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Aseptic Processing & Sterilization in Pharma

December 4 – 6, 2017, Boston, MA

www.aseptic-processing.com

Advance Your Sterile Manufacturing for Drug Product Quality, Competency and Capability for Patient Safety

15+ Speakers Include:

Philip Duncanson
Director of Quality Assurance & Microbiology
AstraZeneca

Dilip Ashtekar
Senior Director, Sterility Assurance & Microbiology Quality
Intarcia Therapeutics, Inc.

Claus Weisemann
Vice President, Quality Affairs
Luitpold Pharmaceuticals

Greg Corcoran
General Manager/ Site Head
AntriaBio, Inc.

"The difference between this event and others is that this allows us to exchange ideas with those with whom we share many common challenges"
AbbVie, Past Attendee

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Welcome to the Aseptic Processing & Sterilization in Pharma Summit

Delivering empirical learning to fast-track the next generation of checkpoint drugs

Recognizing the rise of complex biologics and combination products, as well as tightened cGMP requirements, aseptic processing and sterile manufacturing are second to none for quality products and patients' safety.

Through a series of technical and commercial case studies, the 3-day summit will:

- **Understand GMP requirements** to ensure compliance at all times
- **Assess the latest technologies** to enhance sterility assurance and manufacturing efficiency
- **Benchmark against best practice** of risk assessment for your aseptic processing

This must attend forum will give you access to **practical case studies providing actionable insights** which you can implement immediately to avoid pitfalls.

What Hanson Wade's attendees have said about our meetings

"I enjoyed the discussions and meeting our colleagues at the conference!"
Bristol-Myers Squibb

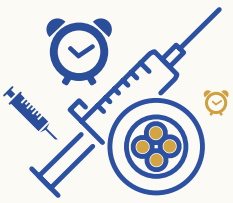
"This conference exceeded all of my expectations. The topics, speakers and suppliers were very relevant to my interests. I was able to walk away with many ideas and contacts to benchmark with!"
GSK

"The meeting and workshop bring together the top experts in the field; the size of the conference and quality of participants are optimal for healthy and fruitful discussions at every level"
Glenmark Pharmaceuticals SA

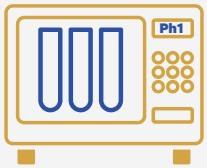
Your 5 Key Takeaways

1.
Merck demonstrates how you can define clear validation framework for process development to ensure quality products and a successful launch

2.
Sanofi Pasteur shares how to maintain cGMP's compliance with aging equipment



3.
AntriaBio, Inc. showcases why you should do clinical sterile manufacturing in-house and consideration during Ph1 to ensure a smooth scale-up



4.
Luitpold Pharmaceuticals guides you through first class quality assurance program

5.
Deep dive in interactive workshops to bridge the commercial and technical gaps of aseptic processing and sterilization

Your Expert Speakers

Sabrina Restrepo
Associate Director, Sterile & Validation CoE
Merck

Jamie Tsung
Associate Director
Alnylam Pharmaceuticals

Dilip Ashtekar
Senior Director, Sterility Assurance & Microbiology Quality
Intarcia Therapeutics, Inc.

Philip Duncanson
Director of Quality Assurance & Microbiology
AstraZeneca

Claus Weisemann
Vice President, Quality Affairs
Luitpold Pharmaceuticals

Mark Yang
Director of Fill-Finish
Sanofi Genzyme

Greg Corcoran
General Manager/ Site Head
AntriaBio, Inc.

Melissa Stefko
Senior Director of QA
Wells Pharmacy Network, LLC

Joshua Hellwig
Lyophilization Manager
Sanofi Pasteur

Evgenyi Shalaev
Research Investigator
Allergan

Nithin Raghunathan
Research Scientist
Purdue University

Tony Van Hoose
CEO
Global Aseptic Process Solutions, LLC

Paul Gold
Principal
Pamigo Aseptic

Nan Yung Lin
Associated Director, Product Development
PiSa BioPharm

Vineet Kumar
Principal Scientist
Janssen

Dominic DeGrazio
Associate Scientist-Large Molecule Drug Product Development
Janssen

> "Conference was excellent. A lot of speakers from different occupational backgrounds that shed light on different challenges faced"
>
> **Vertex**

Conference Day One | Monday, December 4

08.00 Coffee & Registration

09.00 Chair's Opening Remarks

Adhering to and Delivering Beyond Regulatory Requirements

Greg Corcoran,
General Manager/ Site Head
AntriaBio, Inc.

09.10 Keynote Address: Why Would a Startup Self-Perform Phase 1 Aseptic Processing? Case Studies

- What were they thinking?!' Business drivers to self-perform vs. contract
- Aseptic process controls and considerations in Ph1
- Understanding and managing risks, particularly with manual aseptic processes in clinical manufacturing stage
- What is the regulatory expectation for compliance for clinical sterile manufacturing?

Claus Weisemann
Vice President, Quality Affairs
Luitpold Pharmaceuticals

09.40 How to Make Product Good with Aging Facilities and Equipment

- How to validate and define quality standards for sterile products manufactured in aging facilities?
- Quality assurance challenges – routine inspections and audits
- Case study of maintaining cGMP – challenges and solutions

10.10 Morning Refreshments & Speed Networking

The Full Journey of Aseptic Processing & Sterilization

Philip Duncanson
Director of Quality Assurance & Microbiology
AstraZeneca

11.40 New or Old Facility, Understanding, Assessing and Controlling Aseptic Manufacturing Risks

- Contamination control plan – get started before you start: When should you do it? What should it include?
- Impacts and implications of revised version for EU GMP requirements and comparison with FDA's guidelines
- Challenges of ensuring compliance at manufacturing plants across the world

Evgenyi Shalaev
Research Investigator
Allergan

12.10 Terminal Sterilization of Lyophilies: Impact of Ionizing Radiation on Product Stability

- Radiation type and dose
- Product type, e.g. small molecule vs. protein
- Excipients and stability of freeze-dried proteins during irradiation

12.40 Tech-Show at Exhibition Hall

- Live demos from our technology partners to showcase latest AP and sterilization technologies
- Delegates will get the chance to ask questions during this interactive sessions

13.00 Lunch & Networking

Jamie Tsung
Associate Director
Alnylam Pharmaceuticals

14.00 Getting it Right First Time – Challenges with Complex Biologics and Combination Products

- CMC consideration from early stage of drug development
- Formulation consideration for fill/finish and sterilization requirements
- How to maintain product quality from a process and fill/finish perspective?

Moderated by:
Tony Van Hoose
CEO
Global Aseptic Process Solutions, LLC

14.30 Roundtable Discussion – Defining Aseptic Processing and Sterilization Standards, and Translating into Actions with Your Partners

Audience will be split into groups to discuss their thoughts and challenges relating to outsourced aseptic processing and sterilization, and how they should work with their CMO partners to standardize procedures and quality requirements, particularly in multi-sites situation.

At the end of this session, the groups will reconvene to share their findings and one top tip for peers.

15.15 Afternoon Refreshments & Networking

Nan Yung Lin
Associated Director,
Product Development
PiSa BioPharm

15.45 Challenges of Aseptic Processing for Combination Products

- Aseptic process developments for combination products
- Devising robust strategies to produce reliable and reproducible validation of aseptic filling
- Advancing multi-filler technology to improve efficiency and ability to accurately fill all container types

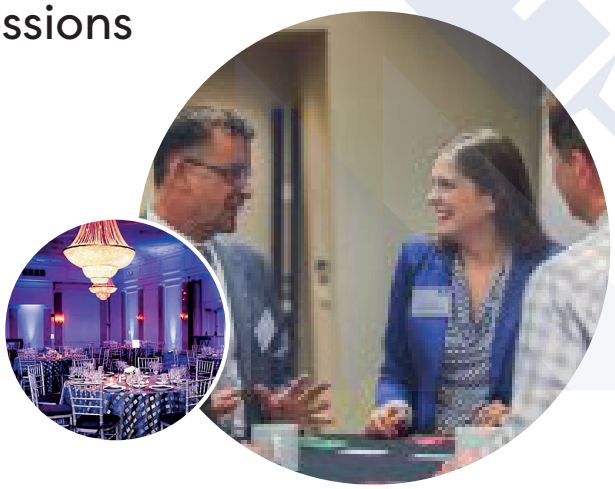
Nithin Raghunathan
Research Scientist
Purdue University

16.15 Advanced Aseptic Process Monitoring

- Real time monitoring of product temperature and environment variation
- Sensor accuracy and latest developments
- Ease of scaling up

16.45 Chair's Closing Remarks

"The meeting was well organized, the agenda well balanced and there was enough flexibility to engage in discussion. The networking sessions were great" **Gilead**



Conference Day Two | Tuesday, December 5

08.00 Coffee & Registration

09.00 Chairs Opening Remarks

The Critical Step – Sterilization for a Safe Product

Mark Yang
Director of Fill-Finish
Sanofi Genzyme

09.10 Case Study: Develop a Robust Formulation and Fill Finish Process to Ensure a Smooth Scale Up and Tech Transfer for Drug Product Manufacturing

- Drug product development starts with high quality and stable drug substance
- Develop a robust bioformulation
- Align early and late stage development for a lasting fill finish process
- Risk mitigation during process scale up and technology transfer
- New technologies and their incorporation for a controlled and consistent fill finish operation

Dilip Ashtekar
Senior Director, Sterility Assurance & Microbiology Quality
Intarcia Therapeutics, Inc.

09.40 How Confident Are You? Sterility Assurance

- How to select the appropriate sterility assurance level and what are the parameters?
- Acceptance level of sterility assurance for parenteral and implant products
- From bioburden to package testing

10.10 Tech-Show at Exhibition Hall

- Live demos from our technology partners to showcase latest AP and sterilization technologies
- Delegates will get the chance to ask questions during this interactive sessions

10.30 Morning Refreshments & Networking

Sabrina Restrepo
Associate Director, Sterile & Validation CoE
Merck

11.00 Mapping Validation Considerations from Process Development to Product Launch and Beyond

- From proof-of-concept to defining a clear framework of validation strategy
- What are the evaluation criteria?
- A quality validation for quality risk management
- Why this is important to successful product launch and patient safety

Ensuring Product Integrity through Advanced Engineering

Melissa Stefko
Senior Director of QA
Wells Pharmacy Network, LLC

11.30 Compounding Pharmacy Transition (503a to 503b) – From Small Batch to Commercial Sterile Manufacturing

- Aseptic process control and considerations during scale-up
- Define your critical quality attributes to ensure compliance
- Understanding the regulatory guidance for pharmacy sterile products and comparing to GMP, and look beyond for future direction

Moderated by:
Paul Gold
Principal
Pamigo Aseptic

12.00 Master Mind: How to Work with Your Internal and External Partners to Enhance AP & Sterility Quality?

The following areas have drawn industry leaders' attention:

- AP and sterilization knowledge and technical skill gap
- Industry standardization of AP and sterilization SOPs
- CMO capability, capacity and cost

The audience will be split into small groups for a knowledge sharing.

Utilize this master mind session to brainstorm and inspire each other for steps required to overcome these issues. Develop an action plan based on your experience and we will share your thoughts at the end of this session.

12.45 Lunch & Networking

Joshua Hellwig
Lyophilization Manager
Sanofi Pasteur

13.45 GMP Compliance for Aging Equipment

- The reality of aging equipment – cGMP challenges for older lyophilizers and other aseptic processing equipment
- How to perform inspection and audits
- Collecting data for quality control of machinery performance and operations
- Evaluating your options: Continuous improvement, renovate or replace

Dominick DeGrazio
Associate Scientist -Large Molecule Drug Product Development
Janssen

Vineet Kumar
Principal Scientist
Janssen

14.15 Current Industrial Practices on Container Closure Integrity Testing (CCIT) for Large Molecules: Gaps with New Regulatory Recommendations and Path Forward

- Development in container closure integrity testing
- Existing regulatory requirements and gaps to be filled

14.50 Chair's Closing Remarks

14.55 Close of Conference

Post-Conference Workshop Day | Wednesday, December 6

Workshop A

Quality Risk Management for AP and Sterile Products

09:00 – 12:00

Validation and quality assurance play a crucial part in the manufacturing process. This area is often overlooked, and could impose delay in product launch – and worst, put patients' safety at risk.

What is the best practice of validation and quality risk management during AP and sterile manufacturing? Instead of a tick box exercise, learn how to customize this to suit your business needs, and translate your validation framework into robust testing and well executed risk program.

Attendees will be able to discuss and be inspired at this session with scenario-based case studies, and understand:

- What a risk management approach is in regards to AP and sterile product manufacturing
- How to apply this approach to minimize potential failures and delays in the project or to ensure the manufacture of quality products through case studies and examples
- How and where to focus your efforts to maximize the returns on your validation dollar

Workshop Leader
Tony Van Hoose, CEO, **Global Aseptic Process Solutions, LLC**

Tony has been involved in the Pharmaceutical Industry for over 35 years as a Quality Assurance/Quality Control professional, both for operating companies and as a consultant. He has been a presenter at numerous IVT, ISPE, PDA and ASM conferences and has been an invited presenter for the FDA Aseptic Process Inspector Training classes. Currently, Tony is the President/CEO of Global Aseptic Process Solutions, LLC. Global Aseptic Process Solutions or GAPS, LLC provides general quality system and technical support for aseptic product manufacturing companies, specializing in modernization and renovation of aseptic manufacturing facilities. He is an expert in sterilization, visual inspection, container closure integrity testing and aseptic manufacturing processes

Workshop B

Bridging the Commercial and Technical Gaps of Aseptic Processing and Sterilization

12:30 – 15:30

Understanding your projects' specific technical needs, and working with your partners strategically to ensure your project is delivered on-time and on-budget, is not a straightforward exercise in today's complex regulatory and technical environment. Too often, pharmaceutical companies struggle to meet aggressive timelines for new products' introduction and/or major capacity expansion. Also, working with many different vendors, internal colleagues and across multiple time zones, leads to delays and cost overruns.

Join with colleagues from other firms and industry experts to learn and discuss

- How to best translate science into business
- Define practical, realistic requirements and expectations for advanced aseptic processing to senior management, your equipment providers and CDMOs
- What the risks to time/cost are, and understand proven techniques to mitigate them
- Setting expectations and getting it right first time to ensure transformation is on-time and on-budget

Workshop Leader
Paul Gold, Principal, **Pamigo Aseptic**

Paul Gold is the owner and principal consultant at Pamigo Aseptic. He is the former Director, Global Aseptic Technology at Pfizer, Inc., from which he retired after a career spanning of nearly 40 years. He has extensive experience in both hands-on execution and team leadership in aseptic processing operations. His expertise in design and execution of aseptic drug product processes and equipment enabled him to lead and implement many different types of commercial and clinical projects on 3 continents. In addition, Paul has executed multiple significant successful projects in the field of process containment for extreme high-potency materials.

ABOUT PARTNERSHIP

Our audience is actively seeking solution providers to partner with them to advance sterile manufacturing. Do you have a service or product matching their needs?

If you have a solution or product to help our community, please get in touch to discover partnership opportunities that will connect you with them via:

Tech Demo: Showcase your latest aseptic processing and sterilization platforms in our exhibition hall with a live demo to our audience.

Tech Talk: Present your work through a thought-leadership piece to help our audience realize it's actually 'easier done than said'.

Engage: Forge relationships with drug developers earlier on and align your services to meet their needs through our structured networking breaks.

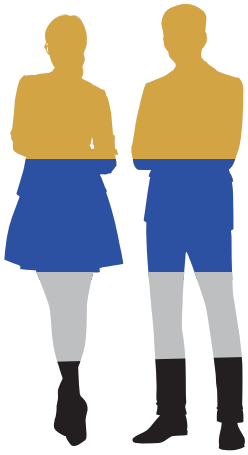
WHO WILL YOU MEET?

60+ VPs, Directors, Heads and Managers of:

- Aseptic Processing
- MS&T
- Sterilization/ Sterility Assurance
- Microbiology
- QA/QC/Validation
- Fill/Finish
- Regulatory Affairs
- CMC

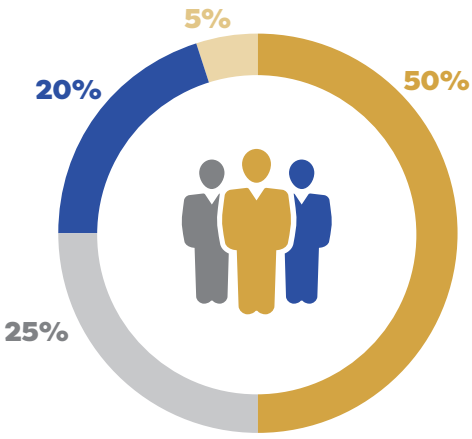
From pharmaceutical, biotechs and medical devices

SENIORITY OF ATTENDEES*



- VP & C-Level: 30%
- Director & Head: 30%
- Manager & Project Lead: 20%
- Scientist: 20%

TYPES OF COMPANIES ATTENDING*



*Based on market research and previous events' statistics

WHO ATTENDED HW EVENTS IN THE PAST?

AMGEN, APOTEX ADVANCING GENERICS, astellas, AstraZeneca, BAYER, Bristol-Myers Squibb, Lilly, Genentech A Member of the Roche Group, gsk, janssen, Mallinckrodt, MedImmune, MERCK, NOVARTIS, SANOFI, Shire, Takeda, TEVA, ucb, VERTEX

GET INVOLVED

Farooq Robinson
Partnership Director
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Team Discounts*

- **10% discount – 3 delegates**
- **15% discount – 4 delegates**
- **20% discount – 5 or more delegates**

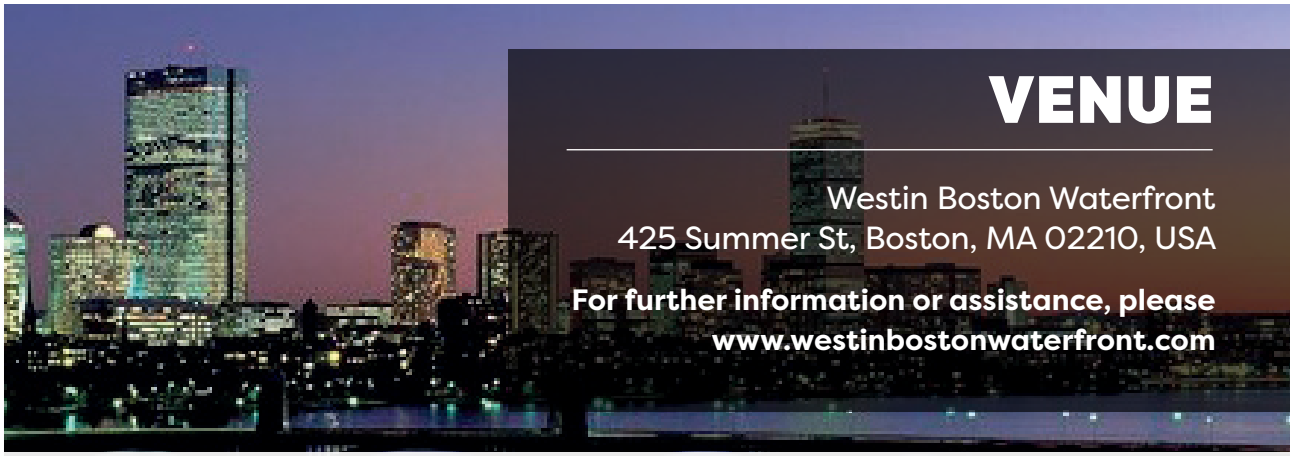
Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.

Contact: register@hansonwade.com

SECURE YOUR PLACE

Package Details	Register & Pay before Friday Sept 15 **Save up to $800**	Register & Pay before Friday Oct 20 **Save up to $500**	Standard Prices
GOLD Conference + 2 Workshops	$2,897	$3,197	$3,697
SILVER Conference + 1 Workshop	$2,498	$2,798	$3,098
BRONZE Conference Only	$2,199	$2,399	$2,499
Workshops (Each)	$599		

*Special 40% off for academics available upon request



VENUE

Westin Boston Waterfront
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For further information or assistance, please www.westinbostonwaterfront.com

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