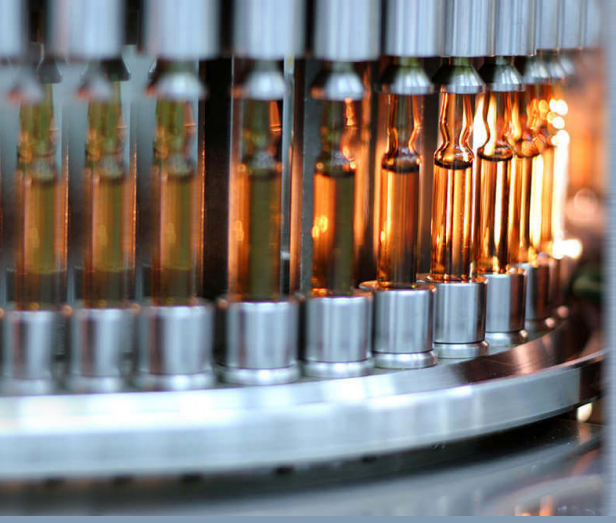


3rd Annual MarketsandMarkets High Potent Medicines Conference

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 breathrough 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?

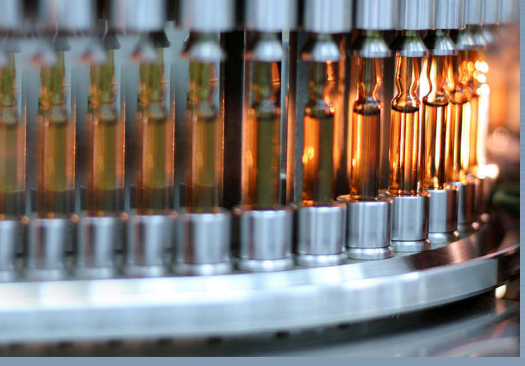
From pharmaceutical manufacturing and Biopharmaceutical manufacturing

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

Departments:

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

For more information please contact Amit at **amit.shelke@marketsandmarkets.com | +91 20 4859 8285**



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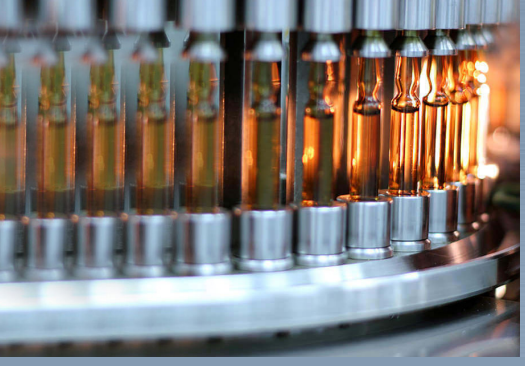

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Scientific Advisory Panel

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
Affygility Soultions, 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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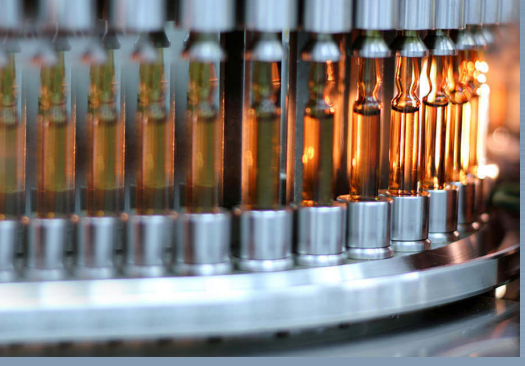

3rd Annual MarketsandMarkets High Potent Medicines Conference

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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

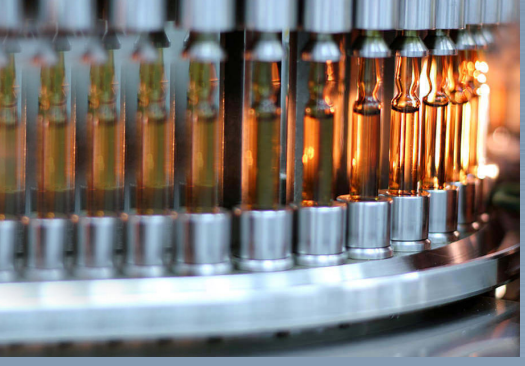
Dean Calhoun, CEO, **Affygility Soultions, USA**

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**