6th Annual

HPAPI Summit

June 20-22, 2017 Aloft Seaport Boston Hotel, US

www.hpapi-summit.com

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

Pfizer

REGISTER BY MARCH 31

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

Gregory Sowell
Principal Scientific Manager, Small Molecule Process Chemistry, **Genentech**

Neil Faiber
Outsourcing Manager
Takeda

Silke Weber
Toxicologist, Occupational Health Specialist
Roche

Bob Sussman
Managing Director, Eastern Operations
SafeBridge

John Roosa
Senior Engineering Specialist - New Technology Development & Industrial Hygiene Lead, **Merck**

Firelli Alonso
Senior Director, Biotherapeutics & Vaccines Outsourcing
Pfizer

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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 6th Annual HPAPI Summit is the definitive event for companies in the highly potent space.

Our uniquely positioned agenda will enable you to implement robust process development and scale-up strategies, enhance EHS and occupational toxicology programs, adopt innovative containment and cleaning solutions, as well as optimize outsourcing and tech transfer strategies.

Incorporating insights from Genentech, Pfizer, SafeBridge, Takeda and Merck, this conference will provide you with a unified outlook on the latest developments in highly potent development.

AGENDA HIGHLIGHTS

Handle early process development and scale-up effectively

Gain the technical expertise of process and analytical chemists working on overcoming early process development, scale-up and technology transfer challenges encountered in the early stages of potent compound development. Learn from **Genentech's** approach to working with HPAPIs in an early stage multi-product facility and understand how **Stealth BioTherapeutics** have moved from lab to commercial scale manufacture successfully.

Successfully identify and prevent risks at every stage of HPAPI development

Whatever the size of your organization, from large pharma to small biotech, investigate how optimum safety standards can be established and maintained. Understand how **Novartis** view control banding, before an interactive panel discussion on the topic with **SafeBridge**. Understand how **Roche** have successfully implemented ADE programs by optimizing internal and external communication strategies.

Implement robust and cost-effective outsourcing strategies

Successfully identify and manage interactions with CMOs by learning directly from outsourcing experts in the highly potent space. Understand how **Pfizer** overcome tech transfer challenges and investigate how pioneering companies such as **Takeda** and **Alkermes** select CMOs with the expertise and facilities to ensure efficiency and containment are maintained throughout the outsourcing process.

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

Seattle Genetics

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21 EXPERT SPEAKERS

Marc Abromovitz
Head, Industrial Hygiene
Novartis

Firelli Alonso
Senior Director, Biotherapeutics & Vaccines Outsourcing
Pfizer

Joel Bercu
Associate Director
Gilead Sciences

Jay Brown
Associate Director, EHSS
Alkermes

Jon Crate
President & Senior Chemist
FAI Testing

Scott Duncan
Director of Chemistry, Technical Operations
Stealth BioTherapeutics

Wendel Doubleday
Senior Director, Chemical Development
Seattle Genetics

Jeremy Eberhardt
Senior Process Engineer
Alkermes

Neil Faiber
Outsourcing Manager
Takeda

Jessica Graham
Senior Research Investigator, Product Quality & Occupational Toxicology
Bristol-Myers Squibb

Kim Hejnaes
CEO
Hejnaes Consult

Scott Patterson
VP, Commercial Sales
ILC Dover

John Roosa
Senior Engineering Specialist - New Technology Development & Industrial Hygiene Lead
Merck

Edward Sargent
Adjunct Full Professor
Rutgers University

Gregory Sowell
Principal Scientific Manager, Small Molecule Process Chemistry
Genentech

alcami

Speaker To Be Confirmed
Alcami

Brad Stanard
Associate Director, Occupational Toxicology & Product Stewardship
MedImmune

Bob Sussman
Managing Director, Eastern Operations
SafeBridge

Silke Weber
Toxicologist, Occupational Health Specialist
Roche

Patricia Weideman
President & Principal
Sakari Consultants

Angela Zhou
Senior Sourcing Manager
Genentech

"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."

Seattle Genetics

CONFERENCE DAY ONE WEDNESDAY JUNE 21

08:00 Registration, Coffee & Networking

08:50 **Chair's Opening Remarks**
Patricia Weideman, *President & Principal,* ***Sakari Consultants***

09:00 **KEYNOTE PANEL DISCUSSION: Investigating Future Trends in the Highly Potent Space**
Highly potent compounds form a larger proportion of industry pipelines than ever before. These compounds have been utilized mainly in oncology indications, but what are the possibilities for these compounds to add value in the future and how can the field grasp these opportunities? Topics to be covered include:
- What new technologies will revolutionize the highly potent space in the coming years?
- What kinds of containment will novel technologies require?
- Looking beyond ADCs in oncology – how can we analyze and effectively contain novel compounds?
- Investigating potent proteins, small molecules and nanoparticles

Bob Sussman, *Managing Director,* ***SafeBridge***
Wendel Doubleday, *Senior Director, Chemical Development,* ***Seattle Genetics***
Patricia Weideman, *President & Principal,* ***Sakari Consultants***

DEVELOPING EFFECTIVE & SCALABLE PROCESSES

09:45 **KEYNOTE: A Holistic View on Highly Potent Compound Development**
- Working with HPAPI in a multi-product early stage facility
- Understanding the end-to-end process evaluation, facility design and personnel training involved in matching production and containment needs with appropriate facilities and equipment
- Considerations of process understanding and technical development when transferring a HPAPI process to a CMO

Gregory Sowell, *Principal Scientific Manager, Small Molecule Process Chemistry,* ***Genentech***

10:15 Speed Networking & Morning Refreshments

11:15 **Handling Potent Compounds Effectively in the Early Discovery Stages**
- How to handle a lack of toxicological information early on in discovery
- Understanding the mechanism of action of a novel compound and translating this into effective exposure and containment controls
- Conducting risk assessments and characterization of early stage potent compounds

Brad Stanard, *Associate Director, Occupational Toxicology & Product Stewardship,* ***MedImmune***

11:45 **Effectively Scaling-Up HPAPI Manufacturing While Maintaining Containment Levels**
- Successfully moving from bench to pilot plant scale to commercial scale manufacture
- Facility considerations throughout the scale-up process
- Engaging third party manufacturers early on in the scale-up of potent compounds

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

12:15 **Topic to be Confirmed**
Alcami

12:45 Networking Lunch

EXAMINING THE LATEST CONTAINMENT TECHNOLOGIES

14:00 **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

John Roosa, *Senior Engineering Specialist - New Technology Development & Industrial Hygiene Lead,* ***Merck***

14:30 **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 strategies to enable more effective and efficient cleaning

Scott Patterson, *VP, Commercial Sales,* ***ILC Dover***
John Roosa, *Senior Engineering Specialist - New Technology Development & Industrial Hygiene Lead,* ***Merck***

15:15 Afternoon Break & Refreshments

INVESTIGATING THE INTERPLAY BETWEEN TOXICOLOGY & REGULATORY AFFAIRS

15:45 **Global Chemical Registrations: Testing Strategies and CMO Communication**
- Overview of International Chemical Registrations – EU REACh, Korea "REACh" and China MEP
- Registrational testing needs and testing strategies for international registrations – Studies required, timing, CRO selection
- Enhancing communications between CMOs and Sponsors around appropriate regulations – what we've learned and how to optimize future communications

Jessica Graham, *Senior Research Investigator, Product Quality & Occupational Toxicology,* ***Bristol-Myers Squibb***

16:15 **PANEL DISCUSSION: Understanding How to Optimize Interactions with Regulators in the Highly Potent Space**
- Understand how the regulators view this field and what you need to demonstrate
- Defining risk and the role of the regulators in ensuring hazards are analysed appropriately
- Learning how the European and US regulatory systems differ in relation to potent compound handling

Patricia Weideman, *President & Principal,* ***Sakari Consultants***
Silke Weber, *Toxicology Project Lead,* ***Roche***
Jessica Graham, *Senior Research Investigator, Product Quality & Occupational Toxicology,* ***Bristol-Myers Squibb***

16:45 **Chair's Closing Remarks**
Patricia Weideman, *President & Principal,* ***Sakari Consultants***

17:15 End of Conference Day 1

CONFERENCE DAY TWO THURSDAY JUNE 22

08:50 **Chair's Opening Remarks**
Bob Sussman, *Managing Director, Eastern Operations* ***SafeBridge***

09:00 **KEYNOTE: Generating Toxicological Limits & Integrating them Effectively Within Organizations**
- How limits such as OELs, PDEs and ADEs can be integrated into the business effectively
- The engagement of diverse functions within your company
- Effective internal and external communications

Edward Sargent, *Adjunct Full Professor,* ***Rutgers University***

IDENTIFYING & MITIGATING AGAINST RISKS

09:30 **Control Banding – The Power of Hypnosis**
- The importance of a risk-based decision making approach versus a hazard-based approach
- Enhancing API risk-management programs by applying insights based on data
- Analyzing case studies detailing effective risk-management plans

Marc Abromovitz, *Head, Industrial Hygiene,* ***Novartis***

10:00 **SPEAKER DEBATE: Evaluating the Use of Control Banding**
This interactive panel session will enable you to participate in a discussion around the value and applicability of the current control banding methods in use in this field. Voice your opinion and interact with the experts on issues such as:
- How relevant and useful are control bands?
- Is it possible to standardize banding across the industry more effectively in the future?
- Can we validate the current banding systems to ensure they are more data-driven , scientific and validated?
- Is there an alternative to the currently implemented model?

Bob Sussman, *Managing Director, Eastern Operations,* ***SafeBridge***
Marc Abromovitz, *Head, Industrial Hygiene,* ***Novartis***

10:30 Morning Refreshments & Networking

11:00 **Establishing Relevant Occupational Health Data & Assessment Processes**
- Successfully translating clinical processes and safety assessments into occupational health processes
- Overcoming the challenge of establishing health and safety procedures in a smaller innovator company environment
- Relaying valuable toxicology data throughout the value chain and ensuring employee concerns are addressed

Jay Brown, *Associate Director, EHSS,* ***Alkermes***

11:30 **INTERACTIVE MASTERMIND SESSION: How Can We Fix the Communication Breakdown?**
Developing Effective Strategies to Overcome Organizational Siloes
Clearly, significant organizational siloes exist within the HPAPI development value chain, leading to breakdowns in communication, inefficiencies and hampering the progress of the field. In this interactive session, participants will discuss the communication challenges they are facing and collaborate on future strategies to improve communication. Topics to be discussed include:
- What is the best way to establish effective communication strategies from the beginning of the highly potent development process?
- How can different departments and disciplines interact more effectively?
- What is the most effective way to get the entire project team to improve communications?

12:00 **Networking Lunch**

13:00 **Integrating Toxicological Information Effectively Throughout Organizations**
- Investigating how limits such as PDEs and ADEs can be integrated into different aspects of the organization effectively
- How can you communicate and engage other functions other to use this data effectively?
- How are effective communication plans made and adhered to?

Joel Bercu, *Associate Director,* ***Gilead Sciences***

13:30 **Integration Of ADEs Into The Drug Development Process**
- Understand Challenges of ADE setting and implementation of an ADE program
- Points to consider for successful implementation of an ADE program
- Establishing effective communications with stakeholders, both internally and externally

Silke Weber, *Toxicologist, Occupational Health Specialist,* ***Roche***

14:00 Afternoon Refreshments & Networking

IMPLEMENTING SUCCESSFUL HPAPI OUTSOURCING STRATEGIES

14:30 **Overcoming Tech Transfer Challenges & Optimizing CMO Management**
- Assessing key factors involved in the timing of outsourcing in the highly potent space
- Managing CMOs effectively and ensuring safety standards are maintained to levels comparable to internal processes
- Ensuring timelines and budget restraints are met by communicating effectively with CMOs throughout the outsourcing process

Angela Zhou, *Senior Sourcing Manager,* ***Genentech***

15:00 **PANEL DISCUSSION: How Large Pharma & Innovative Small Biotech Companies Can Effectively Manage the Outsourcing Process**
- Analyzing the differing requirements of big pharma and smaller innovator companies in ensuring success throughout the outsourcing process
- Which members of the team need to be involved in site visits during the CMO selection process?
- Evaluating the role of analytics in assessing CMO facilities
- Investigating best-practices for successful CMO selection
- Examining the role of CMOs in educating drug developers regarding steps in the process that require high containment
- Validating CMOs by examining past experience with highly potent compounds

Neil Faiber, *Outsourcing Manager,* ***Takeda***
Jeremy Eberhardt, *Senior Process Engineer,* ***Alkermes***
Firelli Alonso, *Senior Director, Biotherapeutics & Vaccines Outsourcing,* ***Pfizer***

15:45 **Chair's Closing Remarks**
Bob Sussman, *Managing Director, Eastern Operations,* ***SafeBridge***

16:00 Close of Summit

PRE-CONFERENCE WORKSHOP DAY
TUESDAY JUNE 20

PLEASE SELECT ONE OF THE STREAMS BELOW

Workshop A 09:00 - 17:00
Outsourcing, Technology Transfer, & CMO-Client Relationships

As potent compounds continue to increase in prevalence, an ever-increasing number of drug developer companies are investing in outsourcing partners for the development and manufacture of potent compounds for clinical studies and commercial supply.

The CMC section of a biopharmaceutical project is typically on a time-critical path, which can prove a challenge for both the client (contract giver) and the CMO (contract acceptor). To ensure a successful collaboration and outcome, client expectations must be aligned with the contracted CMO. This factor is particularly relevant in the highly potent space, where containment facilities and expertise are of paramount importance.

This workshop will allow you to 'wear the hat' of a big pharma sponsor in a safe, educational and entertaining environment, allowing you to **explore a multitude of outsourcing situations in one day, gaining expertise that would usually take years to develop.**

Immerse yourself in interactive, hands-on sessions covering every aspect of the outsourcing journey, including:

CMO SELECTION PROCESS
Take part in an interactive case study, giving you a hands-on experience in selecting CMOs in different geographies and with different experiences, to ensure a successful outsouring process.

TECH TRANSFER
Ensure that the key process and analytical factors are communicated and transferred effectively to external manufacturers.

EXECUTION OF CONTRACT
Learn effective vendor-management tools to create a sense of 'co-ownership' of the project, to facilitate a seamless contract execution and completion.

WORKSHOP LEADERS

Firelli Alonso
Senior Director, Biotherapeutics & Vaccines Outsourcing
Pfizer

Jon Crate
President & Senior Chemist
FAI Testing

Kim Hejnaes
CEO
Hejnaes Consult

Workshop B 09:00 - 12:00
Successful Multifunctional Approaches to Managing Risks Associated with Manufacturing and Quality

Development, manufacturing, and delivery of safe and high-quality pharmaceutical products require input and cooperation of multiple functions throughout the product's life cycle within a company or an organization. This workshop will focus on identification and discussion of **internal and external operational challenges that companies experience and expect to experience in changing regulatory and fast-paced development environments.**

ATTENDEES WILL DISCUSS
- Impact of toxicology on selection of controls for cross-contamination and worker protection
- What teams and their roles are needed in implementation of effective programs to ensure delivery of safe and high-quality products with timely manufacturing schedules
- How to align a company product quality program with regulatory expectations-what are the basics that every regulator wants to see
- Define the similarities and differences between cGMP and worker safety programs-how can we synergize the efforts

WORKSHOP LEADER

Patricia Weideman
President & Principal
Sakari Consultants

Workshop C 13:00 - 16:00
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.

ATTENDEES WILL DISCUSS
- 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

WORKSHOP LEADER

Bob Sussman
Managing Director, Eastern Operations
SafeBridge

WHO WILL YOU MEET?

120+
ATTENDEES

12+
HOURS OF DEDICATED NETWORKING

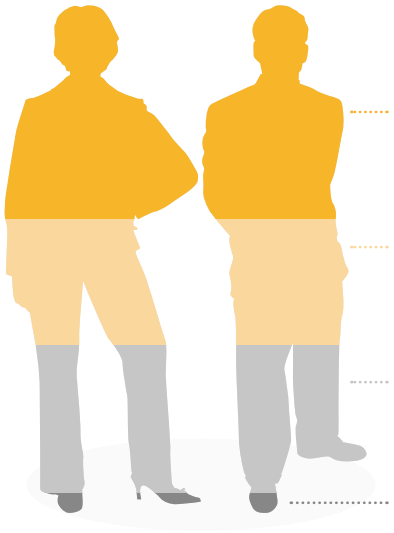
3
INTERACTIVE WORKSHOPS

OVERCOME THE COMMUNICATION BREAKDOWN

Evidently, significant organizational siloes exist within the HPAPI development chain, causing inefficiencies and hampering the progress of the field. In order to combat this, the 6th 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 event with **actionable insights that will drive efficiency, guarantee safety and ensure cost-effectiveness** in all of your HPAPI development programs.

SENIORITY



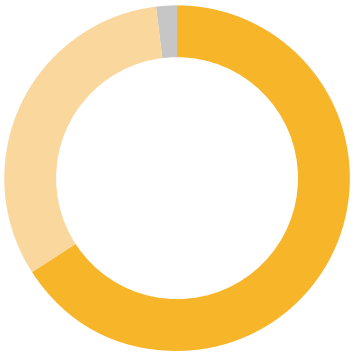
42% Director/CEO/ President/VP

25% Senior Manager/Manager

29% Process/Safety/Outsourcing Specialist

4% Other

COMPANIES BY TYPE



Biopharma	**66%**
Solution Providers	**32%**
Other	**2%**

PREVIOUS ATTENDEES INCLUDE

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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 successfully manufacture highly potent APIs at the necessary yields.

Partner with the 6th Annual HPAPI Summit for a unique opportunity to demonstrate that you have the capabilities to meet the increasing demands of this emerging field.

2017 CONFIRMED PARTNERS TO DATE

Alcami is a world-class supplier of comprehensive pharmaceutical development and manufacturing services headquartered in Wilmington, NC. We offer a world class end-to-end outsourcing opportunity as well as individualized development and manufacturing services that can be integrated for a less fragmented and faster pathway for products through the clinical toward commercialization. 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, clinical and commercial finished dosage form manufacturing (oral solid dose and parenteral), packaging and stability services.

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

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LET'S TALK

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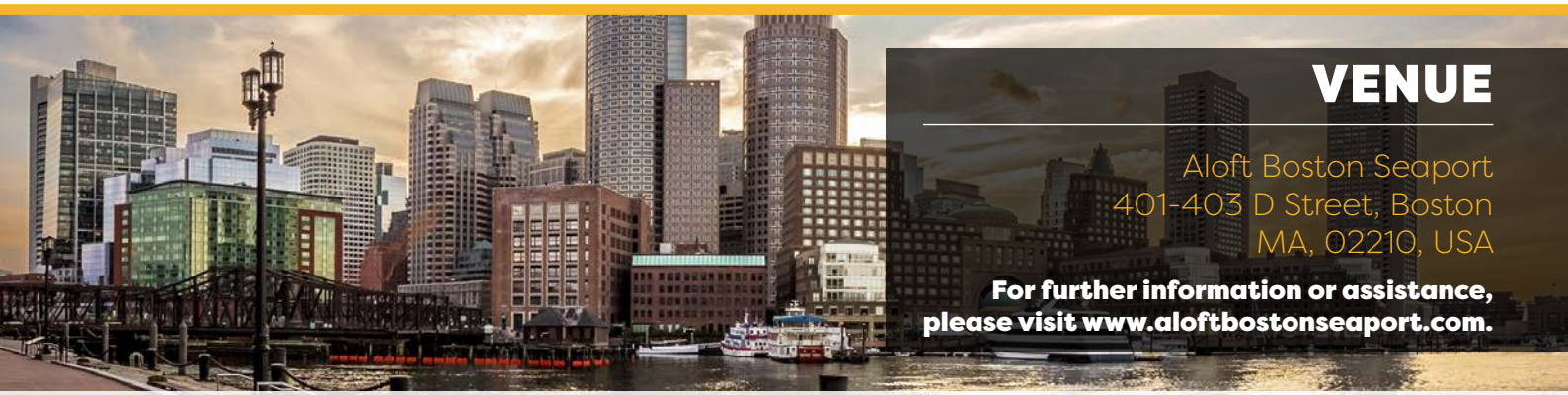
Team Discounts - 3 delegates - 20% discount

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

"I LEARNED A LOT AND GOT A CHANCE TO BENCHMARK WITH OTHERS. I WOULD DEFINITELY ATTEND AGAIN."

Gilead



VENUE

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

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