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5TH ANNUAL

HPAPI SUMMIT 2016

June 21-23 2016

Boston

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

19 Expert Speakers Include:

Marc Abromovitz
Director, Occupational Health & Hygiene
Novartis

Wendel Doubleday
Director, Process Research & Development
Seattle Genetics

Nancy McClellan
Global Occupational Hygiene Manager
Abbvie

Bob Sussman
Managing Principal, Eastern Operations
SafeBridge Consultants

Patricia Weideman
Director, Product Quality & Occupational Toxicology
Genentech

> "This conference is a clear leader in the HPAPI arena"
>
> **Pfizer**

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Welcome to the 5th Annual HPAPI Summit

The **5th Annual HPAPI Summit** will provide you with the tools to safely, robustly and cost effectively produce highly potent APIs.

This is the only meeting to **incorporate perspectives** and **in-depth insight from every stage of the drug development value chain**, from bench to point of outsource. Gain a truly comprehensive overview of the most critical **challenges** and **opportunities** in the development of highly potent compounds.

This year's meeting will include the very latest insights into early process development and scale-up, occupational toxicology, innovative containment and cleaning solutions and optimizing outsourcing strategies.

Join industry experts from **Genentech, Seattle Genetics, Pfizer, Safebridge Consultants plus other leading drug developers** for the most important meeting of your year.

Top 10 reasons to attend this year

1. Develop robust process chemistry to **improve efficiency of early potent compound development**
2. **Optimize scale up from pilot plant to commercial scale manufacturing** while maintaining containment standards
3. **Reduce costs and save time** by learning from effective technology transfer approaches
4. **Improve worker safety throughout the development timeline** by discovering how to establish OELs early in the development process
5. Successfully utilize innovative containment and cleaning solutions to **maximize manufacturing efficiency** and **prevent cross-contamination**
6. **Implement best practices to ensure worker safety** by analyzing data-driven risk assessments
7. Investigate toxicological data required to **improve safety and maximise costs**
8. **Navigate the regulatory landscape effectively** by understanding the implications of the new European Medicines Agency (EMA) guidelines
9. Streamline HPAPI development by **revolutionizing communication strategies throughout the value chain**
10. **Enhance outsourcing strategies** by discovering innovative methods to identify and manage interactions with CMOs

Speakers

Marc Abromovitz
Director, Occupational Health & Hygiene
Novartis

Thomas Brandt
Associate Research Fellow
Pfizer

"Excellent collection of speakers and topics from a broad range of specialties."
Safebridge Consultants

Jack Brown
Senior Principal Scientist
Boehringer Ingelheim

Dean Calhoun
CEO & President
Affygility Solutions

Tom Cleary
Principle Site Manager
Genentech

Wendel Doubleday
Director, Process Research & Development
Seattle Genetics

Michael Groaning
Director, Strategic Development
Endocyte

Theresa Lane
Director, Industrial Hygiene
Merck

"The speakers truly love what they do and it resonated in their presentations."
Regeneron

Jonathan Lee
Director
Aptuit

Nancy McClellan
Global Occupational Hygiene Manager
Abbvie

Melanie Miller
Executive Director, Chemical Development Operations
Bristol-Myers Squibb

Chris Mitchell
Research Investigator
Takeda Pharmaceuticals

Scott Patterson
VP, Commercial Sales
ILC Dover

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

Bob Sussman
Managing Principal, Eastern Operations
SafeBridge Consultants

Vincent Turula
Director, External Supply & Outsourcing
Pfizer

Christine Vannais
Associate Director, EH&S
Fujifilm Diosynth

Jacqui Van Sipe
Senior Manager, EH&S
Vertex Pharmaceuticals

Patricia Weideman
Director, Product Quality & Occupational Toxicology
Genentech

"This conference was excellent. Speakers from different occupational backgrounds shed light on the different challenges faced."
Vertex

Workshops

Workshop A

Date: Tuesday June 21 **Time:** 8:30am - 11:30am

Effective Occupational Health Categorization & Banding

This workshop will improve industry consistency by defining and maintaining categorization. This session will provide a general overview of 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 these novel compounds to workers.

This approach, called "categorization" or "banding," typically places compounds into one of several bands or categories depending on the anticipated potency and toxicity of the compound. A corresponding set of handling guidelines is "linked" to the category or band. The workshop will also cover the difference between categorization for GMP and for worker safety. Discussion will include real life case studies and will address:

- Aligning **hazard assessment classifications**
- Understanding the **toxicological criteria of a potent compound**
- Assigning **banding classifications** and creating an industry standard
- Ensuring **equipment meets requirements** and **development demands**

Bob Sussman
Managing Principal, Eastern Operations
SafeBridge Consultants

Workshop B

Date: Tuesday June 21 **Time:** 12:00pm - 3:00pm

Risk Management & Industrial Hygiene: Preventing Cross Contamination & Employee Exposures In The Context Of HPAPIs

This updated workshop will cover how the right hazard control strategy can **maximize regulatory and manufacturing effectiveness**, and **minimize risk levels** in potent facilities.

Manufacturing high hazard products can be challenging and when manufacturing several in the same facility the risk of cross contamination and employee exposures is a real concern.

Discussion will take real life case studies and focus on:

- So, you want to **calculate OELs/ADEs yourself?** Here's what's involved.
- Do you know **which product is your highest risk?**
- How would you answer the question, "Do I need a **dedicated facility or equipment?"**
- Is your facility **controlling this risk to acceptable levels?**
- EMA Guidance +1: What we've learned after one year of the **EMA Guidance on Setting Health-Based Exposure Limits**
- **Case studies:** The Good, the Bad, and the Ugly.

Dean Calhoun
CEO & President
Affygility Solutions

Workshop C

Date: Tuesday June 21 **Time:** 3:30pm - 6:30pm

Explore the Future of Containment Innovation

Join this interactive workshop to **discuss current and future trends in the containment of highly potent compounds**. Explore case studies and industry insights and come away with a **comprehensive outlook on the future of the field**.

The workshop will be led by John Roosa, who will draw on insights from over twenty years of industry experience. John has extensive responsibility for leading multi-discipline teams, most recently to install new technologies and improve industrial hygiene in an API Pilot Plant.

Discussion will focus on:

- **Lessons learned from current containment technology approaches** in the manufacturing of potent compounds
- Advantages and disadvantages of **flexible and disposable containment solutions**
- **Future trends and analysis** of the evolving containment landscape

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

Conference Day 1 - Wednesday June 22

08.00 **Registration, Coffee & Networking**

08.50 **Chairman's Opening Remarks**
Patricia Weideman, Director, Product Quality & Occupational Toxicology, **Genentech**

09.00 **KEYNOTE: Strategies for Containment Risk Assessment and Control**
- The need and structure for an interdisciplinary approach
- Potential toolbox for risk assessment and control solutions
- Outcomes and the continuous improvement path forward

Nancy McClellan, Global Occupational Hygiene Manager, **Abbvie**

Developing Effective and Scalable Processes

09.30 **Key Strategic Considerations in the Early Stage Development and Manufacture of Potent Compounds**
- Leverage a risk-based process development approach to ensure success upon scale up
- Examine data-driven decisions to change behavior in the early handling of potent compounds
- Maximize collaboration through matrix teams to increase efficiency and speed to patient

Melanie Miller, Executive Director, Chemical Development Operations, **Bristol-Myers Squibb**

10.00 **Speed Networking**

11.00 **Morning Refreshments & Networking**

11.30 **Piloting and Scale-up of High Potent API Processes**
- Handling highly potent APIs in process development
- Facility challenges
- In-house vs CMOs

Tom Cleary, Principle Site Manager, **Genentech**

12.00 **Quick Fire Innovation Talk**
Christine Vannais, Associate Director, EH&S, **Fujifilm Diosynth**

12.15 **Mastermind: 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, participants discuss the communication challenges they are facing and collaborate on future strategies to improve communications.

1.00 **Networking Lunch**

2.00 **Scale-up of HPAPIs and their Unique Challenges**
- Challenges with working with HPAPIs and approaches to scale-up while maintaining safe and compliant environment
- Utilizing cross-functional teams; including engineering, chemistry and IH
- Managing the added complexity of scale-up with limited process understanding

Jack Brown, Senior Principal Scientist, **Boehringer Ingelheim**

2.30 **Quick Fire Innovation Talk**
Jonathan Lee, Director, **Aptuit**

2.45 **Afternoon Refreshments & Networking**

3.15 **Enabling the Development of Highly Potent Cytotoxic Agents in a Biotech Environment – Synthesis, Facilities and Work Practices**
- Importance of designing synthetic strategies to minimize the constraints of handling highly potent molecules
- Design of a process research facility to accommodate high potency and non-high potency synthesis
- Approaches to monitor laboratory practices to enable flexibility in high potency chemistry development

Wendel Doubleday, Director, Process Research & Development, **Seattle Genetics**

3.45 **Internalization of Linker-Payload Route Enabling and HiPo Laboratory Considerations**
- Benchmarking with industry peers for HiPo lab design
- OEL calculation for lead linker-payload and surrogate monitoring results
- Determination of which intermediates to treat as OEB5

Thomas Brandt, Associate Research Fellow, **Pfizer**

Successfully Navigate the Regulatory Landscape

4.15 **Navigating the EU Regulatory Landscape With the Small Molecule Drug Conjugate (SMDC) Vintafolide**
- Novel approach to containment of vintafolide during the drug substance isolation process
- CMC Regulatory interactions with the European Health Authorities during a centralized Marketing Authorization Application review process
- Guided tour of the convoluted landscape traveled to reach a positive CHMP opinion

Michael Groaning, PhD, Director of Strategic Development, **Endocyte, Inc.**

4.45 **Chair's Closing Remarks**
Patricia Weideman, Director, Product Quality & Occupational Toxicology, **Genentech**

Conference Day 2 - Thursday June 23

08.00 **Registration, Coffee & Networking**

08.50 **Chairman's Opening Remarks**
Bob Sussman, Managing Principal, Eastern Operations, **SafeBridge Consultants**

09.00 **KEYNOTE: Evaluating the Impact of the European Medical Agency (EMA) Guidance on Cleaning Limits in Development and CMC Timelines**
- Overcome the challenges encountered in establishing ADEs throughout the development timeline
- Understand the impact of ADEs on containment and product quality
- Navigating and interpreting EMA guidelines

Patricia Weideman, Director, Product Quality & Occupational Toxicology, **Genentech**

09.30 **Interactive Panel: Cross-Disciplinary Perspectives on Flexible Containment Solutions**
- Using flexible facilities to maintain containment throughout the scale-up process
- What levels of containment can be reached in flexible facilities?
- Contrasting flexible with shared use and dedicated facilities – what are the advantages and disadvantages?

This session is a chaired panel interview in which experts in several areas of the development of HPAPIs give their perspective on the subject of flexible containment

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

Scott Patterson, VP, Commercial Sales, **ILC Dover**

Wendel Doubleday, Director, Process Research & Development, **Seattle Genetics**

10.00 **Morning Refreshments & Networking**

10.30 **Innovation Spotlight Session**

10.45 **Innovation Spotlight Session**

Manage Occupational Toxicology and Industrial Hygiene Throughout Development

11.00 **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

Jacqui Van Sipe, Senior Manager EH&S, **Vertex Pharmaceuticals**

11.30 **Applying Risk Based Data Driven Decision Making Processes To Your API Risk Management Program**
- Use data to identify appropriate technical solutions based on risk vs hazard
- Modify technical solutions and work practices based on data
- Eliminate waste with over and under engineering
- Ensure workers are not at risk

Marc Abromovitz, Director, Occupational Health & Hygiene, **Novartis**

12.00 **Networking Lunch**

1.00 **Merck's Journey to Control Workplace Exposures**
- Understanding regulatory requirements for exposure controls
- Developing effective exposure control strategies & tools
- Monitoring and communicating effectiveness of installed controls
- Continuously improving strategy, processes, and tools

Theresa Lane, Director, Industrial Hygeine, **Merck**

Implement Successful HPAPI Outsourcing Strategies

1.30 **Facilitate Effective Transfer of Information Between Drug Developer and CMO**
- Successfully facilitate the transfer of manufacturing processes to CMOs
- Examine the unique challenges posed by technology transfer in the highly potent field
- Strategies to ensure successful management of CMOs

Chris Mitchell, Research Investigator, **Takeda**

2.00 **Afternoon Refreshments & Networking**

2.30 **Optimize Strategies to Select and Oversee CMOs**
- Investigate best practices for successful CMO selection
- Effectively manage vendor relationships and monitor performance
- Case study: Challenges encountered in outsourcing cytotoxic ADCs

Vincent Turula, Director, External Supply & Outsourcing, **Pfizer**

3.00 **Panel: Overview and Analysis of HPAPI Market Trends**
This panel will allow extensive audience participation, incorporating multiple perspectives and insight into the global HPAPI market.
- Interrogating past challenges to develop successful future strategies
- Assessing innovative ideas to overcome the area's greatest challenges
- Insights into the future of potent compound manufacture

Panellists: To come from audience and speaker faculty

3.30 **Chair's closing remarks:**
Bob Sussman, Managing Principal, Eastern Operations, **SafeBridge Consultants**

Who you will meet at the 5th Annual HPAPI Summit

The HPAPI Summit is your opportunity to meet and network with industry leaders involved in every stage of HPAPI development.

Clearly, significant organizational siloes exist within the HPAPI development chain, causing inefficiencies and hampering the progress of the field. In order to combat this, the 5th Annual HPAPI Summit 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**. This event will enable you to benchmark your progress and **critically evaluate** your HPAPI development approach.

Leave the HPAPI Summit with clear actions on how to **drive efficiency, guarantee safety and ensure cost efficiency** in all of your HPAPI development programs.

Technical Focus

Gain the technical expertise of process and analytical chemists working on overcoming the **early process development, scale up** and **technology transfer challenges** encountered in the development of HPAPIs.

Safety Focus

Enhance your safety procedures by meeting **EHS** and **Industrial Hygiene experts from the leading companies in the HPAPI field**. Gain a balanced outlook on this key aspect of potent compound development by learning from best practices and **discovering innovative EHS solutions**.

Sourcing Focus

Successfully identify and manage interactions with CMOs by **learning directly from leading figures in the outsourcing field**. Discover strategies to facilitate effective technology transfer to maintain efficiency and containment throughout the outsourcing process.

Past Attendees Include:

abbvie, Agensys, AMPAC Fine Chemicals, Biogen, BioVectra, Boehringer Ingelheim, Bristol-Myers Squibb, Cambrex, Capsugel, Eisai, Evonik, Fujifilm Diosynth Biotechnologies, Genentech, Gilead, GlaxoSmithKline, Helsinn, Heraeus, DoverPac Containment Systems, Immunogen, ImQuest BioSciences, Jacobs, Hecht technologie, Synthon, Takeda, Lonza, Mallinckrodt Pharmaceuticals, Merck, Mylan, Novartis, Oncothyreon, OsoBio, pci Pharma Services, Pfizer, pharma science, Pierre Fabre, PolyPeptide Group, Regeneron, Sanofi, SeattleGenetics, Sigma-Aldrich, Stemcentrx, Teva Pharmaceuticals

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These drug discovery and development professionals offer proven experience in key therapeutic areas. They share a legacy of success, having advanced a large number of molecules efficiently, expeditiously and economically, from early discovery through clinical development with low attrition rates.

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www.ilcdover.com

Exhibitor

Fermion

Fermion have been manufacturing Active Pharmaceutical Ingredients (API) for both generic and proprietary drug products since 1970.

We have also Contract manufacturing services for APIs including oncology and high potent compounds.

www.fermion.fi

Exhibitor

Heraeus

Heraeus, the technology group headquartered in Hanau, Germany, is a leading international family-owned company formed in 1851. With expertise, a focus on innovations, operational excellence and an entrepreneurial leadership, we strive to continuously improve the businesses of our customers around the world.

www.heraeus.com

> "Hanson Wade again managed to get a highly focused group of experts together. Information and networking was of high value."
>
> **Heraeus**

Partner With Us

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Email: jason.williams@hansonwade.com

Venue

Sheraton Boston Hotel,
39 Dalton Street,
Boston,
Massachusetts, 02199,
United States

Overnight accommodation is not included in the registration fee, however accommodation options will be sent out with your confirmation email upon registering.

> "Enjoyed the meeting and all the speakers. Great for meeting colleagues in many areas"
>
> **Boehringer Ingelheim**

Prices And Discounts

Package Prices	Register & Pay before Friday March 4	Register & Pay before Friday April 4	Register & Pay before Friday May 13	Standard Pricing
Platinum Package Conference & 3 workshops	$4096 **(save $700)**	$4196 **(save $600)**	$4296 **(save $500)**	$4396 **(save $400)**
Gold Package Conference & 2 workshops	$3497 **(save $600)**	$3597 **(save $500)**	$3697 **(save $400)**	$3797 **(save $300)**
Silver Package Conference & 1 workshop	$2798 **(save $500)**	$2998 **(save $400)**	$3098 **(save $300)**	$3198 **(save $200)**
Bronze Package Conference only	$2399 **(save $300)**	$2499 **(save $200)**	$2599 **(save $100)**	$2699
Workshops - individual	$699			

Team Discounts*

3+ Delegates: 10% Discount
4+ Delegates: 15% Discount
5+ Delegates: 20% Discount

The HPAPI Summit is specifically **designed to facilitate cross functional collaboration and break down siloes**. Attend as a group to maximize the opportunity to gain perspectives from every stage of the drug development value chain.

*Please note: Team discounts are only valid when three or more delegates from one company book and pay at the same time. 'Early Bird' discounts require payment at the time of registration (or prior to the cut-off date) to secure the applicable discount. All advertised discounts cannot be combined with any other offer.

When you've made your selections Secure Your Place*

- ✔ **You can register your place quickly and easily online. Visit:**
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  If you require any further information on the event, or would like us to assist you in making your booking, please contact Hanson Wade via the contact details below.

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