



June 19-21, 2018 The Aloft Boston Seaport, Boston

www.hpapi-summit.com

"THIS
CONFERENCE IS A
CLEAR LEADER IN
THE HPAPI ARENA"

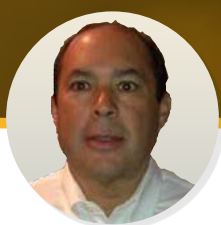
Pfizer

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Enabling Robust, Safe and Cost-Effective Production of Highly Potent APIs



Marc Abromovitz
Head, Industrial
Hygiene
Novartis



Richard Wooster
CSO
Tarveda
Therapeutics



Reinhold Maeck
Head of Corp EHS
Regulatory Intelligence
Boehringer Ingelheim



Paul Richards
Principal, Process
Engineering
Biogen



Jacqui Van Sipe
Associate Director,
EH&S
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WELCOME TO THE INDUSTRY-LEADING HIGHLY POTENT API EVENT

Uniting The Entire Highly Potent Drug Development Value Chain - From Bench To Point Of Outsource

ABOUT US

The HPAPI Summit brings together perspectives throughout the value chain from bench to outsource, providing you with a unified outlook on the latest developments in highly potent manufacturing.

As compounds become increasingly potent, the need for harmonization among distinct groups within organizations around key challenges is more acute than ever before.

By involving multiple perspectives from companies of different size and experience in the field, the HPAPI Summit will enable you to understand how you can implement safe and robust practices in your own organization.

Incorporating insights from Genentech, Pfizer, Vertex, SafeBridge and Boehringer Ingelheim, you will leave this conference with actionable insights that will enable you to produce highly potent APIs more robustly, safely and cost-effectively.

AGENDA HIGHLIGHTS

Explore Unique Potent Compound Case Studies

Gain insights into a range of novel potent compounds and understand the specific containment and developmental challenges they pose. Learn how **Biogen** have mitigated risks of exposure to powder and vapour when working with a potent compound that sublimates, as well as **Tarveda Therapeutics**, who will discuss the sustained release of potent payloads achieved using their miniature drug conjugate technology.

Learn From Realistic Containment Cost Assessments

Arm yourself with the insights required to answer the question: 'How much containment is enough?' Investigate how **Mylan** have controlled old processing equipment to deal with new challenges, as well as how **ILC Dover's** flexible solutions can reduce capital costs and provide ongoing savings by eliminating cleaning requirements.

Establish Robust Internal Manufacturing & Outsourcing Practices

Learn directly from experts working with potent compounds from bench scale through scale-up to making decisions on outsourcing for commercial scale manufacturing. Investigate how **Boehringer Ingelheim** ensure the GMP and worker safety aspects of manufacturing are compliant, and how **Merck** assess CMOs to ensure external manufacturing is safe and efficient.



"THIS CONFERENCE CAN SERVE AS BOTH AN INCUBATOR AND CATALYST TO EDUCATE AND HARMONIZE ACROSS THE INDUSTRY."

Seattle Genetics

YOUR EXPERT SPEAKERS



Marc Abromovitz
Head, Industrial Hygiene
Novartis



Samuel Baron
Associate Director,
Manufacturing
Science & Technology
SK Biotech Ireland



Andrew Brewer
Senior Principal Engineer,
Global Biologics
Manufacturing Science
and Technology
Genentech



Jay Brown
Senior EHSS Specialist
Alkermes



Dean Calhoun
President & CEO
Affyigility Solutions



Scott Duncan
Director of
Chemistry, Technical
Operations, **Stealth
Biotherapeutics**



Abizer Harianawala
Senior Director,
Product Development
& Technical
Operations, **TARIS
Biomedical**



Adam Kujath
Global Senior Director,
Manufacturing
Science and
Technology, **Aicami**



Shaun Larsen
Director, Global EHS &
Industrial Hygiene
Mylan



Timothy Maher
Associate Director,
API Development &
Commercialization
Merck



Reinhold Maeck
Head of Corp EHS
Regulatory Intelligence
Boehringer Ingelheim



Scott Patterson
VP, Commercial Sales
ILC Dover



Paul Richards
Principal, Process
Engineering
Biogen



Bob Sussman
Managing Director
SafeBridge



Evan Thackaberry
VP, Nonclinical
Development
Ra Pharmaceuticals



John Roosa, Associate
Director, New
Technology
Development
and Industrial Hygiene
Lead, **Merck**



Jacqui Van Sipe
Associate Director,
EH&S
Vertex



Michael West
Director, Environment,
Health & Safety
Pfizer



Richard Wooster
CSO
**Tarveda
Therapeutics**



Speaker To Be
Confirmed
AMRI



"I THINK THIS MEETING IS PARTICULARLY USEFUL IN KEEPING ABREAST OF EH&S AND CONTAINMENT TRENDS IN THE INDUSTRY. I ALSO FOUND IT INTERESTING TO LEARN HOW OTHER INNOVATOR COMPANIES MANAGE THEIR HPAPI CMOS."

Takeda

PRE-CONFERENCE WORKSHOP DAY

TUESDAY, JUNE 19

WORKSHOP A

Establishing Practices to Work Effectively With & In Emerging Regions

8:00am – 11:00am

As highly potent compounds become increasingly prevalent, there is a trend towards an increasing investment in facilities and worker training to develop these compounds in emerging areas such as India, the Middle East and North Africa (IMEA) region. It's clear that working in these areas poses a number of unique challenges, and this workshop will be devoted to discussing strategies to identify and overcome these setbacks.

Attendees will discuss:

- Investigating the regulatory landscape governing potent compound development in emerging markets
- Understanding the cultural aspects of working with organizations in emerging regions – what are the most effective ways to establish a safety culture?
- Risk assessments on a global scale – how to establish best practices

WORKSHOP LEADER:



Dean Calhoun
President & CEO
Affyglity Solutions

WORKSHOP B

Navigating the Potent Compound Regulatory Landscape

11:30am – 2:30pm

Regulations governing the development, handling and manufacturing of highly potent compounds are becoming increasingly complex, and it's clear that the expectations of the regulators don't always align with realistically attainable standards. This workshop will analyze the current regulatory frameworks in place and enable you to optimize your work in this area.

Attendees will discuss:

- What the regulators are looking for and how you can meet these expectations effectively
- Understanding how the European regulatory landscape impacts on the US
- How regulatory considerations impact containment and cleaning limits
- Understanding and discussing the quality of documentation and experiences with regulators around ADEs and PDEs

WORKSHOP LEADER:



Reinhold Maeck
Head of Corp EHS, Regulatory Intelligence
Boehringer Ingelheim

WORKSHOP C

Comprehensive Occupational Exposure Banding: Insights for Handling Novel Potent Compounds

3.00pm – 6.00pm

This workshop will improve industry consistency by defining methods to use limited or early-stage data to assess the hazard potential of development compounds. This session will also provide insights into handling recommendations and basic descriptors of safe work environments based on categorization. Qualitative health-based approaches have been developed to assess and communicate the

potential health hazards of compounds to workers. This workshop will also explore new case studies discussing how to handle a variety of NCEs.

Attendees will discuss:

- Assigning banding classifications and creating an industry standard
- Ensuring equipment meets requirements and development demands
- Best-practices for assessing novel potent compounds

WORKSHOP LEADER:



Bob Sussman
Managing Director
Safebridge

	7:30	Registration, Coffee & Networking
 Bob Sussman Managing Director Safebridge	8:20	Chair's Opening Remarks
 Andrew Brewer, Senior Principal Engineer, Global Biologics Manufacturing Science and Technology, Genentech	8:30	KEYNOTE PANEL DISCUSSION: Defining What “Highly Potent” Actually Means & Why It Matters There is clearly a lack of harmonization across industry in defining what constitutes a highly potent compound. This panel discussion will evaluate the factors that influence how conservatively these compounds are treated with the goal of establishing a more unified approach across industries: - Understanding the threshold for potency – what should this be based on? - Investigating the regulatory impact of the term ‘highly potent’ - How conservatively should these molecules be treated? - What factors influence the approaches people take in handling these compounds?
 Bob Sussman Managing Director Safebridge		
 John Roosa, Associate Director, New Technology Development and Industrial Hygiene Lead, Merck		
GUARANTEEING SAFE & EFFICIENT DEVELOPMENT OF POTENT COMPOUNDS AT EVERY SCALE		
 Speaker To Be Confirmed AMRI	9:15	Presentation details to be confirmed
	9:45	Speed Networking This session is the ideal opportunity to get face-to-face time with many of the brightest minds working with highly potent compounds. Benchmark against the industry leaders and establish meaningful business relationships to pursue for the rest of the conference and beyond.
	10:45	Morning Refreshments
 Shaun Larsen, Director, Global EHS and Industrial Hygiene, Mylan	11:15	Highly Potent Containment & Controls in a Generics World - Controlling old processing equipment: Is this possible? - The elephant in the room: How much containment is enough? A cost review - Case studies detailing successful cross-departmental collaboration to enhance potent compound development
 Samuel Baron, Associate Director, Manufacturing Science & Technology SK Biotech Ireland	11:45	Operation of a Fully Integrated & Versatile HPAPI Manufacturing Facility - Effective containment design strategy for handling HPAPIs from g to kg - IH monitoring philosophy - Purification strategy for HPAPIs
	12:15	Networking Lunch
DISCOVERING THE TRUE POTENTIAL OF INNOVATIVE CONTAINMENT TECHNOLOGIES		
 Scott Patterson VP, Commercial Sales ILC Dover	1:45	Flexible Containment Systems for Nanogram Level Containment - Presenting a case study for high containment of an OSD process with a Containment Performance Target of less than 30.0 nanogram/m³ - Sharing the design concept for the process train containment, including the SMEPAC testing method and results - Discussing what the risks for containment to the nanogram level are and how these risks can be mitigated using best in class design and the benefit of a negative pressure system - Establishing the value proposition of flexible containment, including low capital cost and ongoing savings from elimination of cleaning
 John Roosa Associate Director, New Technology Development and Industrial Hygiene Lead, Merck	2:15	A Hands-On Investigation of Potent Compound Handling Techniques - Understanding and mitigating against common failures of techniques - Examining the pitfalls of industrial handling techniques and investigating strategies to improve processes - Sharing best-practices to maintain safety and containment

CONFERENCE DAY ONE WEDNESDAY, JUNE 20



Scott Patterson
ILC Dover



John Roosa
Merck

2:30 **INTERACTIVE PANEL DISCUSSION: Cross-Disciplinary Perspectives on the Relative Benefits of Flexible vs Fixed Containment**

- Investigating the situations in which flexible and disposable containment systems can add the most value
- What levels of containment can be reached by flexible facilities?
- Strategies to clean flexible containment systems – investigating innovative approaches to enable more effective and efficient cleaning

3:15 **Afternoon Break & Refreshments**



Adam Kujath
Global Senior Director,
Manufacturing Science and
Technology
Alcami

3:45 **Risk-Based Design Approach to HPAPI Suite Design in a Multi-Use Contract Manufacturing Facility**

- Understanding the technical, procedural and a perception-based challenges involved in the development and manufacture of HPAPIs in a multi-use facility
- Investigating a risk-based approach to facility and equipment design when faced with the unique challenges of being a Contract Development and Manufacturing Organization (CDMO)
- Insights into user requirement specification development, containment strategy risk assessment and flexible and expandable design

BIOTECH SHOWCASE

As an increasing number innovative biotech companies become involved in the highly potent space, this section of the program is devoted to highlighting the work they are carrying out, as well as the challenges they have faced and overcome in developing and handling these compounds.

NOVEL COMPOUND FOCUS



Richard Wooster
CSO
Tarveda Therapeutics

4:00 **Pentarin Miniature Drug Conjugates: Targeting Potent Payloads to Tumors**

- Pentarins are miniature drug conjugates synthesized by chemistry with high specificity for either cell surface or intracellular cancer targets
- The miniature size of Pentarins drives rapid penetration deep into solid tumors where they accumulate with sustained release of potent payloads
- Pentarins have achieved complete and durable regressions in tumor xenograft models with 2 Pentarins in clinical studies

PROCESS DEVELOPMENT FOCUS



Jacqui Van Sipe
Associate Director, EH&S
Vertex

4:15 **Developing a Robust Occupational Toxicology Framework from Scratch in a Biotech Company Environment**

- Establishing the internal framework to band and handle compounds appropriately
- Developing the right protocol and practises to support smooth relationships with CMOs and CROs
- Improving communication between all stakeholders in the value chain



Scott Duncan
Stealth BioTherapeutics



Evan Thackaberry
Ra Pharmaceuticals



Richard Wooster
Tarveda Therapeutics



Jacqui Van Sipe
Vertex

4:30 **PANEL DISCUSSION: Lessons Learned from Innovative Organizations in the Highly Potent Space**

- Changing perspectives – moving from handling non-hazardous compounds to potent materials in the biotech environment
- Handling a lack of local, internal expertise: How can a complex network of external consultants and contract companies be managed most effectively?
- Establishing robust processes and systems for the internal communication of valuable information about a compound



Bob Sussman
Managing Director
Safebridge

5:00 **Chair's Closing Remarks**

CONFERENCE DAY TWO THURSDAY, JUNE 21



Bob Sussman
Managing Director
SafeBridge

8:50 **Chair's Opening Remarks**



Reinhold Maeck
Head of Corp EHS
Regulatory Intelligence
Boehringer Ingelheim

9:00 **Evaluating Best-Practise Containment & Navigating the High Potent Regulatory Landscape from EHS to GMP**

- Ensuring compliance: GMP and worker safety considerations
- What has changed based on the new European EMA-Guideline?
- How to best link OEL and PDE results discussed on an isolator



Paul Richards
Principal, Process
Engineering
Biogen

9:30 **CASE STUDY: Containment of a High Potency Sensitizer that Sublimes – Unique Challenges & Solutions**

- Understanding the handling challenges of an API on commercial scale
- Designing with appropriate engineering controls to mitigate risks of exposure to powder and vapor
- Supplementing engineering controls with facility controls, PPE, and administrative controls

10:00 **Morning Refreshments & Networking**

MAINTAINING SAFETY AND COMMUNICATION IN NOVEL ENVIRONMENTS



Michael West
Director, Environment,
Health & Safety
Pfizer

10:30 **Continuous Processing: Unique Challenges Encountered in the Construction & Use of a Continuous Processing Suite**

- Understanding the benefits of continuous processing in manufacturing potent compounds
- Detailing the challenges encountered in establishing continuous processing capabilities
- Case studies detailing risk management processes in the context of innovative manufacturing practices



11:00 **MASTERMIND DISCUSSION: Developing Effective Communication Strategies to Break Down Organizational Siloes**

- How can different disciplines interact more effectively to increase productivity and reduce risk?
- Discuss the most pressing communication challenges encountered at various points in the development and outsourcing process
- Leave with clear actions on how to improve future communication strategies

This session facilitates in-depth discussions between participants in an informal environment. After splitting into small groups, discuss the communication challenges you are facing and collaborate on future strategies to improve communications.

12:00 **Networking Lunch**

ESTABLISHING RISK-BASED DECISION MAKING & BEST PRACTICE OPERATOR TRAINING



Marc Abromovitz
Head, Industrial Hygiene
Novartis

1:00 **Applying a Risk Based Approach for Defining Exposure Controls in the Workplace**

- The OEL and band are not the only criteria for selecting exposure controls
- The value proposition for applying risk based data driven decision-making for exposure controls
- The dose makes the poison



Jay Brown
Senior EHSS Specialist
Alkermes

1:30 **Best Practise Potent Compound Training: Understanding the Unique Training Requirements for Operators Handling HPAPIs**

- Detailing specific elements that make training in this field successful
- Establishing expectations around handling potent compounds
- Understanding how to share knowledge most effectively within organizations and with external collaborators

CONFERENCE DAY TWO THURSDAY, JUNE 21

2:00 **Afternoon Refreshments & Networking**

IMPLEMENTING SUCCESSFUL OUTSOURCING STRATEGIES



Abizer Harianawala
Senior Director, Product
Development & Technical
Operations
TARIS Biomedical

2:30 **Enhancing Communication During the Outsourcing Process & Beyond**

- Understanding the key factors involved in maintaining effective relationships with CMOs
- Establishing mutually-beneficial and sustainable partnerships throughout the full life cycle of potent compound development
- Investigating the points at which drug developers should monitor and assess CMOs



Timothy Maher
Associate Director,
API Development &
Commercialization
Merck

3:00 **PANEL DISCUSSION: How Do You Decide on the Right CMO to Work With?**

- Evaluating the key criteria used to assess contract development and manufacturing organizations in the highly potent space
- Understanding the questions you should be asking both at the business and technical level
- How can both small and large organizations work more effectively with contract companies? What are the differences in approach with differently sized companies?
- Which stakeholders and departments should be involved in the CMO assessment and selection process to ensure that it's as robust as possible?



Paul Richards
Principal, Process
Engineering
Biogen



Marc Abromovitz
Head, Industrial Hygiene
Novartis



Bob Sussman
Managing Director
SafeBridge

3:45 **Chair's Closing Remarks**

4:00 **Close of Summit**

"I THOUGHT THE
CONFERENCE WAS VERY
VALUABLE IN MY PERSONAL
EDUCATION AND FOR
ELEMENTS THAT I CAN TAKE
BACK TO MY COMPANY."

PCI Pharma Services

"I LEARNED A LOT, GOT A
CHANCE TO BENCHMARK
WITH OTHER COLLEAGUES
AND THE NETWORKING
SESSIONS WERE
WONDERFUL. I WOULD
DEFINITELY ATTEND AGAIN."

Gilead

WHO WILL YOU MEET?



120+
ATTENDEES



12+
HOURS OF DEDICATED
NETWORKING



3
INTERACTIVE
WORKSHOPS

IMPROVING INDUSTRY HARMONIZATION THROUGHOUT THE VALUE CHAIN

Evidently, there is a lack of communication and alignment between key members of the HPAPI development chain, causing inefficiencies and hampering the progress of the field. In order to combat this, we will bring together the **perspectives of stakeholders at every stage in the production of HPAPIs**, breaking down these siloes and allowing you to gain a comprehensive insight into the development of potent compounds.

Interactive sessions built into the main agenda provide extensive opportunities for cross-functional collaboration. Whether you are approaching this field as a large or small drug developer, CMO or containment company, this event will enable you to benchmark your progress and critically evaluate your approach to dealing with highly potent compounds. Leave the event with **actionable insights that will drive efficiency, guarantee safety and ensure cost-effectiveness** in all of your HPAPI development programs.

ATTENDEES EXPECTED FROM EVERY STAGE OF DEVELOPMENT:



PREVIOUS ATTENDEES INCLUDE



CONFIRMED PARTNERS

PROGRAM PARTNER



ILC Dover

DoverPac® Containment Systems, an ILC Dover brand, is the global pioneer of disposable process and powder containment systems. Launched from a partnership with multi-national pharmaceutical companies to develop high containment for API production and oral solid dosage processing, DoverPac® is the global standard for containment, reliability, and service.

www.ilcdover.com/about-doverpac-containment-systems

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PROGRAM PARTNER



AMRI

AMRI is a global contract research and manufacturing organization, working with the Life Sciences industry to improve patient outcomes and the quality of life for more twenty-five years. AMRI's API Manufacturing business supports chemical development through cGMP manufacture of a diverse range of complex Active Pharmaceutical Ingredients (APIs), including steroids and hormones.

www.amriglobal.com

PROGRAM PARTNER



Alcami

Alcami is a world-class supplier of comprehensive pharmaceutical development and manufacturing services headquartered in Wilmington, NC. With nearly 1,000 employees operating at seven sites globally, our combined capabilities include API development and manufacturing, solid state chemistry, formulation development, analytical development and testing services.

www.alcaminow.com

EXHIBITOR



Buchiglas

Buchiglas is a leading manufacturer of reactor systems and pilot plants for API and fine chemicals Synthesis. Our focus lies with engineered solutions customized according to your lab, pilot or cGMP production requirements. Our reactor systems and pilot plants are suitable for the most demanding corrosion and pressure environments due to our proprietary designs and the use of high performance materials.

www.buchiglas.com

PARTNER



SafeBridge Consultants

SafeBridge Consultants, Inc. is the premier resource to the pharmaceutical and biotechnology industry in occupational health and safety. We have the capability to assist companies in developing the systematic approach to potent compound handling that helps speed products to market and reduce potential worker health effects from occurring.

www.safebridge.com

PARTNER WITH US:

Are you front of mind when pharma and biotech outsource manufacturing and make procurement decisions?

Drug developers have told us they lack visibility on which CMOs and containment equipment providers have the expertise and experience, as well as technology and facilities required to guarantee the robust, safe and cost-effective development of highly potent APIs.

Partner with the 7th Annual HPAPI Summit to demonstrate that you have the capabilities to meet the increasing demands of this emerging field.



LET'S TALK - LIMITED PARTNERSHIP OPPORTUNITIES STILL AVAILABLE

Rob Keast E: sponsor@hansonwade.com T: +1 617 455 4188

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3 EASY WAYS TO BOOK



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Register By
March 2 &
SAVE \$800



Package Details	Register & Pay By Friday, March 2	Standard Rate
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AND ALL THE
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FOR MEETING
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Boehringer Ingelheim

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

*T&Cs APPLY

Small Biotech Pricing is subject to organizer approval, see the website for more details

VENUE

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**For further information or assistance,
please visit www.aloftbostonseaport.com.**

Full payment is due on registration. Cancellation and Substitution Policy: Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

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