October 11th, 2018 - Validation Day Symposium

Marriot, Irvine, CA - Speaker List and Abstracts

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Tim Culbreth

President US Operations for the PolyPeptide Group.

The PolyPeptide Group is the second largest CMO producer of GMP Peptides. The group produces generic peptides and contract peptides for Clinical and Commercial uses. The US Organization with sites in Torrance and San Diego has seen strong positive growth over the last five years. The US Organization has expanded into production for Oligonucleotides and Personalized Neo-antigens for Immuno-Therapy.

Tim has over 32 years of pharmaceutical production experience with Merck, Roche, Johnson & Johnson and the PolyPeptide Group. Tim has held Site and Global positions in Production, QA, QC, Engineering and Compliance. Over his career Tim has visited and toured over 100 pharmaceutical manufacturing facilities around the world.

Tim has been an ISPE member for over 20 years and was a past member of the GMP Guides Steering Committee. Tim has been a member of ASQ for many years and has previously held CQIT, CQA and other ASQ Certifications. Tim has participated in several critical site process improvement initiatives at multiple companies including the Roche Carolina Site which received the Baldrige Performance Silver Award for Quality Excellence and the South Carolina's Manufacturer of the Year Award. Tim holds a Lean 6-Sigma Green Belt issued by Accenture/Roche for "Improvements in the Tech Transfer Process" as well as receiving the Roche President's Award for Excellence for Enhancements in GMP Training.

Presentation Title: Process Validation Concepts Related to Individualized Therapies

The concept of Process Validation has undergone some significant advances and modifications over the years. Originally, many companies were using a Process Control/Capability Retrospective Approach to Process Validation. This approach was challenged and modified with the push from the FDA (Mid-Atlantic Division Guideline and later general guideline) on Prospective Validation and the "Three Batch" Approach. There were also some elements adopted from the Barr decisions regarding acceptable or not acceptable failure rates. More recently the aspects of PPQ and Continuous Process Performance have come to be regarded as the acceptable standard.

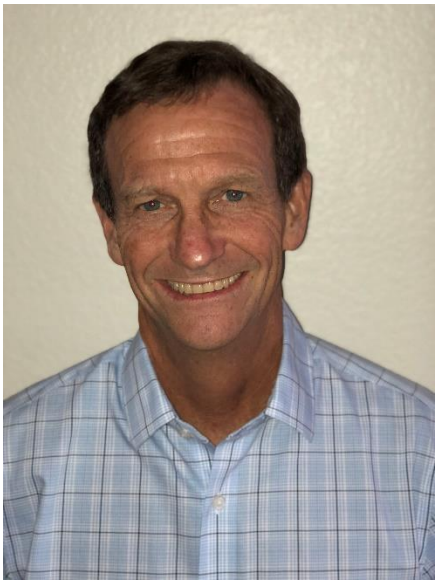
In the treatment and technology area significant advances in diagnostic tools, sequencing, rapid analysis and rapid production have occurred. This has made concepts such as gene therapy for genetic disorders; individualized drug treatments for cancers; and other approaches where the patient's own body is used for therapy possible and increasingly more commonplace.

But how do you validate a Product that is made from an individual's cells? How do you validate a specific drug therapy that is only ever made once in milligram quantities? How do you validate the intersection of drugs, diagnostics, and completely individualized therapies?

This will be discussed today. Clearly all of the answers are not in. The science has outpaced the regulation and it is up to strong groups and forums such as this to play a crucial role in defining expectations.

Joe Page, Ph. D.

President, Eurofins Advantar Laboratories Inc.



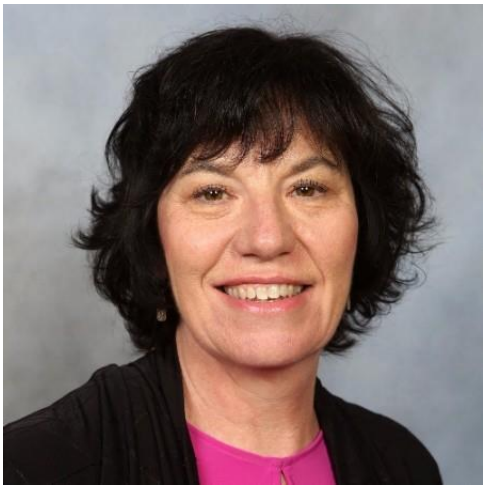
Joe is a pharmaceutical development scientist with 25 years of experience leading Formulation, Development, and Quality Control Groups in advancing clinical drugs to commercialization. Joe has worked for both pharmaceutical (Hybritech, Alliance) and CRO organizations (Magellan, Cardinal Health, Catalent, Eurofins) and has helped both with successful product launches. Joe received his Ph. D. in Chemistry from the University of Washington, Seattle.

Presentation Title: HPLC Method Validations: Navigating the Pitfalls

This presentation will walk through the method validation parameters as defined in the ICH Guidance Document, "Validation of Analytical Procedures: Text and Methodology", Q2(R1). Starting with the validation protocol, we will navigate our way through the potential landmines presented by: accuracy, precision, specificity, LOQ/LOD, and linearity. This talk will alert you to common pitfalls that have derailed previous method validations. The goal of this presentation is to expose the listener to past validation challenges, so they may be better prepared to circumnavigate the traps hidden among the validation parameters.

Tara Scherder

Co-Founder & Managing Partner, SynoloStats



Tara has over 25 years of experience in the chemical and pharmaceutical industries as a statistician, process engineer, and master black belt. She has functioned as both an in-house and external statistical consultant to drug substance and drug product teams across the product lifecycle for the spectrum of product platforms. She frequently speaks at industry forums and publishes on the practical incorporation of statistical methods for Lifecycle Process Validation.

Tara earned a BS degree in Chemical Engineering from the University of Pittsburgh and a MS degree in Statistics from Carnegie Mellon University. As partner at SynoloStats, she passionately shares the opportunity for patient and business benefit through the powerful combination of statistics and process.

Presentation Title: The Goldilocks of Statistics for Process Validation

There is no doubt that the increase in data-based evidence and statistical evaluation that has resulted from implementation of recent validation guidance's can have significant benefit to both patient and business. However, we also know that too little or too much has negative consequences. How can you find the right balance of sampling and analysis? In this talk you will learn how to combine the required elements of fundamental tenets of both statistics and lean thinking. This approach not only assures that sampling and analysis is not wasteful; it also provides adequate risk management. Multiple examples will be presented to illustrate the approach, and the resulting benefit to both patient and business.

Sunil Patel

Senior Global Technical Manager, EcoLab Life Sciences

Sunil has over 12 years of experience working in the engineering and validation fields of cGMP / FDA / EU / ISO regulated industry sectors. Sunil has a strong background in Cleaning Validation (CIP, COP, Manual), Process Validation, Process Design, Clean Utilities (WFI, PW, Clean Steam, Clean Air, Clean Gases), HVAC, Project Management, Sterilization and Processing Equipment Validation. Sunil joined Ecolab in April'2018 and is currently a Senior Global Technical Manager for Ecolab Life Sciences. In this role Sunil provides support and guidance around CIP/COP/Manual cleaning validation practices in a GMP manufacturing operations.

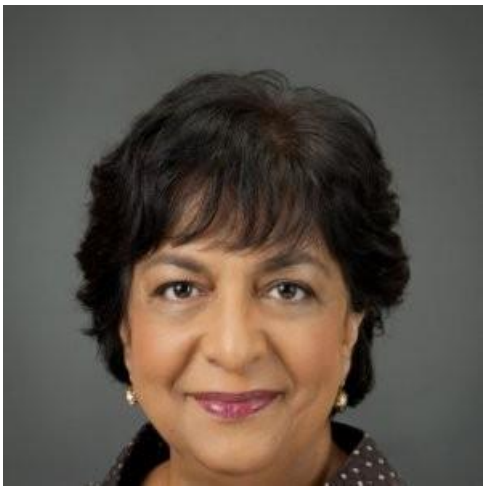
Presentation Title: Cleaning Process Validation Life Cycle for Pharmaceutical Industry

Presentation will focus on the following topics to provide a complete understand of cleaning validation from pain points to continuous improvement and examples of 483 violations.

- FDA 2011 Process Validation Principles
- Industry Pain Points
- Stage 1 Cleaning Process Design and Development
- Stage 2 Cleaning Process Performance Qualification
- Stage 3 Continuous Process Verification
- FDA 483s Stats for last three years specific to cleaning validation area

Ziva Abraham

President & Founder, Microrite, Inc.



Ziva has over 25 years of academic, research, clinical and industrial experience in microbiology, and quality assurance. Ziva has received her Masters Degree in microbiology with a focus on Mycology and has conducted research on developing microbial Insecticides using entomogenous bacteria and fungi for her PhD degree. Her career also includes founding and managing clinical laboratories for Maccabi Medical in Israel. She has trained personnel from various industries in microbiology techniques and methods. She uses her extensive experience to teach why assessing risk of microbial contamination should be in the forefront of any company that has products for human/veterinary use. Her experience in clinical laboratories has provided her with the framework to understand the effects of microbial contamination in products from a patient safety perspective.

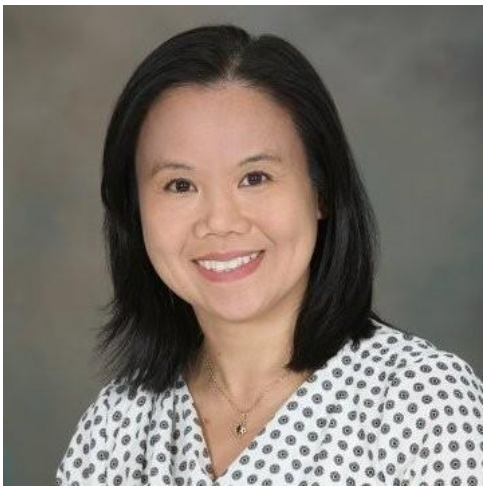
Presentation Title: Why Disinfectant Qualification Studies Fail?

Disinfectant qualification studies are subjective; there are varieties of errors which can occur in the planning and execution stages. Additionally, lack of understanding of the chemical efficacy and material compatibility can add roadblocks to the study. Recovery and method validation is critical to a successful disinfectant qualification study, if these fail, the study is bound to fail. Most of the errors occur during recovery as hard surfaces pose a problem during this phase, leading to variability. Learn from case studies related numerous failed studies and learn how to develop and execute a successful disinfectant qualification.

- Planning stage errors leading to failed disinfectant qualification study
- Learn about the pros and cons of various recovery methods, and which will be most variable
- Common laboratory errors that will lead to a failed study
- Errors made in enumeration, leading to low log reduction
- Common mistakes in developing method validation
- Common gaps in data review
- Consequences of applying a failed study data to the facility's cleaning and disinfection program

Diane Vu

Sr. Manager, Quality Program Management, Medtronic



Diane has a strong working knowledge of terminal sterilization processes: ISO 14160 Liquid chemical, ISO 11137-1 for Radiation, ISO 17665-1 for Moist Heat Sterilization, and ISO 11135-1 for Ethylene Oxide. She has directed cleanroom design and qualification: ISO 14644 series and ISO 14698 series and has cleaning validation expertise for medical device manufacturing cleanrooms. Diane also has experience with Quality System Regulation 21CFR820 and ISO 13485: Medical Devices- Quality Management System. She has supervised CAPA teams to resolve compliance and quality issues related to audit findings or remediation projects using DMAIC process. She has also directed the maintenance of environmental monitoring programs for cleanrooms, laboratory testing results, and sterility assurance and participated in internal and external audits (FDA, MHLW, ANSM, BSI, TGA, and TUV). Diane has a Bachelor of Science in Microbiology from California State University, Long Beach and MBA from Brandman University.

Presentation Title: Case Study- Cleaning Validation for Medical Device

Case study will focus on the following topics to provide a complete understanding of cleaning validation for Medical Device from ISO 14698-1 and -2 to Disinfectant & Cleaning Methods.

ISO 14698-1 and -2:

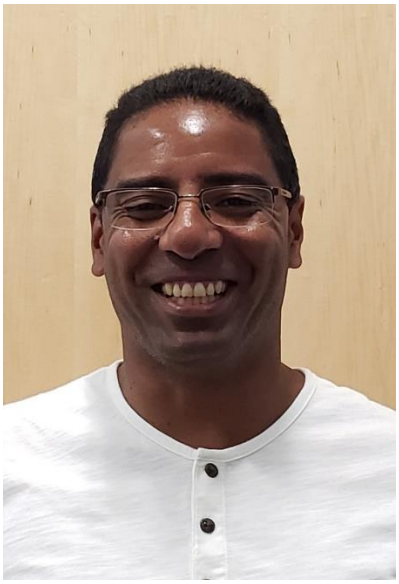
- Risk evaluation for biocontamination control
- Evaluation of product risk and current microbial control with environment
- Cleaning requirement based on risk evaluation (product and product contacting surfaces)

Disinfectant and Cleaning Method:

- Application of disinfectant data – log reduction based on vendor technical datasheet.
- Qualification – in vitro and in situ testing
- Effectiveness of cleaning program – based on routine data (general example of how routine data trending will demonstrate effectiveness of program).

Laurent Saugrin

Sr. Computer Validation Specialist IV at Dexcom



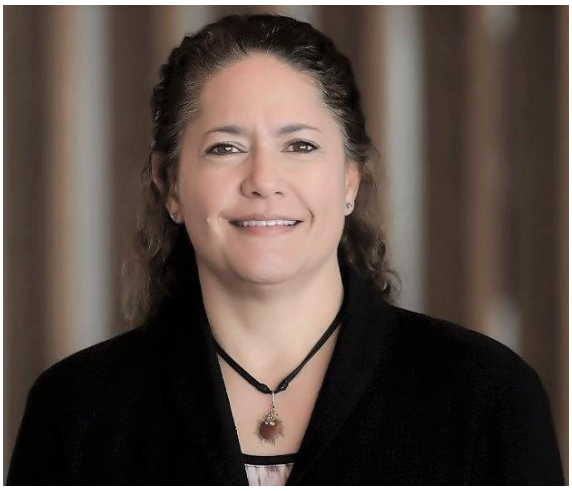
Laurent Saugrin is a Sr. Computer Validation Specialist IV at DEXCOM Inc for the past 2 years. Prior to and for over 16 years, Laurent has been provided consulting services to his clients in the field of Computer Systems Validation (CSV). In his role at DEXCOM, Laurent manages the timeline, resources and tasks for the IT Compliance team responsible for the computer system validation activities of all GxP enterprise systems. During the past two years, Laurent has also been a regular speaker at IVT Conferences on topics related to CSV.

Presentation title: Computer System Validation

This presentation introduces the process of selecting a suitable cloud provider. It also discusses the different procedures (or other supporting documentation) that must be in place to define responsibilities and commitments between the service provider and the client. Finally, the presentation will briefly go over the applicable validation activities necessary to ensure that your GxP data is secured and that the cloud hosted application is successfully qualified and in a validated state for the entire duration of its life cycle. Whether you look for a Software as a Service (SaaS), a Platform as a Service (PaaS) and/or an Infrastructure as a Service (IaaS) provider, the process of selection shall be very similar. Because SaaS is being the most commonly offered service, the presentation will focus on it.

Lisa Garcia Lawson

Global Pharma GMP Advisor, Life Science Division, Particle Measuring Systems



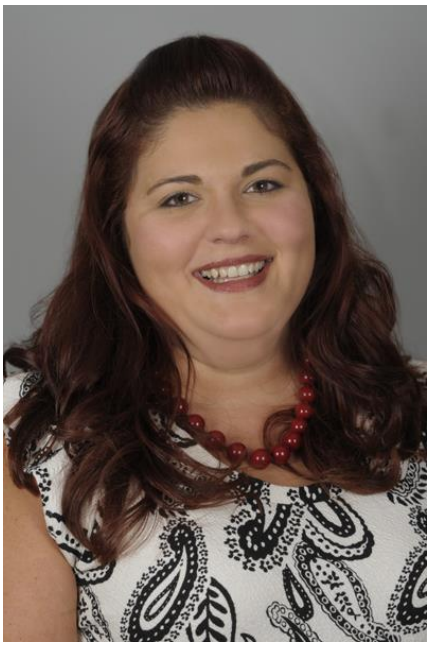
Lisa earned her BS and MS in Microbiology from Colorado State University. She has over 25 years' experience in pharmaceutical manufacturing support, microbiology, sterility assurance, compliance and validation primarily with Amgen where she worked in microbial and mammalian cell culture manufacturing support and worked to validate the EPO manufacturing facility in Longmont, CO. She saw this project through to FDA and international regulatory approval and commercial manufacturing, supported new product introductions and expansion into international markets during her career at Amgen. She has worked with large and small molecules, supported API production, vial and syringe filling, aseptic processing and Quality Management System (QMS) implementation.

Presentation Title: Risk Management Tools for Validation

- Introduction to Quality Risk Management (QRM)
- Understand steps involved
- Application of QRM to Process Validation (PV)
- Introduction to FMEA (Failure Modes and Effects Analysis) as a tool for conducting a Risk Assessment
- Review of case study for use of an FMEA approach for evaluation of a typical biotech production process validation

Simona Mills

Senior Manager, Propharma Group



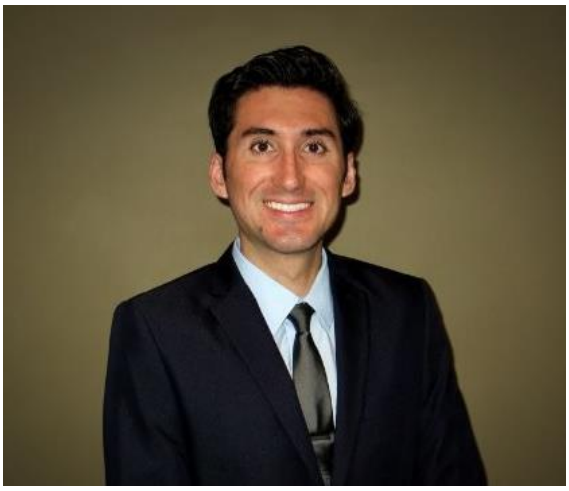
Simona Mills studied Chemical Engineering at The Ohio State University. She has more than 16 years of industry experience in pharmaceuticals and biologics. Simona previously worked for a CMO for 11 years and has recently moved into consulting. Her expertise is in Quality (Validation, Quality Engineering, and Regulatory Affairs) and Project Management, with additional experience in facility construction/start-up, remediation, and technical transfers. Most recently, Simona joined ProPharma Group as the Senior Manager of the Product Lifecycle Management department. She earned her PMP certification in 2015 and has worked on a variety of projects including Tech Transfer, Compliance, PAI Readiness, 505(b)(2) commercialization, etc.

Presentation Title*: Aging Facilities and Equipment: Teaching Old Dogs New Tricks*

Lessons learned from various remediation projects that included aging facilities and aging equipment. This presentation outlines hurdles encountered, real examples of upgrades needed and the compliance behind it, as well as examples of how a costly and large-scale project can be limited in scale, if not even prevented. The aging process is inevitable, as we all know, and that is as true for a pharmaceutical facility and its equipment as it is for people, dogs, etc. But an aging entity is not an obsolete one. Perhaps, from this discussion, you can learn for the miscalculations of others and you too can implement preventative measures to keep that “old dog” learning new tricks

Javier Cardenas

Senior Consultant, Azzur Group



Javier Cardenas, Ph.D. is a Senior Consultant for the Healthcare and Life Sciences consulting firm Azzur Group. During his tenure at the firm, Javier has managed multiple projects including process validation of sterile injectables, as well as supporting new product development in the medical device space. Before joining Azzur, Javier received his doctorate in Chemical and Biochemical Engineering from the University of California – Irvine where he researched metabolic engineering approaches in Baker's Yeast (*Saccharomyces cerevisiae*) for the production of biorenewable chemicals.

Presentation Title: Process Validation

This presentation will discuss Process Validation (PV) principles in the context of the validation lifecycle, with insights from the regulatory bodies. We will cover the three stages to Process Validation as defined by the 2011 FDA Guidance for Industry: *Process Design*, *Process Qualification*, and *Continued Process Verification*, and their role in process improvement. A review of the differences and similarities between FDA / EU guidelines will help demonstrate what to focus on during process validation activities. Lastly, case studies from warning letters will be used to highlight common shortcomings and pitfalls to be avoided.

WILLIAM HONECK

Vice President of West Coast Operations, VTI Life Sciences, Inc

He has over 25 years of experience in the pharmaceutical, biotechnology, and medical device industries. Prior to joining VTI Mr. Honeck held senior positions within the industry including Associate Director positions within Validation, IT, and QA at Gilead Sciences, Johnson and Johnson, and Scios. He received a BSc Degree in Biochemistry from University of California, Davis. Mr. Honeck has led numerous validation projects while serving in Analytical Development, Quality Control, IT, and Quality Assurance capacities. His expertise includes establishment of Quality Systems and validation project management, development of Validation Master Plans, validation SOPs, risk assessments, gap assessments, audits, and qualification protocols for computerized systems, utilities, equipment, and analytical instruments with a focus on data integrity. In addition, he has served as an SME in numerous Regulatory Agency Inspections.

Presentation title: Preparation for Data Integrity Based Inspections

Part 1 – **Prepare for a Data Integrity Inspection**

- Warning Letter Trends
- Create data flow diagrams to demonstrate understanding of data life cycle and system limitations
- Essential site documentation – Policies, SOPs, assessments, tools and how to use them effectively
- What are auditors' expectations during an inspection?
- Identification and preparation of SMEs for Data Integrity questions

Part 2 – **Manage Investigators during a Data Integrity Inspection**

- Prepare for the instrument/system walk-through by investigators
- Good practices for SMEs when dealing with investigators
- Manage findings, prioritizing and implementing corrective action plans
- Overview of common findings/issues

Interactive Knowledge Exchange

Attendees take part in a discussion on any experiences of Data Integrity based audits/inspections.