

3rd Annual MarketsandMarkets High Potent Medicines Conference

28th - 29th May 2019 • Milan, Italy

Event Overview

Drug product development for highly potent APIs (HPAPIs) can be challenging. Complications with the interface between operations in drug substance and drug product handling can result in increased program complexity and cost. The growth in this market is driven by factors such as increasing demand for oncology drugs, growing demand for antibody-drug conjugates, increasing focus of leading pharmaceutical companies on HPAPIs, advancements in HPAPI manufacturing technologies, and growing focus on precision medicine.

MarketsandMarkets is proud to announce the **3rd Annual High Potent Medicines Conference** to be held on **28th-29th May 2019 in Milan, Italy**. The conference will focus on case studies related to development, rapid scaling, validation and commercial production of HPAPI drug substance, as well as integrated containment requirements for particle engineering and drug product. The 2-day event will share the latest industry trends, advancements and future growth in the highly potent medicines market where leading industry experts will discuss the strategies for both pharma and CMO's by presenting expert keynote presentations, live case studies and breakthrough panel sessions.

Key Highlights

- Process validation considerations and scale-up in high potent compounds production
- Strategies for effective management of high potent medicines supply chain
- Overcoming regulatory challenges for ADC's
- Validation of cleaning procedures to avoid cross contamination
- Containment and safety of pharmaceutical toxic powders
- Managing cleaning validation in biologics
- Risk identification and mitigation for HPAPI's

Who should attend?

From pharmaceutical manufacturing and Biopharmaceutical manufacturing

Chief executives, VP's, Directors, Heads, Leaders, Senior Managers, Principal Scientists, Principal Toxicologists, Toxicologists, Fellows, Investigators working in the following departments;

Departments:

- | | |
|--|--|
| • Research & Development | • Environmental, Health & Safety (HSE) |
| • Manufacturing/Operations/Production | • Occupational Toxicology |
| • Maintenance | • Industrial Hygiene |
| • Engineering | • New Products |
| • Quality | • Product Quality |
| • Regulatory | • Innovations |
| • Risk Assessments | • Regulatory |
| • Laboratory Services/Analytical | • Validation |
| • New Technologies | • Formulation Development |
| • Process Development/Technical transfer | • External Supply |

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Scientific Advisory Panel



Ester Lovšin Barle
Head, Corporate
Toxicology
Lonza, Switzerland



Richard Denk
Head, Sales
Containment
Skan AG, Switzerland

Expert Speaker Panel



Ester Lovšin Barle
Head, Corporate
Toxicology
Lonza, Switzerland



Richard Denk
Head, Sales
Containment
Skan AG, Switzerland



Andreas Schreiner,
Manufacturing Science
& Technology (MS&T),
Validation Head,
Novartis, Switzerland



Michel Crevoisier
Senior QA Expert
**Ex-Novartis,
Switzerland**



Stefano Butti
Technical Sales Director
**Food Pharma Systems,
Italy**



Andrew Walsh
President
**Centre for
Pharmaceutical
Cleaning Innovation,
USA**



Dean Calhoun
CEO
**Affyglity Soutions,
USA**



David O'Connell
Director, Scientific
Affairs
PCI Services, UK



Pascal Michoux
Vice President, Bio
Global EHS
**TAPI-Teva Active
Pharmaceutical
Ingredients, Italy**



Rudolf Bechter
Managing Director
**Bechter Consulting
GmbH, German**



Chris Seaman
Managing Toxicologist,
Safebridge Europe, UK



Michael Woelfle
Validation Expert
Novartis



Marc Abromovitz
Director, Occupational
Health and Hygiene
Novartis, USA



Todd Davidson
Associate Director,
Environmental Product
Stewardship
**Bristol-Myers Squibb,
USA**



Andrea Messori
Lead Process Engineer
Process Service, Italy

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Day 1, 28th May 2019

08:15	Registration
08:55	Welcome note from MarketsandMarkets
09:00	Opening Remarks from the Chairman
09:10	Keynote Presentation

Process Development and Scale up

09:45	Manufacturing strategies for highly potent API's
10:20	Morning Refreshments and Poster Presentation One-to-One Networking Meetings
11:10	The development and manufacture of HPAPI drug products throughout the clinical phases • Learn about the complexities for each of the clinical phases from drug in capsule to complex formulations • How to manage high potent API through to commercial supply David O'Connell , Director, Scientific Affairs, PCI Services, UK
11:45	Solution Provider Presentation; Please contact arjun.kar@marketsandmarkets.com
12:20	Consolidating IH programs and Potent Compound controls to enhance Process Safety Management effectiveness Pascal Michoux , Vice President, Bio Global EHS, TAPI-Teva Active Pharmaceutical Ingredients, Italy
12:55	Lunch and Poster Presentation One-to-One Networking Meetings
13:55	HP APIs Engineering – key considerations in HP APIs facilities design • High potent definition, exposure risks and containment strategies • HP APIs engineering project milestones • Facility conceptual design key considerations Andrea Messori , Lead Process Engineer, Process Service, Italy

Regulatory Landscape

14:30	Health-Based Exposure Limits: How Do The EMA's Q&As Compare with New and Upcoming ASTM Standards? • Overview of the new ASTM E3106 Cleaning Standard • Science and Risk based Cleaning Validation following ICH Q9 • EMA's Q&A 7&8: Case Study on Implementing Visual Inspection Andrew Walsh , President, Centre for Pharmaceutical Cleaning Innovation, USA
15:15	Ten common occupational health and safety audit findings from High Potency API facilities in the developing world • Despite wide-spread knowledge of the clear hazards of HPAPIs, there continues to be the recurring occurrence of occupational health and safety deficiencies at HPAPI manufacturing facilities, especially in emerging markets • In this session, the presenter will provide an overview of emerging markets for manufacturing HPAPIs, and present the ten most common occupational health and safety audit findings from these manufacturers Dean Calhoun , CEO, Affygitly Soutions, USA
15:50	Afternoon Refreshments and Poster Presentation One-to-One Networking Meetings
16:30	Break out session
17:05	Closing Remarks from the Chairman
17:10	Drinks Reception & Networking End of Day 1

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Day 2, 29th May 2019

08:15	Registration
08:55	Welcome note from MarketsandMarkets
09:00	Opening Remarks from the Chairman
09:10	Keynote Presentation

Containment and Handling

09:45	Trends in Containment and outlook • What have we learned the last 20years on Containment • What are the trends • Where is the future in Containment in API, OSD or BioTech and why Richard Denk , Head, Sales Containment, Skan AG, Switzerland
10:20	Morning Refreshments and Poster Presentation One-to-One Networking Meetings
11:10	Solution Provider Presentation; Please contact arjun.kar@marketsandmarkets.com
11:45	Containment and safety of pharmaceutical toxic powders

Cleaning Validation and Industrial Hygiene

12:20	The sky is not the limit; HBELs are • How to do a competent toxicological evaluation of HPAPI • How to integrate the process of toxicological evaluation of HPAPI into the business • The added value of HBELs Ester Lovšin Barle , Head, Corporate Toxicology, Lonza, Switzerland
12:55	Lunch and Poster Presentation One-to-One Networking Meetings
13:55	Cleaning and Validation in API manufacturing; Challenges and Solutions • Particularities of multipurpose/multiproduct facilities • Focus cleaning validation on critical situations? • Cleaning risk assessment based on HBEL • Cleaning Validation is Process Validation Michel Crevoisier , Senior QA Expert, Senior QA Expert, Ex-Novartis, Switzerland
14:30	Cleaning Validation as one driver to prevent cross-contamination • Introduction to health based exposure limits • Regulatory requirements and audit experience • Case study Andreas Schreiner , Manufacturing Science & Technology (MS&T), Validation Head, Novartis, Switzerland
15:05	Break out session
15:40	Closing remarks from the Chairman
15:45	End of Conference