Compounding Quality
Center *of* Excellence

2024 ANNUAL CONFERENCE

**LEARNING AND COLLABORATING:
DRIVING TOWARD THE FUTURE OF QUALITY**

PROGRAM GUIDE

MONDAY, AUGUST 19, 2024

**VIRTUAL
PRE-CONFERENCE**

2:00 PM – 5:00 PM ET

Developing a New Outsourcing Facility: Lessons Learned

VIRTUAL ONLY

Learn from established outsourcing facility leaders about the challenges of forming a new outsourcing facility and keys for success. Perspectives will include a hospital system-owned outsourcing facility, a 503A pharmacy that transitioned to an outsourcing facility, an outsourcing facility developed within a pharmaceutical company, and an outsourcing facility formed as a start-up. A panel discussion will share experiences interacting with newly formed outsourcing facilities.

Joe Bagan
STAQ Pharma
Speaker

Andy Basso
Fagron Sterile Services
Speaker

Travis Leeah
QuVa Pharma
Speaker

Meghan Murphy
FDA
Moderator

A panel discussion will share experiences interacting with newly formed outsourcing facilities.

Eric Kastango
Kastango Solutions
Panelist

Maabo Kludze
Premier, Inc.
Panelist

Meghan Murphy
FDA
Panelist

Jody Staggs
SWK Holdings
Panelist

Tony Widenor
FDA
Moderator

DAY ONE: WEDNESDAY, AUGUST 21, 2024

1:00 PM – 1:15 PM ET

Welcome and Opening Remarks

Gail Bormel
FDA
Speaker

Patrizia Cavazzoni, M.D.
FDA
Speaker

1:15 PM – 2:30 PM ET

Opening Plenary | Learning and Growth: Successes and Challenges of a Developing Industry

Explore the evolution of the outsourcing facility industry, including quality and factors influencing long-term viability.

Pallavi Badkar
MedisourceRx
Panelist

Ken Jozefczyk
BayCare Central Pharmacy
Panelist

Susan Schniepp
Parenteral Drug Association
Speaker

Stuart Hinchen
QuVa Pharma
Panelist

Deb McHugh
Fagron Sterile Services
Moderator

2:30 PM – 3:30 PM ET

The Business Case for Quality and Resilience

Discover perspectives from outsourcing facilities and customers on the benefits of investing in quality and resilience.

Caryn Belisle
Brigham and Women's Hospital
Panelist

Dennis Champagne
Leiters Health
Panelist

Jenna Stern
Vizient
Moderator

Anne Marie Davis
Medi-Fare Drug
Panelist

Kevin Hansen
Premier, Inc.
Panelist

Heather Upchurch
AdventHealth
Panelist

3:30 PM – 3:45 PM ET

Break

Day One Concurrent Sessions (1a–1d)

3:45 PM – 4:45 PM ET

Session 1a | Risk Assessment In Aseptic Processing

Learn risk assessment tools for assessing aseptic processing operations that leverage technologies to increase sterility assurance.

Neda Hamandi
FDA
Moderator

Mike Long
AstraZeneca
Speaker

Session 1b | Investigating Environmental Monitoring Excursions

Analyze an investigation of an environmental monitoring excursion highlighting critical aspects, such as microbiology and risk evaluation of the facility.

Doan-Trang Vuong
FDA
Moderator

Jaime Kaho'ohanohano
Microrite
Speaker

Session 1c | Visual Inspection

Learn the importance of visual inspection and review basic concepts illustrated with case studies.

Mina Ahmadi
FDA
Moderator

John Shabushnig
Insight Pharma Consulting
Speaker

DAY ONE: WEDNESDAY, AUGUST 21, 2024 (continued)

Day One Concurrent Sessions (1a–1d)

3:45 PM – 4:45 PM ET

Session 1d | Testing: Industry Perspectives

Explore the advantages and disadvantages of utilizing internal vs. external testing. Examine processes for handling out-of-specification and out-of-trend results.

Marc Glogovsky
ValSource
Panelist

Lisa McChesney-Harris
Prompt Praxis Labs
Panelist

Phil Smith
Fagron Sterile Services
Panelist

Kim Kieffer
AnazaoHealth
Moderator

Greg Rockers
Belmar Pharma Solutions
Panelist

4:45 PM – 5:00 PM ET

Break

5:00 PM – 6:00 PM ET

Top 483 Observations

IN-PERSON EXCLUSIVE

Learn about observations frequently encountered in FDA inspections of outsourcing facilities.

Sena Dissmeyer
FDA
Speaker

Tony Ladner
FDA
Moderator

DAY TWO: THURSDAY, AUGUST 22, 2024

9:00 AM – 9:15 AM ET

Day 2 Welcome

Meghan Murphy
FDA
Speaker

9:15 AM – 10:15 AM ET

Pediatric Considerations for Outsourcing Facilities

Discover how outsourcing facilities can be well positioned to meet many of the unique needs of children's hospitals. Learn how collaboration can ensure pediatric access, quality and safety.

Melissa Chase
Valley Children's Healthcare & Hospital
Speaker

Emily Reyes
STAQ Pharma
Speaker

Terri Wilson
Children's Hospital Association
Moderator

10:15 AM - 11:15 AM ET

Assessing Quality

Gain exposure to strategies and cases studies for internally assessing quality and the state of control within the framework of section 503B and CGMP.

Stephanie Gaulding
Pharmatech Associates
Panelist

Kim Kieffer
AnazaoHealth
Panelist

David Short
QuVa Pharma
Panelist

Christine Hong
AdventHealth
Panelist

Susan Schniepp
Parenteral Drug Association
Moderator

11:15 AM - 12:45 PM ET

Lunch Break

DAY TWO: THURSDAY, AUGUST 22, 2024 (continued)

Day Two Concurrent Sessions (2a–2d)

12:45 PM – 1:45 PM ET

Session 2a | Reframing Perspectives through CGMP Training

Gain understanding about how the training provided in pharmacy and other industries may not align with CGMP thinking. Learn how to align the thinking across the disciplines.

Eric Kastango
Kastango Solutions
Speaker

Deb McHugh
Fagron Sterile Services
Speaker

Peg Panella-Spangler
Board of Pharmacy,
State of California
Speaker

Session 2b | Data Integrity

Examine the expectation that all data related to drug production is reliable and accurate to ensure the safety, efficacy, and quality of drugs.

Melinda Lee
FDA
Moderator

June Page
FDA
Speaker

Session 2c | Navigating State Laws and Regulations

Learn about variable state laws and regulations. Get updates on the latest potential state requirements and trends as they pertain to outsourcing facilities.

Jay Campbell
Board of Pharmacy, State of North Carolina
Panelist

Betty Jones
National Association of Boards of Pharmacy
Panelist

Gillian Staikos
Florida Department of Health
Panelist

Spencer Malkin
SKNV
Moderator

Barb Knightly
Leiters Health
Panelist

Session 2d | Contamination Control in Operations

Review contamination control practices for aseptic processing. Consider concepts and strategies for cleaning and disinfection of classified areas, disinfectant efficacy testing, commodity and component packaging, material transfer, and residue mitigation.

Mina Ahmadi
FDA
Moderator

Brent Watkins
Veltek Associates
Speaker

1:45 PM – 2:00 PM ET

Break

Day Two Concurrent Sessions (3a–3d)

2:00 PM – 3:00 PM ET

Session 3a | Strategies for Developing an Effective Training Program

Learn strategies for developing an effective training program, such as implementation, methodologies, retraining, and connecting initial training to daily work activities.

Jill Hammond
FDA
Panelist

Leslie Riding
Fagron Sterile Services
Panelist

Lena LeVasseur
Leiters Health
Moderator

Christian Torstensson
The Atlantec Group
Panelist

DAY TWO: THURSDAY, AUGUST 22, 2024 (continued)

Day Two Concurrent Sessions (3a–3d)

2:00 PM – 3:00 PM ET

Session 3b | Not Just Blowing Smoke: Why Smoke Studies are Critical

Explore the concept of airflow visualization and critical considerations to ensure an optimum smoke study. Examine standards, regulations, and guidance for airflow visualization, as well as examples demonstrating poor airflow and good airflow.

Pallavi Lele
FDA
Moderator

Morgan Polen
Microrite
Speaker

Session 3c | The Role of the Pharmacist in the Realm of Outsourcing Facilities

Explore the role of the pharmacist in the context of outsourcing facilities and health system pharmacies that interact with outsourcing facilities.

Jeff Hval
STAQ Pharma
Panelist

Cindy Mitman
Leiters Health
Panelist

David Short
QuVa Pharma
Panelist

Eric Kastango
Kastango Solutions
Moderator

Abbi Rowe
AdventHealth
Panelist

Session 3d | Automation: Environment and Facility Considerations

Discover the advantages of incorporating Restrictive Access Barriers (RABs) into aseptic processing operations and when it makes sense to incorporate RABs into a facility. Consider facility design, environmental controls, and aseptic practices considerations. Includes examples of active aseptic operations with RABs.

Mina Ahmadi
FDA
Moderator

Norm Goldschmidt
Genesis AEC
Speaker

3:00 PM – 3:30 PM ET

Break

3:30 PM – 5:00 PM ET

FDA News and Q&A

IN-PERSON EXCLUSIVE

Get updates from FDA on recent developments in compounding relevant to outsourcing facilities, followed by an open question and answer session with the audience.

Kathleen Anderson
FDA
Panelist

Gabrielle Cosel
FDA
Panelist

Ian Deveau
FDA
Panelist

Hidee Molina
FDA
Panelist

Huascar Batista
FDA
Panelist

Alonza Cruse
FDA
Panelist

Edisa Gozun
FDA
Panelist

Meghan Murphy
FDA
Panelist

Gail Bormel
FDA
Panelist

Alissa Denker
FDA
Moderator

Jill Hammond
FDA
Panelist

DAY THREE: FRIDAY, AUGUST 23, 2024

9:00 AM – 10:00 AM ET

Welcome and Impact of Compliance on Product and Patient

Explore the differences and interplay between quality and compliance. Learn from examples that illustrate the impact of non-compliance on the product and patient.

Anil Mathai
STAQ Pharma
Panelist

Deb McHugh
Fagron Sterile Services
Moderator

Susan Schniepp
Parenteral Drug Association
Panelist

Morgan Strickland
OurPharma
Panelist

10:00 AM – 11:00 AM ET

Excipient Quality

Get an overview of excipients within the context of sterile compounding and understand the importance of excipient quality.

Tony Widenor
FDA
Moderator

Janeen Skutnik-Wilkinson
Moderna
Speaker

11:00 AM – 11:15 AM ET

Break

11:15 AM – 12:00 PM ET

Sustaining and Building the Future of Quality Across Networks

Learn about tools available to outsourcing facilities and how to leverage knowledge and create partnerships for the future.

Bill Cover
National Association of Boards of Pharmacy
Panelist

Mike Ganio
American Society of Health-System Pharmacists
Panelist

Mike Porter
Parenteral Drug Association
Panelist

Ian Deveau
FDA
Moderator

Anil Mathai
ISPE
Panelist

12:00 PM – 12:30 PM ET

Closing Remarks

Meghan Murphy
FDA
Speaker