* 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!

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**Monday, 25 March**

07:00 – 19:00
Registration Open
Promenade Lobby

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 (Ticket Required)
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 (Ticket Required)
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
Presenter: David B. Talmage MBA Vice President, Education PDA
**Roundtable 3: 503B Compounding Facilities (Ticket Required)**

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  
**Presenter:** Mike Porter MS  
Senior Director, Education PDA

08:00 – 10:00

**Roundtable 4: Early and Mid-Career Professional Development (Ticket Required)**

**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 (CQV) AtkinsReals

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

09:00 – 12:00

**Dendreon Site Visit (Ticket Required)**

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.

Learn More

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.

Learn More

13:00 – 15:00

**P1: Connecting Minds, Transforming Possibilities**

Grand Ballroom
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.
production, and innovative solutions for formulation manufacturing.

Moderator: Sebastian B Teitz PhD Consultant

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

15:50 – 16:10

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

16:10 – 16:30

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 form late downstream operations where antibody gets concentrated to its final concentration, to final fill 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 use 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

16:30 – 17:00

Q&A
15:30 – 17:00

B1: QRM: The Evolution, Revolution, and Digital Solution
Room 102

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.

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<th>Time</th>
<th>Session Title</th>
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<tr>
<td>15:30</td>
<td>QRM Evolution: Unleashing the Learning Culture Advantage in Line with ICH Q9 R1 Innovations</td>
<td>Lorianne Richter Senior Director, GxP Quality Management Systems ALX Oncology</td>
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<td>15:50</td>
<td>Revolutionizing QRM: The Impact of AI and ML</td>
<td>Ghada N. Haddad PhD Executive Director, Global Quality Transformation Merck &amp; Co., Inc.</td>
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<tr>
<td>16:10</td>
<td>Digital Transition to a Performance-Based QRM: A Case Study</td>
<td>Yowvanaraj Gopal Director Professional Services ValGenesis</td>
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C1: Streamlining the Processes to Enhance Product Quality
Room 104A
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

Platform 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 sanitation 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*

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<td>16:30 – 17:00</td>
<td>Q&amp;A</td>
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15:30 – 17:00

**D1: The Future of Pharmaceutical Drug and Combination Products: Where are We Headed and How Can PDA Help?**

*Room 104C*

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*

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<th>Time</th>
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| 15:30 – 16:00 | Ready or Not! The Next Wave of Novel Pharmaceutical Drug Product Innovation is Arriving

**Presenter:** Michael N. Blackton MBA Founder and CEO *Blackfin Biopharma Advisors*

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<th>Time</th>
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| 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*

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<th>Time</th>
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| 16:30 – 16:40 | PDA’s Role in Supporting Industry and Innovation

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

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<th>Time</th>
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<td>16:40 – 17:00</td>
<td>Q&amp;A</td>
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17:00 – 18:30

**Happy Hour in the Exhibit Hall**

*Exhibit Hall A*

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<td>18:30 – 21:00</td>
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Opening Reception
Pacific Ballroom
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.

Learn More

07:00 – 18:30
Registration Open
Promenade Lobby

07:00 – 08:00
Continental Breakfast

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

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<tr>
<th>Time</th>
<th>Session Title</th>
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<tr>
<td>08:00</td>
<td>Unleashing the Power of AI in CMC</td>
<td>Sara Cook PhD President and Founder IliaCook Consulting</td>
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<td>08:25</td>
<td>Integrating AI for Impact in Drug Discovery: Strategic Insights, Case Studies, and Value Creation</td>
<td>Ravi Starzl PhD Adjunct Professor, Language Technologies Institute Carnegie Mellon University</td>
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<tr>
<td>08:50</td>
<td>Q&amp;A</td>
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## Agenda

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

Exhibit Hall A

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.

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<tr>
<th>Time</th>
<th>Presentation Title</th>
<th>Poster Presenter</th>
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<tr>
<td>09:30</td>
<td>Developing a Method to Learn Capper Settings to Handle Component Variations</td>
<td>Carolina Gonzalez Gaitan PhD, Parenteral Packaging Scientist, Genesis Packaging Technologies</td>
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<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>
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<td>09:30</td>
<td>Transforming Deviation Management for Expedited Closure and Product Release in Cell and Gene Therapy</td>
<td>Christian Spiak, Principal Consultant, Human Performance Business Area, CAI</td>
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<td>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.</td>
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<td>09:30</td>
<td>A Model for a Risk-Based Deviation Investigation Process</td>
<td>Aaron Hubbell, Director, Life Sciences, Barry-Wehmiller Design Group</td>
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<td>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.</td>
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<td>09:30</td>
<td>High Cell Density Cryopreservation for Upstream Process Intensification Using LN2 Vapor Phase Stored Seed Train Intermediates</td>
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<td>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</td>
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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:** **Usha Mehta** MS Regulatory Consultant **MilliporeSigma**

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09:30 – 10:30

**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.**

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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**

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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 do you score a warning letter and the 483 that preceded it?

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

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<td>09:30 – 10:30</td>
<td>Aseptic Transfer of RTU Containers in the Light of the New Annex 1</td>
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<td>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.</td>
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<td><strong>Poster Presenter:</strong> Christian Thieme Sales Director - Americas groninger &amp; co. gmbh</td>
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<td>09:30 – 10:30</td>
<td>Evaluating Your Stopper: Proving Stopper Functionality for Real-World Use Cases Through &lt;USP 382&gt;</td>
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<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 multi-puncture, 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>
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<td><strong>Poster Presenter:</strong> Todd D. Jasinski Senior Specialist, Technical Product Development West Pharmaceutical Services, Inc.</td>
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<tr>
<td>09:30 – 10:30</td>
<td>Isolator/RABS: Risk Minimization Through Correct Glove Management</td>
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<td>- Requirements and challenges (Annex 1) - Glove types/ Selection/ Test methods - FDA study published on &quot; How risky are pinholes&quot; - Possible risks that compromise glove integrity - Necessary activities for good glove management. - Additional literature for self study</td>
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<td><strong>Poster Presenter:</strong> Alex J. Kappani Product Management SKAN AG</td>
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<tr>
<td>09:30 – 10:30</td>
<td>Developing Primary Packaging System for Nanosuspensions: Headspace Design Space Case Study</td>
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<td>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 reassembled 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</td>
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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
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
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
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.

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

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

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

09:30 – 10:30

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
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

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 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 about 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 Ramman 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

Networking Break in the Exhibit Hall

Exhibit Hall A

10:30 – 12:00

C2: Innovations in cGMP Facility Design and Digitization

Room 104A

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 (DMMM) 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.

Presenters: 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 methodologies 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.

Presenters: Patrick Traver AIA US Director Process Architecture Arcadis DPS Group

11:10 – 11:30

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.

Presenters: James P.M. Colley PhD IT Phorum Director BioPhorum

11:30 – 12:00

Q&A

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**

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<td>Accelerating Biopharmaceutical Development Through Data-Driven Strategies, Platforms, and Technology Enablers</td>
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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.**

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<td>A Collaborative Approach to Agile Manufacturing</td>
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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**

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

**Room 102**

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**

**10:50 – 11:10**

**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**

**11:10 – 11:30**

**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**

**11:30 – 12:00**

**Q&A**
10:30 – 12:00

D2: Designing the Products and Processes of Tomorrow
Room 104C
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.

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<td>Next Generation of Platform ATMP-Integrated Manufacturing Operations for Cell Manipulation, Modification, and Expansion</td>
<td>Denyse D. Baker PE, RAC Associate Vice President, External Engagement and Advocacy, Global Quality Compliance Eli Lilly and Company</td>
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<td>11:10 – 11:30</td>
<td>Ensuring the Quality of Manufacturing Processes Through the Concepts of a Strong Quality Maturity Management Program</td>
<td>Denyse D. Baker PE, RAC Associate Vice President, External Engagement and Advocacy, Global Quality Compliance Eli Lilly and Company</td>
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12:00 – 13:30

Poster Presentations in the Exhibit Hall
Exhibit Hall A

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

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<td>Matt Hofacre Senior Director, Technical Services STERIS Corporation</td>
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<td>A Model for a Risk-Based Deviation Investigation Process</td>
<td>Matt Hofacre Senior Director, Technical Services STERIS Corporation</td>
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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

**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

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

12:00 – 13:30

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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

12:00 – 13:30

**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

12:00 – 13:30
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 provide 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

12:00 – 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

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

12:00 – 13:30

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 new Annex 1.

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

12:00 – 13:30

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: Christian Spiak  Principal Consultant, Human Performance Business Area CAI

12:00 – 13:30
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 multiparture.
aplications 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.

12:00 – 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 ADTs / 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 specialty 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
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
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 headscape requirements for nanosuspension products as they need to be well resuspended prior to drug product administration. Thus, the headscape 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

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

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.

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, 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 these 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
Networking Lunch and Tech Talks in the Exhibit Hall
Exhibit Hall A

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 – 14:15
IG01: 503B Compounding

Interest Group Leader: Arie Anahory MS Senior Director, Strategy and Customer Excellence Regulatory Compliance Associates Inc.
Interest Group Leader: David Short Chief Quality Officer QuVa Pharma

13:30 – 14:15
IG03: 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 – 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*

13:30 – 13:37

**Quality Management Systems: Accelerated Pathways for Developing, Scale-up, and Optimization**

Developing, maintaining and optimizing a QMS has significantly shifted in the modern life sciences landscape. A robust QMS must be fit for purpose, operationally agile as well as enable compliance across an organization. A well-defined quality roadmap should be deployed and maintained to ensure the necessary quality business processes are adequately designed, implemented in a timely manner, communicated and well-integrated throughout a company, there must be a clear quality roadmap. This talk will deep dive into the key elements required to develop a robust quality roadmap and how organizations should use this tool to drive and optimize compliance at the enterprise level.

**Presenter:** Mandy Gervasio  
MS  
Vice President, QA & Compliance  
*Comanche Biopharma*

13:37 – 13:44

**Delivering Value Through Quality External Engagement**

Are you looking for ways to directly influence industry, build reputational equity with regulators while delivering inherent value for your patient? If your answer is yes, then QEE is the conduit to promote your company’s external voice within industry. This presentation will illustrate how improving organizational access to information, sharing regulatory intelligence insight, engaging and partnering with regulators and benchmarking within the industry; including active participation in industry trade organizations will deliver that value. Quality External Engagement (QEE), when implemented correctly across the enterprise, also stimulates employee learning, promotes collaboration, and fosters partnerships.

**Presenter:** Cindy Capeloto  
Head of Quality External Engagement  
*Takeda*

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

IG04: 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

IG06: Packaging Science

Interest Group Leader: Anthony A. Perry Regional Director of Quality SCHOTT
Interest Group Leader: Xu Song MS Senior Director AstraZeneca

14:30 – 15:15

IG07: Process Validation

Interest Group Leader: Robert Dream Managing Director HDR Company LLC

14:30 – 15:15

IG08: 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

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 MSc 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, COC's)


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 uses 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

14:30 – 15:15

IG05: Advanced Manufacturing and Applied Process Digitalization

Interest Group Leader: Peter J. Makowensyj MEM Director of Design Consulting G-CON

15:00 – 16:00

Networking Break and Tech Talks in the Exhibit Hall
Exhibit Hall A

15:00 – 16:00

Poster Presentations in the Exhibit Hall
Exhibit Hall A

15:00 – 16:00

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.

15:00 – 16:00

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15:00 – 16:00

**Cleaning Considerations for Lipid Nanoparticles**

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

15:00 – 16:00

**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**

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.

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

15:00 – 16:00

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

**Poster Presenter:**
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

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

**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 headscape 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

**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

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*

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15:00 – 16:00

**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*

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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 biocdecontamination 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*

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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*

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15:00 – 16:00

**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 stopper functionality for clinical use cases. In this presentation, we will discuss the challenges and considerations when designing these experiments to ensure they are robust and representative of real-world conditions. We will also share recent findings and innovations in stopper functionality testing that can help in enhancing the reliability of stoppers in clinical settings.
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.

**15:00 – 16:00**

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.

**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

**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**

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).
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

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.

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.

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.
16:00 – 17:30

D3: The Case for Disruption: Challenging the Status Quo to Ensure a Viable Future
Room 104C

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**

**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
Room 104A

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 in the industry – why an integrated approach is paramount for the success of combination products; fostering a culture of continuous learning, improvement, and organizational excellence; and insights into the successful integration of process analytical technology (PAT) tools for enhanced process intensification.

**Moderator: Michele Simone** Director, Corporate Quality Compliance, Risk Management, and Continual Improvement *Bracco*

16:00 – 16:20

**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*

16:20 – 16:40

**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

16:40 – 17:00

**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

17:00 – 17:30

Q&A

16:00 – 17:30

B3: Revolutionizing Manufacturing: Patient Focus, Tech Excellence, and Intensified Processes  
**Room 102**

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

16:00 – 17:30

**A3: Biopharmaceutical Evolution: Stability, Contamination Solutions, and mRNA Triumphs**

**Room 101**

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.
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.

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.

Q&A
*Documentary Deep Dive: Of Medicine and Miracles (Ticket Required)

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 Cusumano

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

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**Wednesday, 27 March**

07:00 – 16:00

Registration Open

Promenade Lobby

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.

Learn More

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

C4: Automation, Innovation, & Robotics for Annex 1 & CCS Compliance
Room 104A

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 Senior Specialist, Commissioning, Qualification & Validation (CQV) AtkinsRealis

09:00 – 09:20

Embracing Innovation to Meet the Requirements of Annex 1

Years awaiting the revision of Annex 1 are thankfully behind us. At times, the anticipation fueled conjecture, concern, confusion, and trepidation. How real were those perceptions? The revision, while not perfect, is a solid foundation to guide our industry into the future. Yes, there are some discrepancies, some inconsistencies, even contradictions. However, the scope of Annex 1 is simple and clear: “to ensure…contamination is prevented in the final product.” Statements throughout support the use of alternate and innovative approaches and technologies to achieve this overarching goal. Yet, noble intent often becomes smothered under prescriptive requirements that may not apply. For too long, true innovation in aseptic filling processes and equipment has trailed other industries, and certainly has not kept pace with the revolutionary advances in the field of drug substance manufacture over the last several decades. Why is this? With both data and case studies, we explore several topics where adoption of innovative alternative approaches will improve patient safety, including: eliminating the “human factor” via closed isolator workcells; improved particle limits, both visual and sub-visual, for ocular injectable drugs; and understanding theoretical vs. actual “first air” behavior in protecting drug product.

Presenter: Brent Lieffers General Manager, Aseptic Filling Cytiva

09:20 – 09:40

Robotics and Automation: Enabling Higher Quality and Annex 1 CCS Compliance

The recently released EU GMP Annex 1 mentions, within the second section, the use of robotics to “increase the protection of the product from extraneous sources.” This section, and others within the Annex 1, are demanding the reduction or elimination of human intervention within the ISO 5 environment. The goal is to drastically increase product and, ultimately, patient safety. This session will take a closer look at the house of Contamination Control Strategy and how the usage of Automation and Robotics can support a strong CCS. The presentation will review how we currently apply robotics in the pharmaceutical environment based on executed applications within aseptic environments. Furthermore, we will go into detail about how to completely remove an operator from the aseptic environment.

Presenter: Julian Petersen Head of Business Development groninger & co. gmbh

09:40 – 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 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

09:00 – 10:30

Room 101

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 Blaszczynski 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
## Agenda

### 2024 PDA Annual Meeting

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<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>09:40 – 10:00</td>
<td>What New Therapeutic Modality CMC Challenges Tell Us About Facility Design</td>
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<td><strong>Presenter:</strong> Jeff Odum CPIP Practice Lead, ATMPs &amp; Biologics <em>Genesis AEC</em></td>
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<td><strong>Co-Presenter:</strong> Paul Fleming Project Manager <em>Genentech</em></td>
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<tr>
<td>10:00 – 10:30</td>
<td>Q&amp;A</td>
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<td>09:00 – 10:30</td>
<td>D4: What is PDA Working On?</td>
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<td><strong>Room 104C</strong></td>
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<td>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.</td>
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<td><strong>Moderator:</strong> Josh Eaton MS Senior Director, Scientific and Regulatory Affairs <em>PDA</em></td>
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<tr>
<td>09:00 – 09:20</td>
<td>PDA AB Overview and Updates: What are They, How Do They Work, and On What are They Focused?</td>
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<td><strong>Presenter:</strong> Andrew C. Chang PhD VP, Quality and Regulatory Compliance <em>Novo Nordisk, Inc.</em></td>
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<tr>
<td>09:20 – 09:30</td>
<td>PDA IG Overview and Updates: What They Are, What Makes a Successful IG Meeting, and How You Can Get Involved</td>
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<td><strong>Presenter:</strong> Amanda McFarland MS Senior Consultant <em>ValSource, Inc.</em></td>
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<tr>
<td>09:30 – 09:50</td>
<td>PDA Training and Education Overview: What PDA is Doing in This Space, Future Plans, and How You Can Get Involved</td>
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<td><strong>Presenter:</strong> David B. Talmage MBA Vice President, Education <em>PDA</em></td>
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<tr>
<td>09:50 – 10:00</td>
<td>PDA Chapters Overview: The Who, What, Why, and How to Get Involved in One of the 24 Chapters</td>
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<td><strong>Presenter:</strong> Trevor Swan Senior Director, Membership and Chapters <em>PDA</em></td>
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<tr>
<td>10:00 – 10:30</td>
<td>Q&amp;A</td>
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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 as 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, KPIS 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

### 09:00 – 10:30

**B4: Navigating AI, Data Integrity, and Regulatory Challenges**

**Room 102**

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 as the critical role of contract manufacturing organizations (CMOs) will also be discussed.

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

### 10:00 – 10:30

**Q&A**
10:30 – 11:30

Poster Presentations in the Exhibit Hall
Exhibit Hall A

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 be avoided, 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

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

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

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.*

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<tr>
<td><strong>Aseptic Transfer of RTU Containers in the Light of the New Annex 1</strong></td>
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<td>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.</td>
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<td><strong>Poster Presenter:</strong> Christian Thieme Sales Director - Americas <em>groninger &amp; co gmbh</em></td>
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<td><strong>High Cell Density Cryopreservation for Upstream Process Intensification Using LN2 Vapor Phase Stored Seed Train Intermediates</strong></td>
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<td>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.</td>
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<td><strong>Poster Presenter:</strong> Ushma Mehta MS Regulatory Consultant <em>MilliporeSigma</em></td>
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<tr>
<td><strong>Data Analysis ~ Trending and Pattern Recognition for Contamination Control</strong></td>
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<td>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 lightning talk as well</td>
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<td><strong>Poster Presenter:</strong> Susan B. Cleary EMBA Director of Product Development <em>Novatek International</em></td>
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<tr>
<td><strong>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</strong></td>
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<td>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.</td>
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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 glove management

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

10:30 – 11:30

**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

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

**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

**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

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<th>Time</th>
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<td>10:30 – 11:30</td>
<td>Developing Primary Packaging System for Nanosuspensions: Headspace Design Space Case Study</td>
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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

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<td>Centralized Vaporized Phase Hydrogen Peroxide (VH2O2) as Building Utility</td>
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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 biocide contamination method in an ATMP facility. A case study will be presented that outlines: • VH2O2 properties and its use as a biocide contamination 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

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<td>Quality Culture: From Buzzword to What Works</td>
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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

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<td>10:30 – 11:30</td>
<td>The Challenges of Testing Bacterial Spores in Disinfectant Coupon Studies to Meet CCS Compliance</td>
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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

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 Ramam 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

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

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

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*

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*

Networking Break and Tech Talks in the Exhibit Hall

Exhibit Hall A

11:30 – 12:15

IG09: Annex 1 Implementation and Sterile Processing/Parenteral Drug Manufacturing

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

**Interest Group Leader: Julian Petersen** Head of Business Development *groninger & co. gmbh*

11:30 – 12:15

IG11: Management of Outsourced Operations

**Interest Group Leader: Maria Amaya PhD** Lead External Advocacy North America (Quality Policy) *Genentech*

**Interest Group Leader: Morten Munk** Director, Global Alliance Management *FUJIFILM Diosynth Biotechnologies*

11:30 – 12:15

IG12: Microbiology/Environmental Monitoring

**Interest Group Leader: Kurt Jaecques MA** Global Aseptic Technologies Lead Monitoring & Control *GSK*
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
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

<table>
<thead>
<tr>
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<tr>
<td>Data Analysis ~ Trending and Pattern Recognition for Contamination Control</td>
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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

<table>
<thead>
<tr>
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<tr>
<td>Developing Primary Packaging System for Nanosuspensions: Headspace Design Space Case Study</td>
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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 headsapce 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

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<td>Developing a Risk Score for Critical Suppliers Using Artificial Intelligence (AI)</td>
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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

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<td>A Model for a Risk-Based Deviation Investigation Process</td>
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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**

**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**

**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**

**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

**12:15 – 13:45**
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.

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<thead>
<tr>
<th>Time</th>
<th>Presentation Title</th>
<th>Poster Presenter</th>
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<tr>
<td>12:15 – 13:45</td>
<td>Using Toxicological Risk Assessment to Minimize Cross-Contamination</td>
<td>Wendy Haines PhD, DABT, ASQ CQA, PharmEng Technology</td>
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<tr>
<td>12:15 – 13:45</td>
<td>Aseptic Transfer of RTU Containers in the Light of the New Annex 1</td>
<td>Christian Thieme, groening &amp; co. gmbh</td>
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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

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

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*

12:15 – 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*

12:15 – 13:45

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*

12:15 – 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

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12:15 – 13:45

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

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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.

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12:15 – 13:45

Implementing a Disinfectant Program for Advanced Therapy Medicinal Product Manufacturing

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**Poster Presenter:** Dan A. Klein MA  Senior Manager, Technical Services  STERIS Corporation
P3: A Legacy-Driven Mindset: Our Responsibility for Sustainability
Grand Ballroom

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 Underswell’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 Director - Americas  SGD Pharma Packaging

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.
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