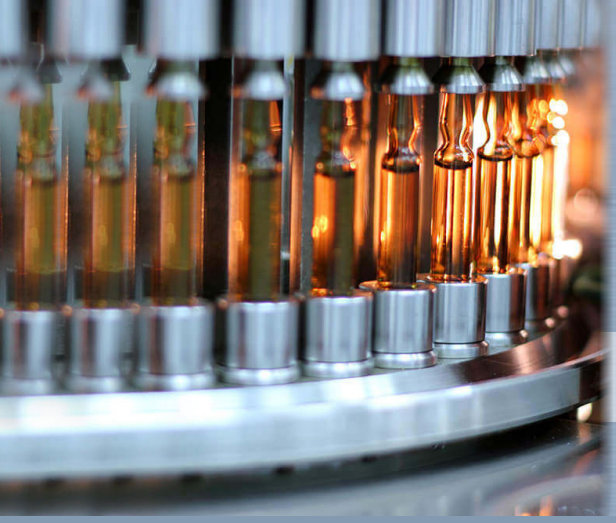


The High Potent Medicines Conference

Exploring comprehensive strategies on containment, robustness, scalability & safety of highly potent compounds

6th-7th June 2017, Steigenberger Hotel, Berlin, Germany

Event Overview

The manufacturing of high potent medicines has provided many challenges in terms of safe production, containment and handling due to their toxic nature. But due to changing strategies and supportive regulatory framework to protect patent infringement, pharmaceutical companies are now focusing on commercialization and development of the high potent medicines to build their pipeline of products.

While most of the highly potent drugs under development are for oncology treatments, there are also new advances in high potent compounds manufacturing particularly antibody-drug conjugates (ADC's) which are the fastest growing segment as they deliver the cytotoxic drugs to the targeted cells.

MarketsandMarkets is proud to announce **The High Potent Medicines Conference to be held on 6th-7th June 2017 in Berlin, Germany.** The conference aims to focus on sharing the current market trends, technological advancements and future challenges in the high potent medicines industry where the leading experts from the industry will discuss the strategies for both in-house manufacturing and outsourcing by presenting expert keynote presentations, live case studies and breakthrough panel discussions.

Key Highlights

- **Process validation considerations** and **scale-up** in high potent API production
- **Strategies** for effective **outsourcing partnership**
- **ADC's requirements** on high containment processing
- **Validation of cleaning procedures** to avoid **cross contamination**
- **Containment and safety** of **highly potent API's**
- Managing cleaning validation in **API small molecules**
- Linking **PDEs, OELs and Banding**

Who should attend?

From pharmaceutical and Biopharmaceutical manufacturing:

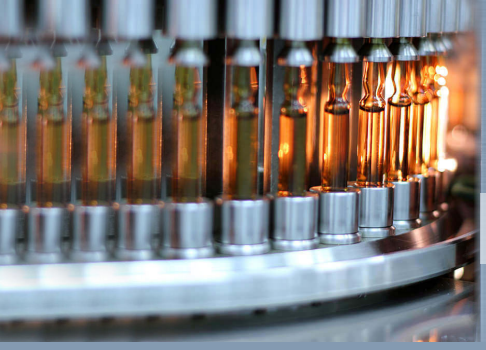
Chief executives, VP's, Directors, Heads, Leaders, Senior Managers, Principal Scientists, Principal Toxicologists, Toxicologists, Fellows, Investigators working in:

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

Why attend?

- Utilizing the best practices to ensure safe and efficient production of high potent medicines
- Training sessions on complex high potent compounds handling and containment issues
- Understanding the updated regulatory guidelines in the HPAPI process
- Implementing response plans to react to an unplanned event
- Knowing the outsourcing strategies to effectively build a reliable supply chain

For more information please contact Salil at **salil.kanwar@marketsandmarkets.com | +91 20 301 08285**



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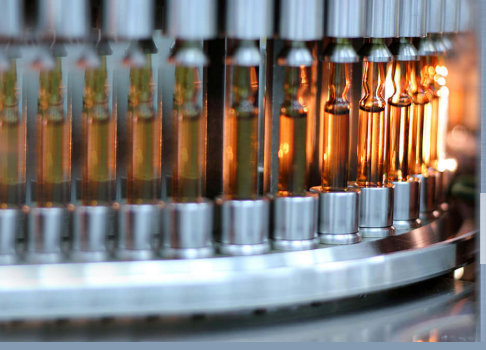

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Advisory Committee

Ester Lovšin Barle, Head, Health Hazard Assessment, **Novartis, Switzerland**

Juergen Knoebel, Head Small Molecules Quality Operations, **F.Hoffmann La Roche AG, Switzerland**

Expert Speaker Panel

Ester Lovšin Barle, Head, Health Hazard Assessment, **Novartis, Switzerland**

Juergen Knoebel, Head Small Molecules Quality Operations, **F.Hoffmann La Roche AG, Switzerland**

Pascal Drago, Principal Technical Manager, Validation & Operations (PTQSP), **F.Hoffmann La Roche AG, Switzerland**

Richard Denk Head, Sales Containment **Skan AG, Switzerland**

Jason Hamm, Director, Chemical Development Operations, **Bristol-Myers Squibb, USA**

Jorge Guerreiro Facilities Manager, R&D **Hovione, Portugal**

Martin Butschies, Head of Laboratory, Process Development Chemicals, **Boehringer Ingelheim, Germany**

Helena Hemming, Senior Toxicologist, **AstraZeneca, Sweden**

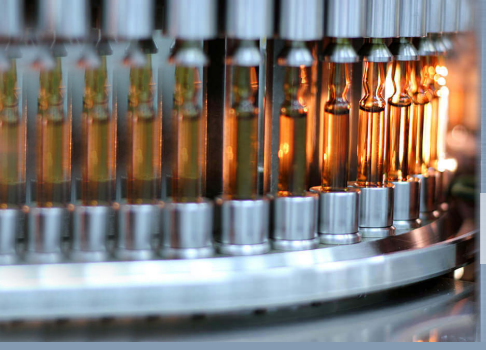
Timothy Briggs, Chair Professional Standards Committee, **Leeds Beckett University, UK**

Maxime Lefebvre Head of Department Pilot Plant **Oril Industrie-Servier, France**

Martin Axon Principal Occupational Hygienist **SafeBridge Europe, UK**

Claudio Salvagnini Sales Director **Minakem High Potent, Belgium**

Karina Versyck Lead, Global Cleaning API Platform **Janssen Pharmaceuticals, Belgium**



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Day 1, 6th June 2017

08:15 **Registration**

08:55 **Welcome note from MarketsandMarkets**

09:00 **Opening Remarks from the Chairman**

09:10 **Keynote Presentation: Manufacturing Strategies for Highly Potent API's**
- Containment controls utilized in API plants for HPAPI's
- Process development - From clinical to manufacturing scale
- Criteria for selecting an external vendor for the manufacture of HPAPI's

Jason Hamm, Director, Chemical Development Operations, **Bristol-Myers Squibb, USA**

Process Development and Scale up of HPAPI's

09:40 **Challenges during the development of chemical processes of HPAPIs – from lab to pilot plant scale**
- Overcoming new challenges faced while handling HPAPIs in lab and pilot plant
- Concepts for workers' safety during process development
- Exposure minimization and risk mitigation measures

Dr. Martin Butschies, Head of Laboratory, Process Development Chemicals, **Boehringer Ingelheim Pharma GmbH & Co. KG**

10:15 **Integrating safe handling of HPAPIs under an R&D state of the art facility**
- Hovione Potent Classification and containment strategy
- Designing a new building from scratch for HPAPIs chemistry and formulation development
- Working with suppliers to improve containment equipment
- Qualification/surrogate testing and training

Jorge Guerreiro, Facilities Manager, R&D, **Hovione,** Portugal

10:45 **Morning Refreshments and Poster Presentation | One-to-One Networking Meetings**

11:35 **HPAPI manufacturing: In-house or Outsourced manufacturing?** (Panel Discussion)
- Increasing costs of R&D
- Regulatory hurdles
- Supplier and Equipment qualification

12:05 **ADCs requirements on high containment processing**
- Demands on GMP and EHS
- Containment from Upstream to Downstream
- Aseptic Containment requirements for ADCs

Richard Denk, Head, Sales Containment, **Skan AG, Switzerland**

12:35 **Development and Manufacturing of Highly Potent APIs: from lab-scale to production scale**
- The Servier approach to develop and to manufacture new HPAPIs (overall methodology and examples)
- Overview of containment equipments on the Bolbec site

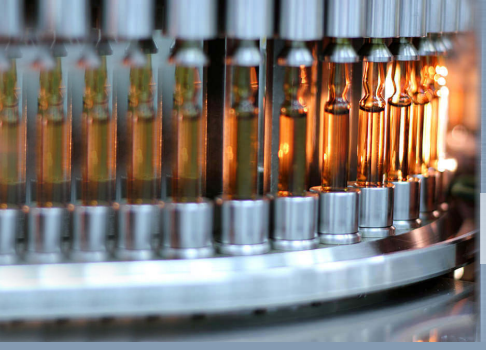
Maxime Lefebvre, Head of Department Pilot Plant, **Oril Industrie-Servier, France**

13:05 **Lunch and Poster Presentation | One-to-One Networking Meetings**

14:05 **Solution Provider Presentation; Please contact Abhinay at abhinay.roy@marketsandmarkets.com**

14:35 **Making a successful outsourcing partnership**
- Broad range of technical capabilities
- Efficient communication & project management

Claudio Salvagnini, Sales Director, **Minakem High Potent, Belgium**



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Containment and Handling Strategies for HPAPI's

14:50 **Containment Equipment and Factors Affecting Containment Performance**
- Facility design, protective equipment and control at source
- Selecting a containment target
- Containment performance capabilities of various equipment
- Factors affecting containment performance

Martin Axon, Principal Occupational Hygienist, **SafeBridge Europe, UK**

15:20 **Handling of highly potent products in a multi-product facility**
- Cross-contamination control procedures
- ADE Concept
- The pillars of the multi-product facility risk management

Dr. Juergen Knoebel, Head Small Molecules Quality Operations, **F.Hoffmann La Roche AG, Switzerland**

15:50 **Afternoon Refreshments and Poster Presentation | One-to-One Networking Meetings**

16:40 **Containment and safety of pharmaceutical toxic powders**

17:10 **Solution Provider Presentation; Please contact Abhinay Roy at abhinay.roy@marketsandmarkets.com**

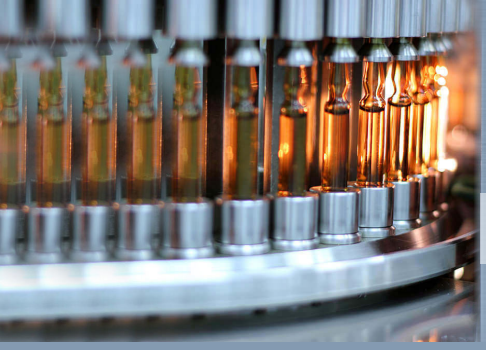
17:40 **Verifying the containment performance of pharmaceutical manufacturing and primary packaging equipment**
- Containment concept
- Dealing with airborne particles
- Dealing with mechanical transfer

Pascal Drago, Principal Technical Manager, Validation & Operations, Global QA, **F.Hoffmann La Roche AG,** Switzerland

18:30 **Closing Remarks from the Chairman**

18:35 **Drinks Reception & Networking**

End of Day 1



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Day 2, 7th June 2017

08:15 **Registration**

08:55 **Welcome note from MarketsandMarkets**

09:00 **Opening Remarks from the Chairman**

09:10 **Keynote Presentation: Using Leadership to Promoting Health**
- Health effects of poor leadership
- How Leadership encourages good health
- The role of the OH team within the leadership remit

Timothy Briggs, Chair Professional Standards Committee, **Leeds Beckett University, UK**

Identification of Risks during Cleaning HPAPI's

09:40 **Linking PDEs, OELs and Banding**
- Best practice in PDE and OEL setting in a nutshell
- The appropriate use of cleaning limits
- Using banding approaches sensibly

Ester Lovšin Barle, Head, Health Hazard Assessment, **Novartis, Switzerland**

10:15 **Cleaning Validation in API Small Molecule**
- Cleaning limit setting in API Small Molecule
- Challenges in API Small Molecule

Karina Versyck, Lead, Global Cleaning API Platform, **Janssen Pharmaceuticals, Belgium**

10:45 **Morning Refreshments and Poster Presentation | One-to-One Networking Meetings**

11:35 **Solution Provider Presentation; Please contact Abhinay at abhinay.roy@marketsandmarkets.com**

12:05 **Identification of high risk products based on toxicological hazards for regulatory purposes**
- High risk products based on regulatory expectations
- What are still existing "certain substances" and what to do with them
- Case study: cytotoxics

Ester Lovšin Barle- Head, Health Hazard Assessment, **Novartis, Switzerland**

12:35 **Cleaning Verification V/s Cleaning Validation of HPAPI manufacturing** — Panel Discussion
- Optimizing critical cleaning parameters
- Assessing process capability of cleaning
- Streamlining validation methods and implementing TOC

13:05 **Lunch and Poster Presentation | One-to-One Networking Meetings**

14:05 **Solution Provider Presentation; Please contact Abhinay Roy at abhinay.roy@marketsandmarkets.com**

Occupational Toxicology and Industrial Hygiene

14:35 **Applying occupational exposure limits on HPAPIs**
- Developing occupational exposure limits for HPAPIs
- Occupational health monitoring aspects on very low exposure limits
- Skin exposure considerations

Helena Hemming, Senior Toxicologist, **AstraZeneca, Sweden**

15:05 **Afternoon Refreshments and Poster Presentation | One-to-One Networking Meetings**

15:55 **Risk identification and mitigation for HPAPI's**

16:25 **Strategies on integrating PAT in QbD process**
- In-line or on-line testing to avoid employee exposure

16:55 **Closing remarks from the Chairman**

End of Conference