Agenda

PDA GMP Comparison Workshop 2024

Please note that there are no posters associated with this event.

Wednesday, 11 September

12:00 – 17:30

Registration Open

16:00 – 17:30

P1: How to Compare Global Sterile Manufacturing Regulations

Join us for an immersive session demonstrating how to leverage PDA's Global Sterile Manufacturing Regulatory Guidance Comparison (2024). Learn practical strategies and approaches for leveraging PDA's comparison tool in achieving regulatory compliance and the potential competitive edge of understanding and addressing regulatory challenges. The expert presenters will reveal the mindset of regulators and share insights into their priorities and concerns, including the limited focus on the global market and the emphasis on local laws and regulations.

Moderator: Joseph C. Frantz, **MS, PhD**, *Consultant*

16:00 – 16:15

Welcome and Opening Remarks from Workshop Chair

Chair: Joseph C. Frantz, **MS, PhD**, *Consultant*

16:15 – 16:35

Seeing the Challenge and Charting the Course

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

16:35 – 16:55

Navigating Regulatory Minds: Strategies and Practices for Compliance

Presenter: Stephen E. Langille, **PhD**, Senior Microbiology Consultant, *ValSource, Inc.*

16:55 – 17:30

Q&A

17:30 – 18:30

Networking Reception in the Exhibit Area

Thursday, 12 September

08:00 – 09:00

Continental Breakfast

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08:00 – 17:00

Registration Open

09:00 – 10:30

P2: Using the Comparison to (Re-)Design a Training Program

A robust training program is critical to ensuring manufacturing staff compliance, however, the design and maintenance of training programs tend to be an afterthought. Gaps in the training of both new and experienced staff include missing references to applicable guidelines, no explanation as to the "why" behind the instruction, and insufficient or lack of training for certain tasks are common. Get an introduction on how to use the comparison document to ensure your training programs are in alignment with Health Authorities and general best practices. Case studies and small group working sessions will illustrate some commonly found gaps in training programs and offer practical experience using the comparison document to identify and remediate them.

Moderator: Christine Sherman, Global Sterility Assurance & Microbiology, *Takeda*

09:00 – 09:20

Building a Solid Foundation by Optimizing Your Training Program

Presenter: Amanda Curtis, Microbiology Consultant, *ValSource, Inc.*

09:20 – 10:05

Designing a Compliant Aseptic Process Simulation (APS): Small Group Work

Presenter: Amanda Curtis, Microbiology Consultant, *ValSource, Inc.*

10:05 – 10:30

Report Out and Discussion

10:30 – 11:00

Networking Break in the Exhibit Area

11:00 – 12:30

P3: Significant Misalignment of Sterile Manufacturing Guidances

The Global Sterile Manufacturing Regulatory Guidance Comparison analyzes seven international sterile manufacturing guidances. Although many requirements and expectations are aligned across these documents, there are differences that exist. In some cases, these differences are vernacular or theoretical, while others are significant. And to make it more challenging, some health authorities require additional measures that are not a part of other sterile manufacturing guidelines. In this session, we will identify and discuss significant misalignments of the seven sterile manufacturing guidances. We also provide an opportunity for industry peers to discuss mitigation strategies and communication approaches for regulatory documents and inspections.

Moderator: Amanda Curtis, Microbiology Consultant, *ValSource, Inc.*

11:00 – 11:15

Understanding the Differences of Sterile Manufacturing Guidance for Personnel, Training, and Qualification

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Presenter: Nidhi Shah, **MBA**, Senior Director, Value Stream CAR-T Manufacturing Operations, *Bristol Myers Squibb*

11:15 – 11:30

Manufacturing Facilities and Equipment: The Old, the New, and the Challenging

Presenter: Brian L. Bell, **PhD**, Senior Director Cellular Sciences, *Amgen Inc.*

11:30 – 12:15

Hands-On Exercise Addressing Challenges in Implementing International Sterile Guidance

Presenter: Brian L. Bell, **PhD**, Senior Director Cellular Sciences, *Amgen Inc.*

Presenter: Nidhi Shah, **MBA**, Senior Director, Value Stream CAR-T Manufacturing Operations, *Bristol Myers Squibb*

12:15 – 12:30

Report Out and Discussion

12:30 – 13:30

Networking Lunch in the Exhibit Area

13:30 – 15:00

P4: Effective Strategies for Comprehensive Gap Assessments

Do you dread the task of completing a gap assessment against a regulatory document or internal Standard Operating Procedure? You're not alone! Many of us have faced the overwhelming challenge of this assignment. Join this session to learn how to conduct a comprehensive gap assessment for your facilities without feeling like you'd rather be at the dentist. Through hands-on exercises, we'll explore the essential components of effective gap assessments and what they should not entail.

Moderator: Brian L. Bell, **PhD**, Senior Director Cellular Sciences, *Amgen Inc.*

13:30 – 13:40

Congratulations! You Have Volunteered to Complete a Gap Assessment

Presenter: Christine Sherman, Global Sterility Assurance & Microbiology, *Takeda*

13:40 – 14:40

Finding the Gaps: Hands-On Strategies

Presenter: Christine Sherman, Global Sterility Assurance & Microbiology, *Takeda*

14:40 – 15:00

Report Out and Discussion

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15:00 – 15:30

Networking Break in the Exhibit Area

15:30 – 17:00

P5: The Impact of Quality Management Systems on Business Operations

A comprehensive quality management system holds significant potential to harmonize business operations with regulatory requirements, leading to efficient solutions that enhance overall quality in a cost-effective manner. In this session, a case study will serve as a practical example showcasing an effective approach. Engage in role-playing exercises that simulate the process of presenting these strategies to senior management for approval. Don't miss the opportunity to gain actionable insights to apply in your own professional settings!

Moderator: Nidhi Shah, **MBA**, Senior Director, Value Stream CAR-T Manufacturing Operations, *Bristol Myers Squibb*

15:40 – 16:30

Creating a Simplified Value Stream Map: Small Group Work

Presenter: Joseph C. Frantz, **MS, PhD**, *Consultant*

16:30 – 16:55

Group Discussion: How to Have Effective Communication with Senior Management

16:55 – 17:00

Closing Remarks from Workshop Chair

Chair: Joseph C. Frantz, **MS, PhD**, *Consultant*