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PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Supplier Conference

Enhancing Supplier Capabilities: A Deeper Dive into Responsible Business Practices

Novartis Knowledge Center | Hyderabad, India | May 8 - 11, 2017

Program Agenda

A 3-day program to further develop the knowledge and understanding of the skills required to manage key areas of labor and EHS-specific topics in the pharmaceutical / bio-pharmaceutical industry. The conference will be preceded by an optional "Early-Bird" Pre-Conference session.

PRE-CONFERENCE SESSIONS – **Monday, May 8, 2017**

Please pick between sessions A & B for the pre-conference day

A) PSCI Basics

Objective: This course will teach the fundamentals of the PSCI Principles and Implementation Guide and will be an open session giving practical guidance for those getting started in meeting the PSCI Principles. The course will focus on the tools already available and give attendees the opportunity to learn basic skills in key HSE topics as shown below.

Target audience: **NOTE: Available to the first 50 registrants only.** This programme is designed for HSE professionals to prepare them for PSCI on-site technical audits.

08:30 – 09:00	Registration
09:00 – 09:15	Welcome and Introduction **Birgit Skuballa**, PhD, Head of HSE Management Systems & Audits, Bayer, PSCI Vice Chair
09:15 – 09:45	PSCI Auditing Overview – how it is supposed to work & PSCI resources **Birgit Skuballa**, PhD, Head of HSE Management Systems & Audits, Bayer, PSCI Vice Chair
09:45 – 10:30	Why this course – Lessons learned from first-time PSCI audits **Roberta Haski**, Health, Safety & Environment Advisor, Elanco Animal Health
10:30 – 11:00	BREAK
11:00 – 12:00	Fundamental Principles of Environmental Fate concerns **Dr. Daniel Rehm,** HSE Associate –EEM-API Elanco Animal Health – Environmental Performance Global Perspective – PSCI principles –PIE / AMR – Technical Requirements -Why your API may or may not be effectively removed and what you may need to do – What do the terms mean: PNEC, AMR – Mass Balance tools

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12:00 – 13:00	Risk Assessment Tools - understanding what is involved and how to get technical help locally **Pierre Reuse**, PhD, Head HSE & BC Third Party Inspection and Compliance, Novartis – Combustible Dust Assessment – HazOp / Process Hazard Analysis
13:00 – 14:00	LUNCH
14:00 – 15:00	RED Flag Concerns in General Safety **Roberta Haski**, Health, Safety & Environment Advisor, Elanco Animal Health – Dangerous Work Programs – Serious Injury Fatality Programs – Confined Space / Hot Work / Electrical / Lockout_Tagout / Contractor Safety
15:00 – 15:45	Industrial Hygiene and Occupational Health Basics **Vijaya Kumar Bendi**, EHS&S External Supply Manager Johnson & Johnson – Basic hazard characterization (including control banding) – Risk assessments (including monitoring – PPE fundamentals – Engineering controls - basics
15:45 – 16:15	BREAK
16:15 – 16:45	Open Forum – answering specific attendee's technical PSCI questions – Speakers will be available to answer technical questions on all topics discussed
16:45 – 17:30	Closing Audit Findings **Birgit Skuballa,** PhD, Head of HSE Management Systems & Audits, Bayer, PSCI Vice Chair – Closing meeting, audit findings and corrective action plan – Demonstrating closure – Follow-up visits – Management support for the needed HSE culture
17:30	**End of Pre-Conference Session A**

B) Chemical Hazard Assessment and the Prevention of Runaway Reactions

Objective: This course will teach attendees how to identify the thermal and chemical reactivity hazards associated with a chemical process based on the principles of scale-up and development. Attendees will learn how to conduct risk analysis of reactive systems to ensure safety prior to process operations and how to interpret the results of preliminary screening tests using chemical engineering concepts relating to safe plant operation. The course will discuss characterization of thermal runaway reaction through calorimetry methods and the latest techniques for process optimization.

Target audience: **NOTE: Available to the first 50 registrants only.** Chemical engineers, process engineers/scientists, plant/process safety/risk managers, facilities managers and others who need to understand the risks and hazards that can lead to accidents, injuries, property damage and business interruptions to the plant.

08:30 – 09:00	Registration
09:00 – 09:15	Welcome and Introduction **Dr. Swati Umbrajkar, PhD,** Manager, Chemical Process Evaluation Group, DEKRA
09:15 – 09:45	How and Where Hazards Arise

	– Case Histories involving Runaway Reactions and Current Legislation
09:45 – 10:30	Chemical Reaction Hazard (CRH) Assessment Strategy – CRH vs. Process Life Cycle
10:30 – 11:00	BREAK
11:00 – 12:00	Fundamental Principles of Scale-Up and Reaction Runaway – Vapor Pressure Effects – Heat of Reaction – PHI Factor – Adiabatic Temperature Rise – Reaction Rate – Reaction Kinetics – Kinetics of Heat Release/Loss – Heat Loss Considerations – Reactant Accumulation
12:00 – 12:30	Small Scale Screen Tests
12:30 – 13:00	Identification of Highly Energetic Materials – Strategy for Assessing Explosivity – Oxygen Balance – CHETAH Calculations – Testing for Explosive Properties
13:00 – 14:00	LUNCH
14:00 – 15:00	Reaction Characterization Through Calorimetry Characterization of Thermal Runaway Reaction Through Adiabatic Calorimetry – Accelerating Rate Calorimetry – Adiabatic Dewar Calorimetry – Pressure Compensated Calorimetry Inherently Safe Process – Safe Process – Integrating Safety Considerations into Process Design
15:00 – 15:45	Problem Solving Sessions
15:45 – 16:15	BREAK
16:15 – 16:45	Video Presentation
16:45 – 17:30	Q&A/Group Discussion Quiz Course Evaluation Feedback Form
17:30	**End of Pre-Conference Session B**

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CONFERENCE DAY 1 – **Tuesday, May 9, 2017**

08:30 – 09:00	Registration
09:00 – 09:25	PSCI Board Welcome and Opening Address **Birgit Skuballa,** PhD, Head of HSE Management Systems & Audits, Bayer, PSCI Vice Chair
09:25 – 09:45	Responsible Procurement **Wolfgang Rauch**, Chief Procurement Officer, Novartis

Process Safety Management Session

Objective: To provide an in-depth overview of Process Safety Management targeting specific topics as instructed by highly recognized subject matter experts. Examples related to the pharmaceutical industry will be used to demonstrate key concepts in this session.

Target audience: EHS practitioners, Managers, including shop floor supervisors

09:45 - 10:45	Quantitative Risk Assessment in Pharmaceutical Industry Introduction to Quantitative Risk Assessment and how the QRA tool can be used to estimate the risk associated with the identified hazards. **Sakila Bhadu,** Dekra Senior Manager
10:45 – 11:15	BREAK
11:15 – 12:15	PSM in the Pharmaceutical Industry and Enterprise Sustainable Development Brief introduction to OSHA and CCPS PSM programs: Suggestions and tips for building robust PSM systems for pharmaceutical companies **Jitendra Kumar**, Director, DEKRA
12:15 – 13:15	LUNCH
13:15 – 14:15	Typical Ignition Source Analysis in Pharmaceutical Plants Description of 13 potential ignition sources and methods for their assessment and control **Naveen D,** Assistant Manager, DEKRA
14:15 – 15:00	Fire and Explosion Hazards in the Pharmaceutical Industry Introduction to fire and explosion hazards associated with the processing/handling of combustible dust and flammable gas/vapor/liquid and practical measures for their control **Sunil Ramdas Deshmukh,** DEKRA Senior Process Safety Consultant
15:00 – 16:00	Hazardous Area Classification Introduction to hazardous area classification based on NFPA and IEC standards **Pierre Reuse, PhD**, Head HSE & BC Third Party Inspection and Compliance, Novartis
16:00 – 16:30	BREAK
16:30 – 17:30	Process Safety Accidents in Pharmaceutical Industry and Lessons Learned Description of several common accidents and typical approaches used to conduct the accident investigation **Sunil Ramdas Deshmukh,** Senior Process Safety Consultant, DEKRA
17:30	End of Conference Day 1

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CONFERENCE DAY 2 – **Wednesday, May 10, 2017**

08:30 – 09:00	Registration

Sustainability & Environmental Performance Management

Objective: This session is designed to highlight the critical importance of sustainability and environmental management programmes.

Target audience: Managers and site leaders responsible for these subject areas

09:00 – 10:00	Environmental Compliance Emerging Issues and Regulatory update **Hitesh Kaushik (Hons), MIGS,MIRC**, Country Manager, Golder Associates Consulting
10:00 – 11:00	Pharmaceuticals in the Environment (PiE) / Anti-Microbial Resistance (AMR) **Bharat Shevkar**, EHS&S External Supply Manager**,** Johnson & Johnson
11:00 – 11:30	BREAK
11:30 – 12:30	Initiating a Waste Management Assessment Programme **David Chng**, Director of Asia-Pacific/Oceania, CHWMEG
12:30	LUNCH

Industrial Hygiene Session

Objective: To provide an in depth understanding on selected industrial hygiene challenges in the pharmaceutical / bio-pharmaceutical industry. This session will cover relevant best practices and state of the art techniques for potent compound handling and protection.

Target audience: EHS practitioners, managers, including shop floor supervisors

14:00 – 15:00	PSCI Potent Compound Banding System **Pinky Bhatt,** India Project Manager, International Safety Systems
15:00 – 15:45	LEV and HVAC concepts and design **Arun Verma**, Business Lead for Containment Technology, Camfil, India
15:45 – 16:00	BREAK
16:00 – 16:45	Potent Compound Containment concepts and applications **Anil Nair**, Business Lead for Dust Collection Technology, Camfil, India
16:45 – 17:30	Dust Combustibility and design of protection systems **Latheesh Mohanan**, Application Lead for Dust Collection Technology, Camfil, India
17:30	End of Conference Day 2

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CONFERENCE DAY 3 – **Thursday, May 11, 2017**

08:30 – 09:00	Registration

Business Ethics and Labour Rights Session

Objective: To provide a clearer view of the business ethics and labour rights issues concerning the pharmaceutical industry, as well as the relevant best practices suppliers can draw upon for implementation of the PSCI Principles. The session includes a mixture of presentations and case study examples.

Target audience: Managers and site leaders responsible for these subject areas

09:00 – 11:00	Business Ethics Insight on PSCI ethical principles, a deep dive into compliance topics through case studies, and a walk through the "Compliance" toolbox. **Rincy Joseph**, Corporate Health, Safety and Sustainability Expert, Bayer AG
11:00 – 11:30	BREAK
11:30 – 12:30	Business Ethics in India **Anuranjan Prasad**, Director Legal – Emerging Asia, Baxter
12:30 – 13:30	LUNCH
13:30 – 14:30	Human Rights Outlook **Sarah Kerrigan**, Head of Human Rights Strategy, Verisk Maplecroft
14:30 – 15:00	Why and how do we approach Labour Rights? **Stephan Tschudin**, Global Head Compliance Procurement, Novartis
15:00 – 15:45	Labour Rights – forced labour, migrant workers, fair working conditions **Dinesh Subhedar**, Responsible Procurement Manager, Asia, Novartis **Houtan Homayounpour**, Project Manager, ILO
15:45 – 16:00	BREAK
16:00 – 16:45	Opportunities across the supply chain, panel discussion **Sarah Kerrigan**, Head of Human Rights Strategy, Verisk Maplecroft **Anuranjan Prasad**, Director Legal – Emerging Asia, Baxter **K.V. Raghava Reddy,** Sr. GM – HR, Hetero Drugs Ltd. **M. Prabhakar,** Associate VP – HR, Hetero Drugs Ltd. **Shilpi Sahay,** AGM HR, Gland Pharma Ltd. **Girish Haldankar,** Deputy General Manager**,** Global Sourcing, Sandoz **Stephan Tschudin**, Global Head Compliance Procurement, Novartis **Rama Rao VVS,** VP & Head --Corporate HR & Administration, Sai Life Sciences Limited
16:45 – 17:00	Closing Comments **Annabel Buchan Sitrângulo**, Partner, Carnstone Partners LLP, PSCI Secretariat
17:00	Conference adjourns

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