Agenda

PDA Alternative Microbiological Methods Workshop 2024

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

Wednesday, 9 October

12:00 – 17:30

Registration Open

14:00 – 15:30

P1: Evolution of Alternative Microbiological Methods and Regulatory Insights

Dive into the past twenty-year evolution of alternative microbiological methods and regulatory insights. Explore the change drivers, including modalities and the critical time to result for short-shelf-life release testing, shaping current industry needs. Discuss emerging next-generation scientific technologies and the key enablers facilitating the adoption of alternative methods. The second half of the plenary is focused on a comprehensive understanding of the regulatory advancements and their impact on alternative methods in the pharmaceutical, compounding, and biologics products domain. Current and former health authority regulators will share invaluable insights, including initial observations, concerns, current perspectives, and adaptations of alternative methods.

Moderator: Marc Glogovsky, **MS**, Business Unit Manager - Microbiology, *ValSource, Inc.*

14:00 – 14:15

Welcome and Opening Remarks from Workshop Chair

Chair: Marc Glogovsky, **MS**, Business Unit Manager - Microbiology, *ValSource, Inc.*

14:15 – 14:40

Current Industry and Regulatory Drivers for Alternative and Rapid Microbiological Methods

Presenter: Michael J. Miller, **PhD**, President, *Microbiology Consultants, LLC*

14:40 – 15:05

Alternative Microbial Methods: Perspectives from Both Sides

Presenter: Andrew D. Hopkins, **BSc Hons PGDip**, Director, Operation Quality QA Audit and Compliance, *AbbVie Inc.*

15:05 – 15:30

Q&A

15:30 – 16:00

Networking Break in the Exhibit Area

16:00 – 17:30

P2: Real-Life Challenges to Implementing AMM

During this session, we'll explore the historical and present challenges associated with various Alternative Microbiological Methods (AMM) technologies. We'll highlight key considerations necessary for successful implementation of a specific AMM. Additionally, participants will engage in a case study exercise to identify

regulatory risks, technology hurdles, and potential costs involved in the process.

Moderator: Christopher A. Murdock, PhD, CQA, VP, Sterility Assurance and Microbiology Support, *Eli Lilly and Company*

16:00 – 16:15

Overview and Introduction: Adopting AMMs is Easy, Right?

Presenter: Kevin I. Wright, PhD, Director, Corporate Quality Assurance - Industrial Microbiology, *Procter & Gamble*

16:15 – 17:00

Simulating the Company Experience of AMMs: Small Working Groups Challenge

Presenter: Kevin I. Wright, PhD, Director, Corporate Quality Assurance - Industrial Microbiology, *Procter & Gamble*

17:00 – 17:30

Report Out and Discussion

17:30 – 18:30

Networking Reception in the Exhibit Area

Thursday, 10 October

08:00 – 09:00

Continental Breakfast

08:00 – 16:45

Registration Open

09:00 – 10:30

P3: Regulatory Expectations on Alternative Microbiological Methods

Hear U.S. FDA's perspective on alternative microbiological techniques proposed for compounded and short shelf-life biologic products. FDA representatives will share the necessary supporting controls, investigations, and validation data required for these alternative methods. Gain additional insights into the complexities of conducting sterility testing for cell-based biologic products and patient safety during the interactive case study discussion.

Moderator: Erin A. Wall, PhD, Senior Pharmaceutical Quality Assessor, OPQ, CDER, *U.S. FDA*

09:00 – 09:20

Alternative Sterility Test Methods for Compounded Products: Points to Consider

Presenter: Ian F. Deveau, PhD, Division Director, OC, CDER, *U.S. FDA*

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09:20 – 09:30

Q&A with Ian Deveau

09:30 – 10:10

Interactive Case Study: Short Shelf-life Cell and Gene Products: Assessing Alternatives and Ensuring Patient Safety

Presenter: Elizabeth Lessey-Morillon, **PhD**, Senior Biologist, OTP, CBER, *U.S. FDA*

10:10 – 10:30

Report Out and Discssion

10:30 – 11:00

Networking Break in the Exhibit Area

11:00 – 12:30

P4: Releasing the Power of Alternative Microbiological Methods

Rapid alternative microbiology methods offer benefits for the timely quality release of the finished product, but one method may not be sufficient to replace the traditional method and fully comply with release specifications. Using examples and a case study, this session provides context for the use of alternative methods in sterile and hygienic manufacturing by employing a data-based approach from a finished product release focus to ensure measured process reliability and risk-managed release.

Moderator: Kevin I. Wright, **PhD**, Director, Corporate Quality Assurance - Industrial Microbiology, *Procter & Gamble*

11:00 – 11:10

Introduction: Progressing to AMM Use in Quality Manufacturing Versus Quality Release

Presenter: Kevin I. Wright, **PhD**, Director, Corporate Quality Assurance - Industrial Microbiology, *Procter & Gamble*

11:10 – 11:35

Integration of Rapid Bioburden Testing into Production Quality Management Systems and Process Control

Presenter: Irina Ramos, **PhD**, Director of Bioprocess Technology and Engineering, *AstraZeneca*

11:35 – 12:15

Designing a Risk Strategy Using the Current Regulations to Replace Traditional Methods

Presenter: Terra Kremer, Director of Microbiological Quality, *Johnson & Johnson*

12:15 – 12:30

A Future of MQL and Managing Risk Release

Presenter: John Logar, Director, Radiation Sterilization, *Johnson & Johnson*

12:30 – 13:30

Networking Lunch

13:30 – 15:00

P5: From Cultures to Code: Alternative Microbiology at the Molecular Level

In this session, gain familiarity with the current landscape of available DNA-based products and systems, what to consider when choosing a product or system, the process for implementation including risks and benefits, and the featured applications. Alternative, rapid, and growth-based technologies can be used to support the release of cell and gene therapies in seven days compared to the 14-day compendial sterility test. This accelerated timing still poses challenges to products with the life-saving requirement for immediate administration. Many challenges cannot be foreseen by vendors of molecular kits and technologies. The promising lure of molecular methods and their unique challenges will be discussed and collaboratively debated in an interactive case study.

Moderator: Olivia Venhuizen, **PhD**, Process Development Principal Scientist, *Amgen Inc.*

13:30 – 13:50

Detecting DNA: Past, Present, and Future

Presenter: Cliff Hogan, **PhD**, Environmental Monitoring Manager, *FUJIFILM Cellular Dynamics*

Presenter: Amy L. McDaniel, **PhD**, Director, Microbial Center of Excellence & Operations, *Bristol Myers Squibb*

13:50 – 14:15

Implementing Molecular Methods Part 1: Mycoplasma Testing

Presenter: Cliff Hogan, **PhD**, Environmental Monitoring Manager, *FUJIFILM Cellular Dynamics*

Presenter: Amy L. McDaniel, **PhD**, Director, Microbial Center of Excellence & Operations, *Bristol Myers Squibb*

14:15 – 14:25

Report Out and Discussion: Part 1

14:25 – 14:50

Implementing Molecular Methods Part 2: Sterility Testing

Presenter: Cliff Hogan, **PhD**, Environmental Monitoring Manager, *FUJIFILM Cellular Dynamics*

Presenter: Amy L. McDaniel, **PhD**, Director, Microbial Center of Excellence & Operations, *Bristol Myers Squibb*

14:50 – 15:00

Report Out and Discussion: Part 2

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15:00 – 15:30

Networking Break in the Exhibit Area

15:30 – 17:00

P6: Future Directions for Alternative Microbiological Methods

Microbiology laboratories often rely on traditional methods, which can limit efficient contamination control. This session delves into the current state and future potential of rapid alternative microbiology methods (AMM), examining their benefits and the challenges that may hinder their widespread adoption. By understanding these challenges, we can develop strategies to address them and unlock the full potential of rapid AMM. These advanced technologies promise to significantly reduce errors associated with manual processes, thereby enhancing contamination control and product quality. The presentation will also explore the potential role of Artificial Intelligence (AI) in facilitating the adoption and advancement of rapid AMM. AI integration could revolutionize these technologies, making them more accessible and effective. To conclude, we invite you to participate in an open discussion about the future of AMM. Share your thoughts, insights, and ideas on how we can collectively shape the evolution of microbiological methods.

Moderator: Marc Glogovsky, **MS**, Business Unit Manager - Microbiology, *ValSource, Inc.*

15:30 – 15:50

Rapid Alternative Microbiology Methods: Stalled Progress or on the Verge of a Breakthrough?

Presenter: Kumbirai Dhliwayo, **MS**, Founder and Principal Consultant, *Kumby Consulting*

15:50 – 16:45

The Evolution of Alternative Microbiological Methods: Audience Insights

16:30 – 16:55

Report Out and Discussion

16:45 – 17:00

Closing Remarks from Workshop Chair

Moderator: Marc Glogovsky, **MS**, Business Unit Manager - Microbiology, *ValSource, Inc.*