WORKSHOP SERIES ON OCCUPATIONAL HEALTH, HYGIENE & SAFETY

ASSESSMENT AND CONTROL OF WORKER EXPOSURE TO POTENT DRUGS & CHEMICALS

At: INDIAN INSTITUTE OF CHEMICAL TECHNOLOGY, HYDERABAD, ANDHRA PRADESH, INDIA
Wednesday, Feb. 10 – Saturday, Feb. 13, 2010

nayati INTERNATIONAL
Working For Better Quality Of Life Through Research and Education

Indian Institute of Chemical Technology Hyderabad, Andhra Pradesh

National Institute for Occupational Safety & Health, USA

This workshop is for you, if you:

- ✓ Are a Health and Safety Professional
- ✓ Are responsible for health and safety for your work force and want it to be better
- ✓ Want your organization to gain competitive advantage acquiring skills to implement OHS programs of international standards.
- ✓ Want to network and participate in building a profession committed to "Safe Work"
- ✓ Want to update or acquire OHS skills and tools for better job performance
- ✓ Want to Increase your employability

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Meet the Experts :

Ms. Donna Heidel, CIH, is currently the Research Industrial Hygienist and Coordinator for the Prevention through Design program at NIOSH, USA. Ms. Heidel has 25 years' experience in the health care industry, spending 15 years building a world-class, global, integrated occupational toxicology and industrial hygiene program at Johnson & Johnson, a decentralized company consisting of 230 operating companies in 57 countries; implemented their global health hazard and control banding programs. Internationally, she established effective industrial hygiene processes in 32 operating companies in Europe, the Middle East and Africa and supported capital projects throughout North America, Puerto Rico, Europe, China, Singapore, Japan, and Latin and South America. Ms. Heidel is an expert in hazard and risk assessment and exposure control of highly potent compounds with extremely low occupational exposure limits, including cancer chemotherapy drugs and nanoparticles.

David M. Eherts, Ph.D., CIH, is currently the Vice President, Environmental Health and Safety, Sikorsky Aircraft Corporation. Dr. Eherts has decades of experience in the Pharmaceutical industry: He was Merck's Global Occupational and Environmental Toxicologist after which he joined Rhone-Poulenc (later merged to become sanofi-aventis) as Site Director of EHS for a 2,000-person R&D site; as global head of EHS for R&D and as Worldwide Director of Occupational Health and Industrial Hygiene; he was the Global Director of Industrial Hygiene, Environment and Product Stewardship at the company's U.S. headquarters in New Jersey. He later joined Purdue Pharma as Executive Director of EHS at its corporate headquarters in Stamford. Outside Sikorsky, Dr. Eherts heads the Return-on-EHS-Investment (ROEHSI) Taskforce for the Organization Resources Counselors (ORC) group and is a frequent presenter at design and aviation safety conferences, occupational toxicology roundtables and other industry events.

PLEASE SHARE THE INFORMATION WITH YOUR COLLEAGUES, FRIENDS AND PEERS

Registration forms can be found at www.nayati.org

Contact nayati at services@nayati.org

Looking forward to seeing you

Curriculum Summary (Daily agenda will be posted on the web site shortly)

Identification of Occupational Health Issues Associated with Active Pharmaceutical Ingredients

- Pharmacology and toxicology of active pharmaceutical ingredients (APIs), including high-potency APIs and chemical process intermediates (CPIs)
- Occupational routes of exposure
- Interpretation of in-silico, in-vitro and animal testing and human clinical data and application to the derivation of safe worker exposures
- Occupational toxicology testing and interpretation of data

Developing Health Hazard Bands and Occupational Exposure Limits for APIs

- Health Hazard Bands
  - Default" health hazard bands for new molecular entities; Health hazard banding for investigational new drugs and APIs and CPIs with limited toxicology and/or human health data
  - Workshop #1: Developing a health hazard band for an investigational new drug
- Occupational exposure limits
  - Where to find OEL and communicate information for APIs (e.g., safety data sheets); Understanding the basis for OEL establishment, including assumptions; Developing OELs
  - Workshop #2: Developing an occupational exposure limit for an API

Qualitative Risk Assessment and Exposure Monitoring of Workers

- Industrial hygiene sampling and analytical methods
- Development and validation of new methods: Air sampling; Surface sampling
- Industrial hygiene qualitative risk assessment
- Workshop #3: Qualitative risk assessment of pharmaceutical processes
- Conducting exposure monitoring surveys
- Interpreting exposure monitoring results
- Surrogate testing
- Selection of appropriate surrogates
- Interpretation of results
- Workshop #4: Interpreting IH data sets
- Communicating exposure monitoring results with Management; Workers; Occupational health (physicians, nurses)

Controlling Worker Exposure Risks (A Control-Banding Approach)

- Principles of control banding :
  - History/successes in the pharmaceutical industry; 3, 4 and 5 band models; Development of control band technology based on exposure monitoring results, published data, and/or peer data
- Appropriate task-based controls/containment for bands and range of expected exposure controls
- Selecting the appropriate control band based on the health hazard band/OEL and determinates of exposure
  - Physical form; Task duration; Amount; Dilution with excipients; Process
- Control band technology for low, moderate, high, to extremely high potency APIs
- Workshop #5: Selecting the appropriate control band
- Verifying controls
- Use of work practice controls and PPE to supplement engineering controls
- Workshop #6: PPE selection, donning, doffing

Application of Prevention through Design to the Pharmaceutical Drug Discovery, Drug Development and Drug Manufacturing Process, Facilities and Equipment

- Prevention through Design applied to the drug development process
  - Laboratory, kilo lab, pilot plan, clinical supplies manufacturing and scale-up for manufacturing H&S activities to support each stage of development
- Prevention through Design applied to drug synthesis and formulation processes
  - Synthesis and formulation process considerations for high potency APIs
- Prevention through Design applied to facility design and equipment selection
  - Appropriate levels of containment and control during facility and process equipment design, specification, and commissioning
- Developing effective business cases