirements**

There is an incredible level of complexity, investment and risk with building a sterile manufacturing facility. When the facility will serve the global needs of a diverse contract manufacturing customer base, it must be built for agility, efficiency, scalable and most importantly for global compliance-known today and what’s over the horizon. Examples of holistic design utilized in Kindeva’s new aseptic manufacturing facility;  • Levo-magnetic drive motors- reducing wear and particulate generation • Disposable bagging systems in formulation tanks reducing cross-contamination risk and establishing more efficient change overs • Automated PUPSIT systems integrated into the filling process providing continuous filter integrity. • Filling machines utilize isolators eliminating the need for traditional gowning and aseptic training, reducing grade A areas to the isolator interiors, and reducing time to qualify operators. • Modular filling suites- operating independently eliminating facility wide shutdowns • In-process fill check technology tracks individual drug containers allowing for automatic removal of individual containers not meeting quality parameters. Product quality, operational efficiency and compliance isn’t determined by any single process or design element. These are only achieved and maintained through holistic design principles that collectively meet the need of the market and regulators tomorrow and over the horizon.

**Poster Presenter: Chad Hafer MEng Senior Manager Aseptic Operations Kindeva Drug Delivery**

### 12:15 – 13:45

**In-Line Real-Time Monitoring of Perfusion CHO Cell Culture Critical Process Parameters and Critical Quality attributes using Raman Spectroscopy and Chemometric modelling**

Cell culture processes are complex and highly variable and yet only a handful of key parameters such as temperature, pH, and dissolved oxygen (DO) are typically controlled in real time. While measurement and control of these parameters are essential for a robust process, they provide only broad assumptions on the culture’s true state and offer limited insights into the process and cell growth. In contrast, critical process parameters (CPP) such as glucose, lactate, and key performance indicators (KPI) such as total cell density (TCD), viable cell density (VCD), antibody titer, osmolality provide direct indication of the culture’s content and state. These measurements are typically measured offline, however, and do not provide real-time information or effective process control. This presentation describes use of the MilliporeSigma’s ProCellics™ Raman Analyzer with Bio4C™ PAT Raman Software (also known as Raman PAT Platform) to perform inline and real-time measurement of TCD, VCD, Antibody titer, Osmolality and the concentration of glucose and lactate a bench-scale bioreactor.

**Poster Presenter: Ushma Mehta MS Regulatory Consultant MilliporeSigma**

### 12:15 – 13:45

**An Alternative Approach to Standard Operating Procedures**

The classic paradigm of training and executing SOPs in BioPharma- is to Read and Understand, to observe someone else perform the procedure, and then to demonstrate it yourself. Once this initial training phase is complete, you are left solely with a written SOP to reference. This heavy reliance on written instructions can lead to a higher chance of ambiguity and unnoticed or overlooked errors. My proposed solution aims to address this issue by accommodating diverse learning preferences and seamlessly integrating visual aids, such as videos, directly into procedures. To address this challenge, I have embedded QR codes directly within procedures. This approach enables employees to access instructional videos quickly and conveniently, providing clear guidance, especially for more complex steps, thus reducing errors and preventing confusion during execution.

**Poster Presenter: Max Falcone Analyst Tunnell Consulting**

### 12:15 – 13:45

**A New Calibration Technique for Light Obscuration Sensors to Improve Counting Accuracy of Aggregated Proteins**
Light obscuration liquid particle counters used for USP <788> and <787> are calibrated using polystyrene latex (PSL) particles with a refractive index (RI) value of 1.58. This calibration approach generates accurate results for large particles with a similar RI value in the critical size ranges of 10 & 25 µm. Various sources have pointed out the inaccuracies in results for protein particles where the RI value of approximately 1.4 is much closer to water, especially at smaller particle sizes. This presentation will describe a new calibration technique for light obscuration/scattering sensors using the new NIST RM 8634 and present results of aggregated proteins with both the historic PSL and the new protein calibration techniques. The calibration procedure used is described in ISO 11171:2020, using the new NIST RM 8634 to create a “protein calibration curve”.

Aggregated protein samples were then analyzed by the single particle optical (SPOS) technique using both the historic PSL and new protein calibration curves. Results using the protein calibration curve reported higher particle concentrations at a given size.

**Poster Presenter:** Mark Bumiller Technology Manager Entegris, Inc.

12:15 – 13:45

### Breaking Out of the Human Factors Study Loop, For the Benefit of Patients

Human Factors Engineering (HFE) is a critical component of development and life cycle management for combination drug products. Human factors (HF) studies assess whether combination products are safe and effective and, when properly designed, can eliminate millions of dollars in future life cycle management costs. These studies seek to understand how patients interact with products, what patients expect from products, enable manufacturers to design out risks, and ensure positive patient outcomes and compliance. HFE is never a one-and-done activity. It involves an iterative series of experimentation, testing and qualification. Each HF study yields new observations and options for continuous improvement. This can create a loop which, if not managed properly, can delay the implementation of design improvements and instructions that will benefit patients and users at all stages of a product’s life cycle. This presentation will discuss how principles of Use Related Risk Analysis have been incorporated into autoinjector HF studies ranging from early prototypes to on-market products. It will present a process which balances the iterative process of HF engineering with focus on the end goal, delivering outcomes for patients.

**Poster Presenter:** Amy Lukau Senior Human Factors Lead Kindeva Drug Delivery

12:15 – 13:45

### Behavior of Molded and Tubular Vials During Depyrogenation

Depyrogenation is a key step in the aseptic filling process. Dry heat depyrogenation is the method of choice for glass vials. Most depyrogenation tunnel manufacturers consider the power necessary is proportional to the weight of glass vials. This study shows the reality is different for small vials below 30 ml. An industrial depyrogenation tunnel was used, filled with 100H molded vials and in the center of the conveyor, in the same row two 20R, two 20H and two 20H EasyLyo. The temperature was monitored with thermocouples. The temperature curves for molded and tubular 20ml vials are close and similar. The times recorded to achieve the 3 log reduction were 18 min 13s for the tubular vials, 19 min 28s for ISO vials and 19 min 37s for EasyLyo vials. The accumulated destruction factors FD for these 2 vials are significantly equivalent. There was no direct correlation between the weight of vials and the energy needed for depyrogenation for glass vials below 30ml. The measured time to achieve a 3 log reduction did not differ by more than 8%, while the weight difference was 70%. This understanding opens new perspectives for drug manufacturers in terms of sustainability and machinability.

**Poster Presenter:** Jingwei Zhang PhD Group R&D Director SGD Pharma

12:15 – 13:45

### Using Toxicological Risk Assessment to Minimize Cross-Contamination

Conducting a risk assessment to evaluate the toxicity of a product helps to ensure patients’ safety and prevent unwanted cross-contamination and recalls. Data from both pre-clinical and clinical trials provides insight on safety margins, adverse effects, and pharmacokinetic parameters (i.e., absorption, distribution, metabolism, and excretion). Toxicologist can determine Permitted Daily Exposure (PDE) and/or Accepted Daily Exposure (ADE) across the product lifecycle and use adjustment factors to address both uncertainty and known toxicities associated with a product. Overall toxicological risk characterization for product development, cleaning validation, manufacturing process, and laboratory testing is critical to ensure patient safety. This talk will briefly highlight some of the regulations, risk assessment process, and provide case-studies to determine health-based exposure limits (HBEL).

**Poster Presenter:** Wendy Haines PhD, DABT, ASQ CQA Director of Toxicology & Technical Services PharmEng Technology

12:15 – 13:45
Microneedle patch technology has progressed to the pre-clinical and early human clinical stage by many developers, but Kindeva is one of the few companies that has made it to Phase 3 clinical studies and has commercial scale equipment. Kindeva Drug Delivery provides recommendations for process development and manufacturing based on its coated microneedle patch drug delivery platform. Manufacturing process scale-up with intention of regulatory submission follows a strategic path. At each stage (lab bench, pilot, and commercial) it’s critical to document data, decisions, and key learnings in support of a design history file and regulatory submission. Documents should be raised at the time of data generation and cover topics including product development decisions, process development milestones, and device development choices. Likewise, methods and specifications mature during development. Data destined for regulatory submissions should be collected consistently over time. If a method changes, comparison data sets utilizing the two methods and same set of samples should be generated to support the change. Specification setting is also evolutionary, with specifications growing more detailed and narrower as the development proceeds. This evolution will be illustrated through Kindeva’s experience in scale up from lab to commercial scale processes for manufacture of coated microneedles.

Poster Presenter: Andrew Riso Director of Business Development Kindeva Drug Delivery

12:15 – 13:45

Isolator/RABS: Risk Minimization Through Correct Glove Management
- Requirements and challenges (Annex 1) - Glove types/ Selection/ Test methods - FDA study published on "How risky are pinholes" - Possible risks that compromise glove integrity - Necessary activities for good glove management. - Additional literature for self study

Poster Presenter: Alex J. Kappani Product Management SKAN AG

12:15 – 13:45

Data Analysis ~ Trending and Pattern Recognition for Contamination Control
The regulations are evolving, EMA Annex 1 earlier versions did not mention trends, the current draft version mentions it 23 times. WHO, and FDA also talk about trending, root cause analysis, investigation, and using the data for these purposes. Trending the data is now a regulatory requirement but what trends should we use? This presentation will discuss how often we should trend, what events should trigger trending, root cause analysis, and investigations. Also, which trend tools should we use for the different contamination control processes, cut off method, Control charts (Shewhart, etc.), Quantiles, percentiles, Weibull distribution, scatter plot, regression analysis for slope (upward/downward trends). FYI... Would present as a lightening talk as well

Poster Presenter: Susan B. Cleary EMBA Director of Product Development Novatek International

12:15 – 13:45

Centralized Vaporized Phase Hydrogen Peroxide (VH2O2) as Building Utility
Application of a disinfection and sporicide rotation is a critical component of a contamination control strategy per EU Annex 1. Many current applications deploy a manual process for sporicide application. Automated systems are desirable as they minimize people and equipment required to enter the classified spaces and minimize operating costs and errors as part of the process. These systems provide enhanced coverage in the critical environment areas and are especially critical for ATMP facilities that have strict contamination control requirements. This presentation will explore the use of a centralized, automated system to apply VH2O2 as a biodecontamination method in an ATMP facility. A case study will be presented that outlines: • VH2O2 properties and its use as a biodecontamination method in biopharmaceutical applications. • VH2O2 integration into the facility HVAC for distribution to clean rooms and RABS. • Equipment integration with the facility building management system (BMS) for control and cycle reporting functions including 21 CFR Part 11 and EU Annex 11 considerations. • Safety considerations for the users and the facility. • Qualification and validation of the process. Users will take away how VH2O2 centralized, automated systems can be implemented for enhanced contamination control strategy practices.

Poster Presenter: Matt Hofacre Senior Director, Technical Services STERIS Corporation

12:15 – 13:45

High Cell Density Cryopreservation for Upstream Process Intensification Using LN2 Vapor Phase Stored Seed Train Intermediates

Agenda

2024 PDA Annual Meeting

Standard seed train operations start by thawing of a single 1 ml vial with cell densities of $10 \times 10^6$ VC/ml. For reaching a sufficient absolute cell number for production bioreactor inoculation, several expansion steps, starting with shake flasks, need to be performed. These open cell culture operations result in long ramp up times, high room classifications during the whole process, and are a major source of process variability. High cell density cryopreservation is a method where cells can be frozen in bags with cell densities higher than nowadays standard processes. This leads to the advantage that cell expansion and batch production can be separated. Lower room classification for the cell culture area in GMP manufacturing might be a result due to the reduction of manual handling steps before the main stage bioreactor (closed processing). Furthermore, these intermediates allow global distribution from a central expansion facility to decentralized global production facilities. Currently, we have demonstrated that SU bag assembly was modified to withstand liquid nitrogen vapor phase storage and the process of freeze and thaw was also optimized to maintain cell performance and SU bags integrity after thaw.

**Poster Presenter:** Ushma Mehta MS Regulatory Consultant MilliporeSigma

---

12:15 – 13:45

Maintaining Superior Viral Vector Recovery in Cell and Gene Therapy Applications by Using Daikyo Crystal Zenith® Vials

AAV8 and AAV9 were chosen as representative adeno-associated virus (AAV) serotypes, with respective titers in a common buffer formulation, and evaluated in different 2ml vial types: Daikyo Crystal Zenith® (CZ) vial, and two commercially available borosilicate vials. To simulate viral vector recovery in cell and gene therapy applications, the vial combinations were tested across five challenge conditions: 1. 3 months at -80C, recommended condition for long term storage 2. 2 months at 5C, recommended condition for temporary refrigerated storage 3. 3 weeks at 25C, simulating room temp clinical ambient conditions 4. 72 hours of 250RPM agitation, to mimic handling during manufacturing/shipping 5. 5 cycles of Freeze/Thaw, to mimic handling during manufacturing and the potential for structural damage to proteins or DNA In all conditions, the Daikyo CZ vial demonstrated improved viral vector recovery compared to borosilicate glass vials. The data shows that there were no significant changes in product quality due to container storage in the Daikyo CZ vials, and that the CZ vials may comparatively improve viral vector recovery across common storage and handling conditions.

**Poster Presenter:** Eric Kurtz Manager, Technical Product Development West Pharmaceutical Services, Inc.

---

12:15 – 13:45

A Model for a Risk-Based Deviation Investigation Process

Deviation investigation process owners often find themselves swamped with investigations, lacking quantitative tools that allow them to discriminate between minor low-risk events and critical high-risk deviations. Additionally, the business processes that support deviation investigations are often not purpose-built to enable the speed and investigational rigor that allow for timely closure and effective corrective action. This talk will present a proven model for building a quantitative risk-based deviation classification system and will discuss assigning investigational tools to assigned deviation risk levels. Supporting business processes will also be discussed, including professionalizing deviation investigators as an expert role within an organization as well as developing daily operational practices and metrics for effective management of the deviation lifecycle: identification, assessment, investigation, assignment of corrective/preventive actions, and approval/closure.

**Poster Presenter:** Aaron Hubbell Director, Life Sciences Barry-Wehmiller Design Group

---

12:15 – 13:45

Identification of Foreign Particulate Matter in Assembled Autoinjectors Through Long-Time Tracking of Individual Particles’ Trajectories

Part of the challenge in detecting foreign particles in a liquid parenteral is to discriminate them from bubbles or other intrinsic objects, which do not constitute a defect, but can lead to false rejects. We have implemented an innovative methodology to identify foreign particles in a complex autoinjector device. For this application, we combine a handling adapted to mobilize particles in solution with image processing algorithms for particle tracking. In our test system, the devices circulate in a linear transport system and are turned upside down prior to the image acquisition. In this way, particles which might be stuck on the walls or at the bottom of the device are released in the solution, which facilitates their detection. By acquiring up to hundreds of images we are able to track the particles’ motion for longer than 1 second, distinguishing whether they tend to move downwards or upwards and identifying them as particles or bubbles, respectively. The strength and novelty of our machine design rely on the fact that the additional time for image analysis is obtained without compromising the speed of the machine.

**Poster Presenter:** Matthias Kahl Head of R&D and Lab Services WILCO AG

---

12:15 – 13:45
Aseptic Transfer of RTU Containers in the Light of the New Annex 1

The poster will compare the different methods on how to introduce RTU Containers into the aseptic environment with focusing on the operating, sterility and validation principle. Transfer methods as H2O2, NTT, Ebeam and pulsed light are being compared. These methods will be put into conclusion with then nex Annex 1.

**Poster Presenter:** Christian Thieme Sales Director - Americas groninger & co. gmbh

12:15 – 13:45

Exploratory Assessment of an On-Body Delivery System for Large-Volume SC Delivery: Facilitating Rapid Thermal Equilibration to Ambient Temperatures for Immediate Utilization Post-Refrigeration

In the evolving field of healthcare, ensuring prompt and efficient medication delivery remains a top priority. This study undertakes an exploratory assessment of an on-body delivery system tailored for large volume subcutaneous (SC) delivery. The design is crafted to accelerate thermal equilibration to ambient temperatures, enabling immediate use post-refrigeration. The movement of the drug through the fluid path is central to warming the drug swiftly to near ambient temperatures. Our analysis dives into the performance and efficiency of this system across varied environmental conditions. The data, which will be shared in detail during the presentation, unveils a significant trimming of the time needed to reach ambient temperatures, thereby potentially reducing wait times and enhancing user experience. These preliminary findings highlight the promise of this system and beckon further exploration to ascertain its real-world applicability and advantages, aspiring to advance the sphere of patient-centric medication delivery solutions.

**Poster Presenter:** Mehul Desai PharmD, MBA Vice President, Medical Affairs Enable Injections

12:15 – 13:45

Benefits of Single-use for ATMPs in Regards to Annex 1

The presentation will give an overview about technical standards and trends. The presentation highlights regulatory aspects, e.g. EU-GMP Annex one and will also touch the field of aseptic risk reduction and will show how to increase the quality of sterile drug manufacturing. Annex 1 drives technical solutions for ADCs / ATMPs more and more towards: - Isolators / Containment Isolators - Single-Use and Ready-To-Use components - Automated or at least semi-Automated processes for better reproducibility Human interventions are to avoid, to eliminate potential contamination risk factors. Standardized documentation according to latest norms are required. Why does single-use and ready-to-use best possibly comply to EU GMP Annex 1 Why does single-use specially make sense in dealing with new types of medicinal products like ATMPs and ADCs. What are market standards and trends and where is pharma manufacturing moving to.

**Poster Presenter:** Juergen M. Metzger Product Specialist/Senior Consultant Final Filling Sartorius North America Inc.

12:15 – 13:45

System-Based Drug Manufacturing Inspections: An Inspectional Approach to Help Assure Readiness

System-Based cGxP Inspections review the establishment of the quality system used by an organization. Such audits look at a particular system which includes multiple processes and can spread across several employees and departments. This presentation provides an overview of the system-based approach to auditing (and inspections), demonstrating how the main parts of the pharmaceutical or healthcare organization can be divided up into interrelated systems. By assessing performance through the systems approach, the auditor is able to establish: • Is the organization following the established procedures, processes and standards? • Are the personnel involved knowledgeable, and familiar with regulations and all appropriate procedures, processes and standards? • Is documentation available demonstrating training, monitoring, and compliance programs? • Is data from the various parts of the quality system being evaluated to make appropriate risk-based decisions? In terms of the core systems, the six systems represent comprehensive and rational categories in relation to the different standards to which an organization needs to adhere. The systems provide an indication to an auditor as to the overall performance of the organization and across all areas of manufacturing.

**Poster Presenter:** Mitchell A. Wheeler ASQ CQA, CMDA, CPGP, CMQ/OE Senior Quality Consultant PharmEng Technology

12:15 – 13:45

Quality Culture: From Buzzword to What Works
Warning letters consistently cite firms for failing to establish a Quality unit with the responsibility and authority to execute its responsibilities across all GMP systems. With the recent focus on quality maturity models and quality metrics to, in part, ensure the continuity of the drug supply, building a sustainable culture of quality is essential for all GMP-regulated facilities. The term “Quality Culture” has been around for years, but few companies have mastered what it means or how to implement and measure a culture of quality in a GMP-regulated environment. This presentation will provide attendees with an overview of the concepts behind quality culture, as well as some strategies for implementation and metrics for measuring performance.

Poster Presenter: Sean Lloyd MSc Principal Consultant SRL Pharma Ltd

12:15 – 13:45

Developing a Risk Score for Critical Suppliers Using Artificial Intelligence (AI)

The modern economy is familiar with many examples of risk scores, like credit scores, insurance scores, and more. Supply chains are one area where risk scores haven’t yet been fully developed and utilized. In the pharmaceutical industry, where the supply chain has a direct impact on patient safety and health outcomes, supply chain risk scoring is of particular importance, yet as an industry, we have a lot of progress to make. With more data available than ever before, plus the capabilities unlocked by AI and ML, pharmaceutical sponsors can now accurately score the relative risk of all of the organizations upstream from them, like CMOs, API manufacturers, and excipient manufacturers. Takeaways: - Which variables should be used to calculate pharmaceutical supplier risk? - What are some roadblocks to developing a supplier risk score and how can they be overcome? - Entity resolution - you can’t accurately calculate a risk score for a particular entity unless the dataset you’re using has appropriately resolved all of the permutations of the entity name into one profile. - How those variables interact with one another (i.e. how do you score a warning letter and the 483 that preceded it?)

Poster Presenter: Michael de la Torre CEO Redica Systems

12:15 – 13:45

Evaluating Your Stopper: Proving Stopper Functionality for Real-World Use Cases Through <USP 382>

With the upcoming implementation of USP <382> in 2025, there is an increased emphasis on designing clinically representative experiments to prove that the required, optimal container system is achieved regarding piercing performance and resealability. Not only are medical professionals taught varying techniques on how to pierce a stopper, but industry opinions on the best needle and method have led to more questions than answers. To reduce risk to the patient, it is critical to show that one’s stopper will maintain integrity throughout multiple piercings, or multipuncture, applications through demonstrated resealability performance under exaggerated test methods. Early evaluation will provide confidence that your stopper will be able to withstand the various piercing techniques and reduce downstream risk. This poster highlights a comparative study conducted by West on different stoppers using a modified USP <382> protocol for fragmentation and coring, penetrability, and resealability. Data will be provided showing how the multipuncture performance of stoppers with different formulations, designs, and sizes is affected by stopper sterilization methods (steam versus gamma) and penetration needle gauge (18G versus 21G). Fragments down to the subvisible level were counted in addition to the ≥150µm particles required in the compendia to align with testing for real-world applications.

Poster Presenter: Todd D. Jasinski Senior Specialist, Technical Product Development West Pharmaceutical Services, Inc.

12:15 – 13:45

Supply Chain Verification for API Manufactured by a Third Country

This poster explains the Supply Chain Verification and Risk assessment carried out by Qualified Persons for API imported from a Third Country.

Poster Presenter: Farah Nadeem QP Trainee Paul Palmer Ltd

12:15 – 13:45

Transforming Deviation Management for Expedited Closure and Product Release in Cell and Gene Therapy

This case study, conducted in partnership between a prominent cell and gene therapy manufacturer and a consulting firm, sought to streamline the deviation management process within the organization. The main goals were to define ownership in the process and enhance departmental knowledge and skills resulting in expedited deviation closure, while maintaining a high level of Quality. A detailed examination of the deviation lifecycle included identifying communication gaps, redundant meetings, delays resulting from information or decision bottlenecks, and the non-value-added activities in the process. This analysis, enriched by stakeholder involvement, led to the creation of an innovative workflow engineered to
promptly resolve low-level deviations within a challenging 24-hour period, or ideally during the same manufacturing shift. To ensure a seamless integration, training sessions were deployed to ensure personnel were aligned with the new workflow and overarching site goal. In the initial weeks following go-live of the new workflow, the data showed a two-thirds reduction in the overall cycle time for low-level deviations. This was a substantial step towards reducing deviation closure time, along with allowing more time to focus resources on critical issues. Importantly, there were additional improvements in the pipeline, which, when implemented, were expected to streamline the process further.

**Poster Presenter:** Christian Spiak Principal Consultant, Human Performance Business Area CAI

13:45 – 15:30

**P3: A Legacy-Driven Mindset: Our Responsibility for Sustainability**

In the bio/pharmaceutical sector, achieving sustainability and lowering environmental impact can present a difficult challenge when balancing corporate and environmental interests. According to The Underwell’s Founder and Lead Instructor, Derek Sabori, while sustainability is a complex and urgent topic, it is also one of the biggest economic opportunities of our lifetime! This closing plenary will kick off with Mr. Sabori sharing stories of collaboration from the apparel industry on achieving confidence and competence on sustainability matters through a transformational learning system. Following these encouraging examples from outside our industry, closer-to-home sustainability case studies from SGD Pharma and Amgen will be shared. Participants will leave this closing session of the 2024 PDA Annual Meeting inspired and excited to make a positive difference in their organization’s sustainability legacy.

**Moderator:** Kenneth Paddock Quality Director, Sterility Assurance Baxter Healthcare

13:45 – 14:05

**Sustainability in Pharmaceutical Manufacturing**

**Presenter:** Derek A. Sabori MBA Senior Director, Communications thinkPARALLAX

14:05 – 14:30

**Sustainable Glass Packaging: Supply Sector Contributions**

**Presenter:** Kevin McLean Quality and Technical Manager - Americas SGD Pharma

14:30 – 14:55

**Sustainability in Manufacturing and Clinical Supply**

**Presenter:** Margaret Faul PhD Vice President, Manufacturing and Clinical Supply Amgen Inc.

14:55 – 15:25

**Q&A**

15:25 – 15:30

**Closing Remarks from Meeting Co-Chairs**

**Co-Chair:** Kenneth Paddock Quality Director, Sterility Assurance Baxter Healthcare

**Co-Chair:** Susan J. Schniepp Distinguished Fellow Regulatory Compliance Associates Inc.