

Occupational Hygiene aspects in the Pharmaceutical Industry 1

SYMPOSIUM

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The objective of this symposium is to cover specific topics of Industrial Hygiene in the Pharmaceutical Industry. Developing, implementing and supporting an Industrial Hygiene program in a Pharmaceutical Industry creates specific challenges and requires therefore specific expertise to fully understand the broad range of hazards, related risks and exposure evaluation. During this symposium new insights and case studies will be shared by Senior Industrial Hygienists and Occupational Toxicologists with an extended level of experience supporting Global Pharmaceutical Companies. This will help the Occupational Hygienist working at a Pharmaceutical Company to stay up to date and to connect with peers dealing with similar challenges in this environment. The various use of the terms and their inconsistent definitions of highly hazardous or highly potent drugs in the companies and by the regulators may impact pharmaceutical manufacturing, as well as stakeholders downstream, such as health care personnel. We will address the issues with the NIOSH hazardous drugs list and recent attempt by the EU commission to generate a similar list and how they are being addressed by pharma. Important results of a recent scientific study performed on the use of the IOM dust sampling head to evaluate the exposure to Active, Pharmaceutical Ingredients will be shared. In addition, 2 recent case studies will be presented: Monitoring results of drug product exposure during reconstitution powder for oral solution and Enzymes Exposure Assessment. The last 2 presentations will focus on controlling the exposure. A new online tool, which uses exposure modelling based on the Advanced Reach Tool to assign control banding strategies, will be shared for the first time. Finally an overview of Personal Protective Equipment Management in the Pharmaceutical Industry will be presented.

Are we talking the same language: the case of highly hazardous/potent drugs

Ester Lovsin Barle (Takeda Pharmaceuticals International AG, Switzerland)

The SWEET science of API Analysis

Michel Vangeel (Johnson & Johnson, Belgium)

Monitoring results of drug product exposure during reconstitution powder for oral solutions (POS)

Cordula Meier (Roche, Switzerland)

MODERATOR



Michel Vangeel

Michel is leading since 2016 the Global Occupational Hygiene program at Johnson & Johnson. Before he was managing the Occupational Hygiene and Ergonomics program at the Janssen Campus sites in Belgium. He is a Certified Industrial Hygienist, Ergonomist and Safety Professional working 35 years for the company. He is the President of the Belgian Society for Occupational Hygiene and representing BSOH as Board Director in the International Occupational Hygiene Association (IOHA). He also is a guest Lecturer at the University of Leuven in Belgium.

SPEAKERS



Ester Lovsin Barle

Ester Lovsin Barle, DVM, MSc, PhD, MScTox is the Head of Product Stewardship and Health at Takeda. She lives in Zurich, Switzerland. Her responsibilities include Safety Data Sheet process, maintaining article and material regulatory compliance and scientific development and cross-organizational implementation of health based exposure limits (HBEL) in support of research and manufacturing in Takeda globally, global implementation of occupational hygiene and product stewardship sustainability activities. Previously she has held corporate positions at Lonza and Novartis. She received her PhD in veterinary sciences from University of Ljubljana, Slovenia and a second masters degree in toxicology and risk assessment from Medical University in Vienna.



Cordula Meier

Industrial Hygienist at Roche Headquarter Basel. All important Pharma divisions are represented on the site: Research, chemical/ pharmaceutical development, production (biotech, pharma, chemical, packaging). I am a safety engineer and swiss certified IH. I am working at Roche since 2014, previously I worked 10 year for Novartis My special expertise are pharma production, noise, monitoring of chemicals.