

APPLIED OCCUPATIONAL HYGIENE IN PHARMACEUTICAL INDUSTRIES

Learning Outcomes

- Representative (task-based and full-shift) exposure monitoring. Identifying excursion exposures and addressing challenges in high potent compound exposure monitoring.
- Significance of surface wipe sampling in pharmaceutical industries.
- Likely, API exposure levels, based on pharmaceutical unit operations' exposure profiles.
- Successfully substituted potentially harmful disinfectants.
- Particulate containment technologies and their effectiveness in reducing exposure below API exposure limits. Solvent exposure profile and controls.
- Work practices, zoning, gowning-degowning for potent compounds
- Unique challenges in respiratory protection, including variability in APF.

Abstract

Occupational hygiene is the highest priority in pharmaceutical industries. Potent Active Pharmaceutical Ingredients (APIs) with nanograms per cubic meter exposure limits are handled. The API manufacturing plant uses highly hazardous chemicals like methylene chloride and dimethyl formamide.

This PDC will share lessons learned from 200+ pharmaceutical industries in 20+ countries in exposure assessment and containment verification. Potent compound handling, including enzymes, hazard banding and control banding, exposure controls, work practice, and respiratory protection. Addressing unique challenges in achieving a detection limit lower than the potent compound API exposure limits, particulate containment to reduce exposure below exposure limits, and effective use of respiratory protection will be discussed.

Exposure profile from statistical analysis for 5000+ API exposure and surrogate monitoring results for various pharmaceutical unit operations (e.g., weighing, dispensing, charging, granulation) will be discussed.

Often ignored concerns for disinfectant exposure will be discussed based on a lesson learned from disinfectant exposure assessment.

Agenda

Time	Topic
00:00 – 00:05	Welcome Participants Introduction
00:05 – 00:30	Health Hazards in Pharma Industries - OEB classifications and lessons learned (Potent Vs High Potent, Low Potent also needs attention if controls not provide and large volume used). Non-API potent compounds (e.g., Chemical potency, e.g., Dimethyl Formamide, Sodium Cyanides), Enzymes, Disinfectants
00:30 – 01:00	Exposure Assessment, Containment Verifications – e.g., effective qualitative assessment tools, unique challenges on exposure monitoring for ultra-low OEL compounds, IOM-Vs Disposable Inhalable Sampler, surrogate selection for containment verification, surface wipe sampling and cross contamination of APIs
01:00 – 01:30	Workshop among participants and faculty on health hazards and exposure assessment challenges and solutions
01:30 – 02:00	Break
02:00 – 02:30	Particulate Containment and Exposure Controls – Lab scale to liquid potent APIs, Challenges in containment, rigid Vs. flexible containment – contributory factors for containment failures – Work Practices and culture and behaviours potentially contributing to exposures and solutions.
02:30 – 03:00	Gowning/degowning, Zoning, PPE, and RPE. Protection factor variability for RPE
03:00 – 03:30	Workshop among participants on exposure controls, work practices, PPE, and RPE

Presenters, affiliations, and biography *



**Maharshi Mehta, CIH, CSP, FAIHA,
International Safety Systems, Inc.,
Monmouth Junction, USA**

Maharshi Mehta, CSP, CIH, FAIHA, has 30+ years of experience conducting exposure assessment, training, and potent compound handling advice in 200+ pharma companies. Patricia has 15+ years of experience at pharmaceutical site and also in consulting organizations. Prasanth K, Associate Director, has 12+ years of experience in developing and supporting occupational hygiene programs in 50+ pharma companies.



**Prasanth Kondragunta, ISS EHS
Ireland Ltd, Carlow, Ireland**

Prasanth Kondragunta was a Certified Industrial Hygienist from Board for Global EHS Credentialing (from 2015 to 2022) with 13+ years of experience in conducting Industrial Hygiene and safety assessments at over 150 client sites in 20 plus countries and managing the Europe team of 10 dynamic EHS professionals with International Safety Systems based in Ireland, Dublin.

Presenters, affiliations, and biography *



Patricia McDonnell
Associate Director, Global EHSS
Alkermes Pharma Ireland Limited

Patricia has a BSc(Hons) in Microbiology, MSc in Health and Safety and Ergonomics and PhD in Industrial Hygiene; has worked as a consultant IH across many industries and 15+ years in pharma industry. Experienced in potent compound handling, design of high containment suites, safety culture, occupational toxicology and overseeing global industrial hygiene program.