SafeBridge
Global Potent Compound Congress & Expo®

Agenda

June 10-11, 2025
W Hotel, Boston

DAY 1 - TUESDAY, JUNE 10		
8:00 am	Registration and Continental Breakfast	
8:30 am	Welcome and Opening Comments	Allan Ader (SafeBridge)
	Session 1 - Recognizing and Identifying Hazards	**Session Chair - Robert Sussman**
8:45 am	**Elements of a Successful Potent Compound Safety Program** ▶ Effective Environmental, Health, and Safety (EHS) programs within potent compound-handling settings must embrace a scientific, risk-based philosophy that integrates toxicology, environmental monitoring, engineering, occupational health, shipping/receiving, maintenance and quality. ▶ A robust program often leans heavily on the industrial hygienist to serve as the liaison between all interested stakeholders. ▶ Particular attention will be paid to hurdles experienced within the CDMO space.	Casey Cosner (Millipore Sigma)
9:15 am	**Hazard Evaluation and the History of Occupational Exposure Banding** ▶ Identifying the hazardous endpoint ▶ Other endpoints that determine hazard ▶ Determining hazards for compounds with limited data	Robert Sussman (SafeBridge Consultants)
9:45 am	**Tailored Treatments & Safer Workplaces: Bridging Personalized Medicine, New Chemical Entities, and Hazard Evaluations** ▶ Precision medicine revolution and evolution: Where are we? ▶ What got you here won't get you there: Novel modality hazard assessments ▶ Beyond the comfortable: Where do we go from here and how do we get there?	Michelle Hernandez (Merck)
10:15 am	**On-boarding of New Chemical Entities (CDMO Perspective)** ▶ Enhancing your CDMO occupational toxicology program and improving toxicology data transfer between CDMO and innovator ▶ Determining health-based exposure limits or default bands for potent compounds and active pharmaceutical ingredients with limited toxicity data, and the evolution during the life-cycle of development, from pre-clinical stage to market ▶ Partnering with Sales, EHS, Quality, Regulatory, and others, from the quotation stage through to the project being awarded and on-site, to ensure worker safety and patient safety, and to meet client and regulatory expectations for a multi-product facility	Joe Galati (ThermoFisher)
10:45 am	Break	
11:15 am	**The Rise of Potent Biologically Derived Drug Substances: Shifting Trends in Pharmacodynamics and Pharmacokinetics** ▶ Monoclonal antibodies, fusion proteins, and cell & viral gene therapies are evolving thanks to advances in modern biotechnology. ▶ Traditional pharmacodynamic and pharmacokinetic paradigms are shifting with longer drug half-lives, immunomodulatory actions, and the ability to target immune-privileged sites. ▶ Several case studies will be highlighted showcasing market trends from a manufacturing perspective and how we ensure worker and patient safety.	AJ Troiano (Fujifilm Diosynth Biotechnologies)
11:45 am	Panel Discussion	Above speakers
12:15 pm	Lunch	

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	Session 2 - Evaluating Facilities, Equipment, and Risk	Session Chair - Ryan Graff
1:15 pm	**Evaluation and Selection of CDMO for Highly Potent Compounds** ▶ Determining your project requirements ▶ Assessing potential program risk ▶ RFP to CDMO Selection – How to proceed	Brian James (Rondaxe Pharma)
1:45 pm	**Critical Aspects of a Robust Highly Potent Compound Containment Program** ▶ Holistic Containment Strategy: Successful containment requires more than engineering controls—it demands integration with a strong containment culture and soft elements such as organizational values, behaviors, and proactive planning. ▶ Integrated Industrial Hygiene Program: Embedding containment culture and soft elements (e.g., innovative process development, health pre-planning, and change management structures) into the industrial hygiene program, ensures a consistent and effective approach to potent compound safety. ▶ Sustainable Success Through Soft Elements: Trained staff, robust monitoring tools, budget allocation, data-driven decisions, and clear communication are critical soft elements that reinforce containment efforts and maximize the return on containment investments.	Amy VanAntwerp (Corden Pharma)
2:15 pm	**HPAPI Manufacturing: Key Engineering Challenges for Existing Facilities** ▶ HVAC: Bridging the gap between best practices and current facility conditions. ▶ Airlocks: Why do I need it? Which type? How do I implement? ▶ Engineering Controls: Aren't PPE and Respirators enough?	Hari Floura (Floura LLC)
2:45 pm	**ADCs - Leveraging Containment Techniques & Strategies in HPAPI Synthesis through Primary Packaging** ▶ In-depth look at the containment challenges throughout the ADC manufacturing process ▶ Review potential strategies to help overcome product & personnel risk	Ashley Harp (CRB)
3:15 pm	Break	
3:45 pm	**Assessing Aerosol Migration Pathways from Single-Use Equipment Process Upsets** ▶ Ambient and pressurized releases during process upsets from single-use processing trains were evaluated to understand potential exposure and migration pathways. ▶ The potential for employee exposure from these releases must be carefully considered. ▶ Positive pressurization schemes used in Grade C and D GMP processing suites can result in aerosolized materials migrating outside of airlocks and suite boundaries when process upsets occur. ▶ Building ventilation and air handling systems have the potential to become contaminated with aerosolized materials and result in contaminant migration throughout the facility during single-use equipment process upsets.	Lisa Schubert (Merck)
4:15 pm	Panel Discussion - Facility Design	Above speakers
4:45 pm	Day 1 - Wrap-up	Ryan Graff / Allan Ader / Robert Sussman
5:00 pm	Reception - Sponsored by ILC Dover	

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DAY 2 - WEDNESDAY, JUNE 11

8:00 am	Registration and Continental Breakfast	
	Session 3 - Controlling and Managing Exposures	**Session Chair - Lily Stauder**
8:30 am	**ISPE Containment Guide** ▶ Fundamental considerations and developing a containment strategy ▶ Primary and secondary containment systems ▶ Associated elements (occupational hygiene, cleaning, administrative)	George Petroka (IES Engineers)
9:00 am	**Ventilation Controls - Effectiveness, Design, and Applications** ▶ Optimized Hood Design for Dust Capture Efficiency ▶ Ventilation System Integration within your Containment Strategy ▶ Exhaust system utilities, filtration, and contained dust collector powder discharge	Robert Hermann (Rheo)
9:30 am	**Providing Comprehensive Potent ADC Research & Manufacturing Capability** Providing facility, equipment, and process interconnectivity to enable API and ADC capabilities in an efficient, rapid manner. ▶ Protect people, product, and facilities ▶ Rapid cost-effective implementation which is “Right First Time” ▶ Sustainable utilization throughout lifespan of equipment/facility ▶ Capability spans preclinical, clinical, and manufacturing	John Roosa (Merck)
10:00 am	**HPAPI Isolator Design and Operation** ▶ Regulations and Standards ▶ Concept > Design process ▶ Ergonomic Verification ▶ Process Equipment Integration and Considerations ▶ Material Transfer and Layers of Containment ▶ Containment Performance	Ryan Knight (Howorth)
10:30 am	Break	
11:00 am	**Meeting the Needs of Today & Beyond: Important Considerations before Renovating Multi-Product Injectable Facilities to Better Handle Highly Potent Compounds** ▶ Clarifying the vision – product considerations & future capabilities ▶ Identifying the Musts vs the ‘Nice-to-haves’ ▶ Minimizing disruption to the existing business	Rich Arnett (Pharmascience)
11:30 am	**Trends in Containment** ▶ Room Concepts ▶ Automation / Robotics ▶ Continuous processes	Michael Maintok (Glatt)
12:00 pm	**Example of the Versatility and Flexibility of a Flexible Isolator System** ▶ Versatile flexible isolator systems for formulation and product development suites ▶ Multi-function individual isolators create an à la carte containment suite ▶ Automation additions and functionality enhancements addressed	Adam Persans (ILC Dover)

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12:30 pm	Lunch	
1:30 pm	Panel Discussion	Above Speakers
	Session 4 - Verifying Control and Continuous Improvement	**Session Chair - Allan Ader**
2:00 pm	**Advancements in Containment Perfomance Assessments: Key Updates from the 3rd Edition of the ISPE Good Practice Guide (GPG) on Standardized Measurement for Equipment Particulate Airborne Concentrations (SMEPAC)** ▶ ISPE Overview and GPG Purpose: The ISPE (International Society for Pharmaceutical Engineering) provides guidance for the pharmaceutical industry on many topics, and the SMEPAC Good Practice Guide aims to standardize measurement practices for assessing the containment performance of pharmaceutical equipment. ▶ Key Updates in the 3rd Edition: This edition includes new and updated content on containment performance assessments, sampling strategies, containment equipment test protocols, data analysis and interpretation, and documentation practices to promote effective risk management and compliance. ▶ Practical Application: The presentation will highlight how the revised SMEPAC GPG is an effective tool for conducting thorough containment performance assessments, focusing on equipment used with potent compounds.	Karen Whitaker (Merck)
2:30 pm	**To Pass or Not to Pass a Containment Performance Assessment – Is That the Question?** ▶ Best practices for containment performance assessments include the use of statistical tools or decision rules in the analysis of the data, for good reason. Simply “eyeballing” the data compared against a target is often insufficient. ▶ The pros and cons of several different approaches based on current standards and best practices will be discussed. ▶ Not all “passing” or “failing” results are equal. Additional factors to consider when either passing or failing will be presented.	Brent Altemose (ALTIH)
3:00 pm	**How Alignment with ISO 45001 Helps Integrate Your OH&S Management** ▶ Whether the management of the OH&S program in an organization is done by one or multiple cross-functional teams, integrated solutions on the market today can enable teams to seamlessly access consistent information and encourage greater collaboration, making workplaces safer and more sustainable. ▶ Learn to build a framework for OH&S maturity, with a proactive emphasis on risk identification and control, and employee engagement by leveraging the ISO45001 framework. ▶ Illustration of how an integrated approach can / has helped decision makers build their business case for program improvements.	Marc Juaire and Lyn Ip (Velocity EHS)
3:30 pm	Wrap-up	Robert Sussman (SafeBridge)
3:45 pm	Adjourn	