2026 SafeBridge® Global Potent Compound Congress & Expo

Agenda

May 20-21, 2026
The W Hotel, Philadelphia

DAY 1 - WEDNESDAY, MAY 20

7:30 am	Registration and Breakfast	
8:30 am	Welcome and Introduction	Robert Sussman
	Session 1 - Recognizing and Identifying Hazards	**Session Chair - William Hawkins**
8:45 am	**Adapting Hazard Assessment & Communication to Navigate the Growing Landscape of Antibody-Drug Conjugates** • A refresh of hazard assessment & document types — which tools to use and when • Antibody-Drug Conjugate overview — what makes ADCs unique and what are some key considerations in assessing their hazards for safety in manufacturing • Best practices in ADC hazard communication — learnings from an occupational toxicologist	Elizabeth M. Vancza (Merck)
9:15 am	**Degrade the Target, Not Your Workforce: Hazards and Exposure Limits for Cereblon Modulators** • Understanding the mechanism of cereblon-modulating drugs and how it leads to durable, high-impact biology • Examining how the pharmacology of cereblon-modulating drugs contributes to occupational hazards • Developing a practical blueprint for establishing health-based exposure limits for cereblon-modulating drugs	Jedd Hillegass (Bristol Myers Squibb)
9:45 am	**Using Models to Assess the Potential Risk of Dermal Contact with Potent Compounds** • Evaluation of potent pharmaceutical compounds with emphasis on the dermal route of exposure • Advancement of in silico and weight of evidence approaches to characterize skin penetration and systemic bioavailability • Development and utility of acceptable surface limits, integrating refined exposure assumptions, handling patterns, and hazard characterization principles	Janet Gould (Trinity Consultants Life Sciences)
10:15 am	Break	
10:45 am	**"No Data Available": Safety Data at the Innovator-Manufacturer Interface** • Intro to discovery & development pipeline & where safety data is developed vs needed • Emerging challenges due to evolving business timelines • Types of data requested and changing nature of such, differences between disciplines (e.g., clinical vs CMO) • Contrast between Innovator & Manufacturer approach • Contrast between internal and external manufacturing • Emerging trends in new molecule evaluation for manufacturing • Plans and recommendations	Michael Marino (Regeneron Pharmaceuticals)
11:15 am	**Case Studies in Hazard Assessment: To be Potent, or Not to be Potent, that is the Question** • Establishing key criteria for potency classification • Defining and differentiating the critical parameters used to categorize non-potent versus potent compounds • Applying case studies to evaluate the hazard • Incorporating case studies and an interactive toxicology quiz to determine Toxicity Categories / Occupational Exposure Bands (OEBs) for Active Pharmaceutical Ingredients (APIs) • Integration of toxicity banding with Environment, Health and Safety (EHS) handling and containment strategies • Aligning toxicity categorization banding systems with EHS handling guidelines and appropriate containment solutions	Joe Galati (Thermo Fisher Scientific)
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	**External Manufacturing Sourcing Due Diligence for Potent Compound Handling** Evaluation of external manufacturing site: • Potent compound program • Competency & resources • Qualitative & quantitative assessments • PPE & RPE programs • Containment strategy & systems • Past experience	Prem Pyreddy (Eli Lilly and Company)
1:45 pm	**CMO Perspective on Audit Preparation and Readiness** • How to be prepared for that next GMP/Regulatory or client audit within a multi-product shared facility which includes high-potent products • The kind of products that inspectors are more interested in and what they are looking for, including controls and risk management • How the approach of certain agencies can be very different	Rich Arnett (PharmaScience)
2:15 pm	**Measured and Managed: Merck's SMEPAC Playbook for Containment Verification** • Hey IH, What's the Design Criteria? How we define and communicate containment performance targets so suppliers, engineers, and operations design, purchase, and qualify the equipment to a measurable protection goal • Verify in Three Acts: FAT → SAT → PQ – Different approaches for research and development vs. manufacturing. Does the current strategy support manufacturing of the future? • Make Performance Durable, Not One and Done – Embed containment verification into written plans, operator training, engineering feedback loops, and periodic re-sampling so controls are continually measured, managed, and improved across their lifecycle • No Respirators, Really? – Case studies on designing to a no-respiratory protection standard	Nicole Wenk (Merck)
2:45 pm	Break	
3:15 pm	**Case Study: API and Surrogate Sampling in R&D Scale-up Activities** • Intro to sampling strategies • Overview of developing a new sampling method with R&D team • Sampling activities using sampling method for specific API • Results • Overview of surrogate method determination with R&D Team • Sampling activities using surrogate • Results • Conclusions	Mary Lucot (Sanofi)
3:45 pm	**Potent Compound Industrial Hygiene Programs: A Value-Added Asset** • Business value can be generated directly or indirectly • Industrial hygiene programs are uniquely positioned to add considerable indirect value to organizations • Several applications of IH programs generating value in areas such as sampling, ergonomics, and business development/retention will be showcased with an emphasis on the CDMO industry	Casey Cosner (Millipore Sigma)
4:15 pm	Panel Discussion	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 - THURSDAY, MAY 21

7:30 am	Registration and Breakfast	
	Session 3 - Controlling and Managing Exposures	**Session Chair - Stephen Nowakowski**
8:30 am	**Comparative Analysis of Flex and Rigid Isolator Systems** • Containment solutions • Fixed isolator systems • Flexible isolator systems • Comparison: Fixed vs. flexible isolator systems • Case Study • Q&A	Norwin Voegeli (Lugaia)
9:00 am	**Powders, Potency, and Painful Lessons: Questions That Drive Safe System Design** • Why containment failures happen after commissioning — and how understanding the full process lifecycle (interventions, cleaning, abnormal operations) changes your design approach • The critical questions engineers must ask early — covering powder behavior, process steps, intervention frequency, and cleaning strategy before a containment solution is selected • How to design for durability — ensuring containment performance holds up through ongoing operations, maintenance, and when a process doesn't go as planned	Robert Hermann (Rheo)
9:30 am	**Large Volume, Bulk Powder Handling with Containment Level <1 microgram/m³ with Applications Presented** • Challenges in reactor vessel charging and packing off materials with low OEL containment requirements • Use a simpler method to charge a reactor than messy, difficult to clean pneumatic transfer systems • Big Bag or DoverPac, methods to bring a clumpy, hydroscopic material into solution with minimal fuss • Explosive hazard? O2 sensitive materials? Trusted weight? Solutions explored	Adam E. Persans (ILC Dover)
10:00 am	Break	
10:30 am	**When Biologics Go Potent: End-to-End Containment for ADC Manufacturing** • Antibody-Drug Conjugates (ADCs): What We Know — Overview of current knowledge around ADC occupational exposure limits (OELs), the role of highly potent payloads, and the containment challenges these compounds introduce • Ask the Experts — Insights from industry experts on the biggest challenges faced when preparing facilities to safely handle ADCs • Typical ADC Development Process & Containment Considerations — Review of key ADC development process steps and appropriate containment strategies for handling materials, samples, and waste throughout development and manufacturing • When Biologics Go Potent — Introducing containment into processes that historically handled non-potent biologics, and the operational and engineering challenges this transition creates	Ryan Knight (Howorth Air Tech)
11:00 am	**Case Study: Containing Blister Filling Operations to Minimize Exposures**	Andy McCreadie (Prosys) & David Phasey (3P Innovation)
11:30 pm	Panel Discussion	Above Speakers
12:00 pm	Lunch	

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	Session 4 - Verifying Control and Continuous Improvement	Session Chair - Allan Ader
1:00 pm	**TBA**	Andrew Lemaire (DEC Group)

1:30 pm	**Containment For Drugs – Another Look At How CFD Is Used**
	• Computational Fluid Dynamics (CFD) is a useful tool to study air movement
	  • Commonly used for clean rooms or HVAC systems
	  • Limited use during design of containment devices
	• Demonstration of CFD in fume and powder enclosure design
	  • Examples of designs and the predicted airflow patterns
	  • Validation of predicted versus actual results
		Allan Goodman (Flow Sciences)

2:00 pm	**New Approaches to Annex 1 Compliant Cleaning & Disinfection Methods** • EU Annex 1 new requirements • Cleaning validation vs disinfectant efficacy • Surface criticality, direct, in-direct, non-product contact • Goals for each SOP? • Test data review • Change control if necessary	Tom Hanney (Benchmark Products)
2:30 pm	Break	
3:00 pm	**Case Study: From Upset to Control: Aerosol Containment in Single-Use Systems, One Year Later** • Recap of initial study outcomes, highlighting potential airborne exposure scenarios, API migration pathways, and resulting recommendations derived from process upset scenarios in single use processing trains • One year later: review of recommendation implementation, with emphasis on practical application and demonstrated effectiveness in reducing potential employee exposure • Focused evaluation of API migration potential at process waste collection tank roof vents and implications for future risk control strategies	Lisa Schubert (Merck)
3:30 pm	**Highly Potent Products in Multiproduct Manufacturing Facilities: Bridging Toxicology and GMP Cross-Contamination Risk Management** • Highly potent products introduce cross-contamination risks that cannot be managed by toxicological limits alone, end-to-end process understanding and oversight is required; they require robust GMP control strategies across facility design, operations, and lifecycle controls • Effective risk mitigation depends on robust toxicological assessment, layered engineering and procedural barriers, including containment design, controlled flows, validated cleaning and analytical methods, disciplined changeover practices, and operational robustness during non-routine conditions where personnel-dependent variability is highest • Cross-contamination control is a lifecycle obligation, requiring verified robust change management and new product introduction processes to ensure containment strategies remain evidenced and validated as facility operations and product portfolios evolve	William Hawkins & Brian Tamashiro (Trinity Consultants Life Sciences)
4:00 pm	Day 2 Closing Comments	Allan Ader