

# The Latest Techniques in HPAPI Facility Design

*Update on SMI's 3rd Highly Potent Active Pharmaceutical Ingredients Conference - focus on Facility Design*

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Amongst the myriad of potential pitfalls for the Highly Potential Active Pharmaceutical Ingredients ([HPAPI](#)) industry there is a requirement for all parties involved to have a blueprint in place to ensure all containment procedures are followed correctly. Yet, there is also a need to ensure that operations are maintained at the highest standards. At SMI's 3rd Annual Highly Potent Active Pharmaceutical Ingredients Conference these issues will be discussed along with design and build of a new compound, risk assessment of HPAPI products and utilisation of control matrices.

Key Sessions include:

## PANEL DISCUSSION:

Control matrices, control algorithms, containment guides and confidence

- Importance of control matrices and algorithms
- Current status of containment guides
- Methods of optimising confidence towards worker safety
- Future of containment designs

Mr Peter Marshall, Associate Engineering Director, AstraZeneca

Mr Nigel Saunders, Technical Engineer - SME Containment, GSK

Dr Thomas Adam, Head of Global Quality Assurance Chemical APIs, Bayer

Internal procedure guide in handling high potent compounds

- Bayer quality organisation guidelines
- Internal procedures to minimise the risk of handling HPAPIs to workers
- Deciding the correct control based on a correctly identified hazard

Dr Thomas Adam, Head of Global Quality Assurance Chemical APIs, Bayer



SMI Presents the 3rd Annual Event...

## Highly Potent Active Pharmaceutical Ingredients

13 - 14  
MAY 2019  
London, UK

[www.highlypotentapi.com](http://www.highlypotentapi.com)

Development and manufacture of HPAPI products through the clinical phases from molecule to market

- How HPAPIs can be developed into suitable drug dosage forms
- Strategies to adhere to the highest quality standards
- Complexities at each stage of the development cycle from FiM studies to global supply

Mr David O'Connell, Director Scientific Affairs, PCI Pharma Services

#### DEEP DIVE – CASE STUDY

Risk assessment of highly potent APIs cross-contamination and transportation parameters

- Guidelines regarding quality risk management
- Case study 1: technical aspects and complexity in cross contamination risk analysis
- Case study 2: temperature deviation during transportation

Dr Ildikó Ziegler, Distinguished Validation Expert, Gedeon Richter

Design and innovation of a new compound facility

- Reconstruction guidelines for adapting existing facilities to meet the needs of HPAPIs
- Ensuring facility reconstruction meets GMPs
- Additional assets required for HPAPI adaptation
- Designing controls and training to address worker safety

Dr Jack Brown, Senior Principal Scientist, Boehringer Ingelheim

View the programme at <http://www.highlypotentapi.com>

Registrations made before or on January 31st will include a £400 discount of the standard price.

Conference: 13th and 14th May 2019

Post-conference workshop: 15th May 2019

Holiday Inn Kensington Forum, London, UK

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