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SMi Group Proudly Presents the 3rd Annual Conference on...

Highly Potent Active Pharmaceutical Ingredients

Putting worker safety and product quality at the forefront of the HPAPI Industry

CONFERENCE: 13TH-14TH
WORKSHOPS: 15TH

MAY 2019

COPTHORNE TARA HOTEL, LONDON, UK

HIGHLIGHTS FOR 2019:

- **LISTEN** to **Gedeon Richter** on the risk assessment of highly potent APIs; from cross-contamination to transportation parameters
- **LEARN** from **AbbVie** about containment improvement strategies
- **ASSESS** the challenges of verifying containment performance of a HPAPI OSD facility in **GSK's** presentation
- **REVIEW** adaptation of containment designs with **AstraZeneca** to cope with the high demands of HPAPIs
- **ATTEND** the post-conference workshop which is a **step-by-step road map** assessing how to successfully roll out highly potent API projects

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CONFERENCE CHAIR FOR 2019:

Mr Justin Mason-Home, Director, **HPAPI Project Services Limited**

FEATURED SPEAKERS:

Dr Olindo Lazzaro, Director, Global EHS Technical Operations, **AbbVie**

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

Mr Peter Marshall, Associate Engineering Director, **AstraZeneca**

Dr Thomas Nittoli, Director, **Regeneron**

Mr Nigel Saunders, SME Containment, **GSK**

Dr Jack Brown, Senior Principal Scientist, **Boehringer Ingelheim**

PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS | WEDNESDAY 15TH MAY 2019, COPTHORNE TARA HOTEL, LONDON, UK

A: A Step-by-Step Road Map Assessing How To Successfully Roll Out Highly Potent API Projects

08.30 - 12.30

Workshop Leader:
Mr Justin Mason-Home, Director, **HPAPI Project Services Limited**

B: The Roadmap: Planning and Execution of a Successful Containment Performance Testing Campaign

13.30 - 16.30

Workshop Leader:
Mike Perry, Director, **Pharmadagio Limited**

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Highly Potent Active Pharmaceutical Ingredients

Day One | Monday 13th May 2019 www.highlypotentapi.com

8.30 Registration & Coffee

9.00 Chair's Opening Remarks
Mr Justin Mason-Home, Director, **HPAPI Project Services Limited**

HPAPI HAZARD ASSESSMENT AND HANDLING IMPLICATIONS

9.10 OPENING ADDRESS:
Practical elements in rolling out HPAPI projects
- Hazard assessment and strategic business matters
- Proper risk assessment
- Containment and control "hardware" and "software"
- Dealing with engineers and equipment vendors
- Verification of a safe working environment

Mr Justin Mason-Home, Director, **HPAPI Project Services Limited**

9.50 **Occupational exposure limits - how are they derived and what do they say?**
- Do you have a highly potent drug and don't know what it means for workers?
- What goes into the OEL?
- What are the limits of the OEL?

Ester Lovsin Barle, PhD, MScTox, ERT, Lonza AG

10.30 Morning Coffee

11.00 **Manufacturing of Oncological Drug Products & Drug Substance by a CDMO**
- New Product Introduction
- Case Study: ADC Manufacturing
- Waste & Wastewater treatment
- Project phase out

Fabio Zenobi, EHS Director, **BSP Pharmaceuticals S.p.A.**

11.40 **Demonstrating that exposure controls are effective**
- Examples of control devices and their performance
- Where does the data come from?
- ADCs – can we really measure nanogramme concentrations?

Mr Martin Axon, Principal Occupational Hygienist, **Safebridge**

12.20 Networking Lunch

13.20 **OH/containment strategy and NPI at AbbVie**
- OH/ containment improvement targets and LRP
- OH exposure risk assessment and improvement projects
- NPI and tech transfer
- Team approach - community of practice
- OH metrics

Dr Olindo Lazzaro, Director, Global EHS Technical Operations, **AbbVie**

FACILITY DESIGN AND ADAPTATION

14.00 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**

14.40 **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**

15.20 Afternoon Tea

15.50 **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**

16.30 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**

17.20 **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**

18.00 Chair's Closing Remarks and Close of Day One
Mr Justin Mason-Home, Director, **HPAPI Project Services Limited**

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Trusted by major players in HP API & ADC development, **Solo** bring high performance containment solutions in innovative single use packages. Solo's solutions include toxin-linker compounding as well as NCE molecule development isolators and now extend to Grade A aseptic fill/finish isolators – all supported by validation documentation and containment performance testing.
www.solocontainment.com

8.30 **Registration & Coffee**

9.00 **Chair's Opening Remarks**
Mr Justin Mason-Home, Director, **HPAPI Project Services Limited**

CONTAINMENT SOLUTIONS AND ADC DEVELOPMENT

OPENING ADDRESS:

9.10 **Principles of pharmaceutical containment in isolator designs**
- Innovative solutions to dealing with the increasing toxicity of ADCs
- Designing single use systems
- Considerations when choosing between single use Vs traditional use systems
- Real world examples of single use systems in industry

Mr Peter Marshall, Associate Engineering Director, **AstraZeneca**

SPOTLIGHT:

9.50 **Antibody drug conjugate manufacturing – coordination of linker-payload synthesis and antibody conjugation**
- Technology transfer
- Scale-up
- Qualification
- ADC toxicology lot
- ADC GMP lot

Dr Thomas Nittoli, Director, **Regeneron**

10.30 **Morning Coffee**

11.00 **Adaptation of containment designs to cope with the high demands of HPAPIs**
- Overview of up to date containment manuals
- Containment for HPAPIs with low OELs
- Challenges of reconstructing new facilities in alignment with GMPs

Dr Jeff Parry, Senior Formulation Scientist, **AstraZeneca**

11.40 **The challenges verifying containment performance of a HPAPI OSD facility**
- Real life examples of facility success and challenges
- Strategies to verify containment performance
- OSD facilities vs alternative facilities

Mr Nigel Saunders, Technical Engineer – SME Containment, **GSK**

12.20 **Networking Lunch**

13.20 **Outsourcing late stage CMC development and bio-manufacturing for fast track projects with accelerated timeline – the challenges and needs**
- Drivers for accelerated CMC development
- Pathways open for expedited regulatory review and approval
- Considerations for CMC development and regulatory submission
- Challenges and risks of accelerated projects, especially when outsourcing bio-manufacturing

Dr Ulrich Ruemenapp, Head of Launch Preparation and Coordination, **Bayer**

14.00 **Respiratory APIs: peculiarities of development and formulation**
- Purpose & target of a respiratory API
- Equipment & analytical instruments in containment grade
- Strategy for the development & for industrialization
- New trends

Dr Enrico Bettetini, R&D Technology and Pilot Manager, **Teva**

PANEL DISCUSSION:

14.40 **CMO outsourcing options and selection methodologies**
- Criteria for CMO selection
- Confidentiality
- EHS compliance
- Efficiency at every step

Dr Ildikó Ziegler, Distinguished Validation Expert, **Gedeon Richter**
Jack Brown, Senior Principal Scientist, **Boehringer Ingelheim**
Thomas Nittoli, Director, **Regeneron**

15.20 **Chair's Closing Remarks**
Mr Justin Mason-Home, Director, **HPAPI Project Services Limited**

15.30-16.00 **Afternoon Tea and Close of Day Two**

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HALF DAY POST-CONFERENCE WORKSHOP A
WEDNESDAY 15TH MAY 2019 | 8.30 - 12.30
COPTHORNE TARA HOTEL, LONDON, UK

Workshop Leader:
Mr Justin Mason-Home, Director, **HPAPI Project Services Limited**

A Step-by-Step Road Map Assessing How To Successfully Roll Out Highly Potent API Projects

Workshop overview:
Biopharmaceutical companies embody application of the scientific method to identify and deliver new patient therapies. The same systematic, scientific principles should be used to develop and deliver research, development and production facilities that are fit for purpose and which protect healthy workers. This workshop will explore key steps in rolling out an HPAPI project, helping define and deliver HPAPI projects that are technically sound, based on justifiable data which can underpin robust and defensible investment.

Why you should attend:
- Learn key HPAPI project elements
- Assess what factors are important and how to build information designed to underpin HPAPI project investments
- Providing a pathway to systematic and scientific project design

The objective will be the delivery of efficient facilities with process matters at the centre and suitable and defensible worker protection measures integrated into and set around the process.

About the Workshop Leader:
Justin Mason-Home is an organic chemist with extensive health, safety, environmental and chemical engineering experience in senior technical, legal and commercial aspects of the pharmaceutical, biochemical, chemical and other industries. He has held senior positions and worked globally in potent biopharmaceutical occupational health and safety global environmental consulting, board level positions in a biotechnology company and corporate environmental management. Mr Mason-Home has worked on many HPAPI projects, contributing potent compound project support advice for many years. He specialises in technically complex and strategic projects, including unique experience in managing sensitive highly potent and toxic biopharmaceutical compound matters.

Agenda

8.30	**Registration and Coffee**
8.45	**Strategic HPAPI Project Considerations**
9.15	**Hazard Assessment – It All Starts with the Hazard**
9.45	**Process is Primary**
10.10	**Real Risk Assessment – Risk to Product and Risk to Workers**
10.30	**Morning Coffee**
10.50	**Facility Design Features**
11.20	**Containment for Higher Risk Activities and Control for Lower Risk Activities**
11.40	**Verification of Control/Containment Performance**
12.00	**Occupational Health and Safety Management Systems**
12.30	**Workshop Leader's Closing Remarks**

About HPAPI Project Services Limited:
HPAPI Project Services Limited is a new company formed by Justin Mason-Home, following over 11 years heading up the European operations of a well-known potent compound safety consulting firm. Core objectives of the company are to support companies design, invest and deliver better.

HALF DAY POST-CONFERENCE WORKSHOP A
WEDNESDAY 15TH MAY 2019 | 13.30 - 16.30
COPTHORNE TARA HOTEL, LONDON, UK

Workshop Leader:
Mike Perry, Director, **Pharmadagio Limited**

The Roadmap: Planning and Execution of a Successful Containment Performance Testing Campaign

Workshop overview:
Mike will provide first-hand experience and guidance in this interactive workshop which aims to provide a launch pad for the planning and execution of containment performance testing in pharmaceutical settings, whether using in-house personnel or external consultants. The ISPE guide constitutes an excellent platform and key resource for testing, but requires careful interpretation and agreement from the outset to ensure meaningful and consistent outcomes are generated. Key issues will be discussed and explained as part of a step by step walk through of a typical project, including the special considerations faced when aiming to demonstrate performance against very low performance targets.

Why you should attend:
The main benefit of attending the workshop will be to gain an understanding of the technical considerations and practical requirements for a successful testing campaign, such that a company will be in a good position to evaluate and select a suitably competent resource to carry out the testing and to manage the work effectively. The data may then be used as the starting point for longer term continuing development and strengthening of risk assessments through quantitative assessment for the safe handling of active pharmaceutical ingredients (APIs), including highly potent compounds. Another key benefit of attending will be to enable informed decisions to be made with respect to the procurement of containment equipment through critical appraisal of supplier's containment performance data. As well as helping to ensure appropriate containment and control is achieved relative to toxicity of materials handled, and hence establishing a safe working environment, application of knowledge gained through the session will help to ensure funding for engineering control is appropriate for the situation in which it is to be used.

Who should attend:
Managers/Head of/ Director of:
• OH • Safety • Containment • Engineering

About the Workshop Leader:
Mike Perry has been providing specialist occupational hygiene services to the pharmaceutical industry for 12 years. His career in the industry began in 2007 when he joined the European branch of SafeBridge Consultants Inc, recognised leaders in the field of potent compound safety. After nine years he left to form his own company, Pharmadagio Limited, and has been developing an increasing presence in the industry and providing regular support to Clients in Portugal, Greece, Bulgaria and the UK.

Agenda

13.30	**Registration and Introduction**
13.40	**• Understanding containment performance targets and method sensitivity • Understanding the differences and limitations of surrogate performance testing versus API assessment**
14.00	**• Understanding the role of personal sampling and static sampling • Understanding the statistical limitations of small data sets**
14.30	**• Applying an appropriate statistical tool to small data sets • The testing environment, personnel and training considerations • The differences between FAT (factory acceptance testing) and SAT (site acceptance testing)**
15.00	**Afternoon Tea**
15.30	**• Sampling strategy options and development of a suitable sampling plan • Equipment, calibration and record keeping • Sample handling and avoidance of cross contamination**
16.00	**• Communication with the laboratory, storage and shipping requirements • Reporting and approaches to presentation of results • Communication of results to senior management**
16.30	**Workshop Leader's Closing Remarks**

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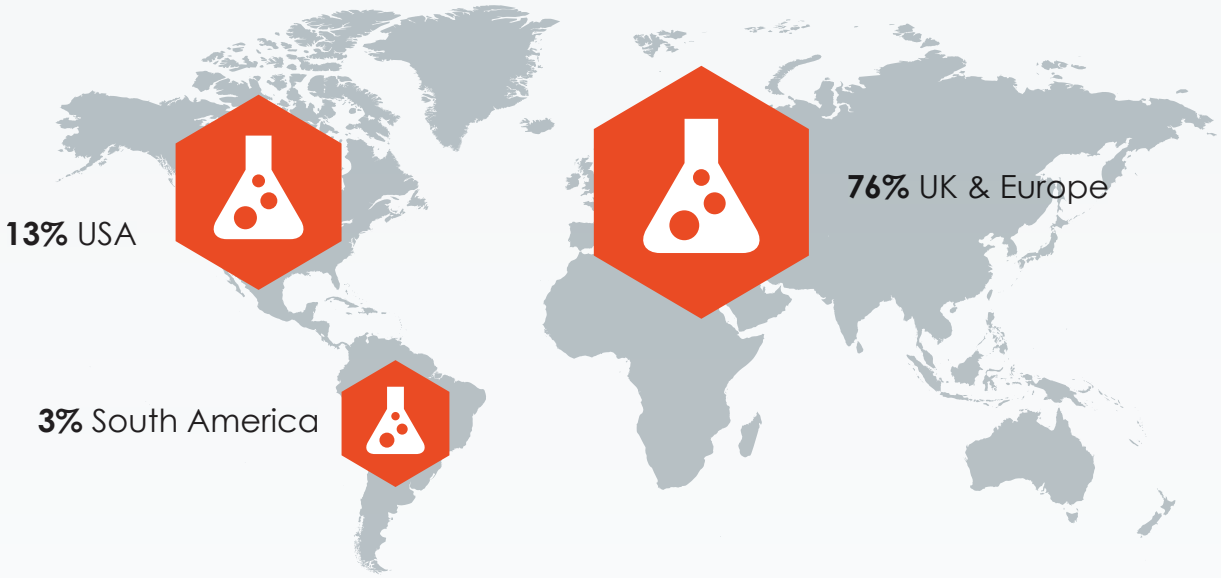

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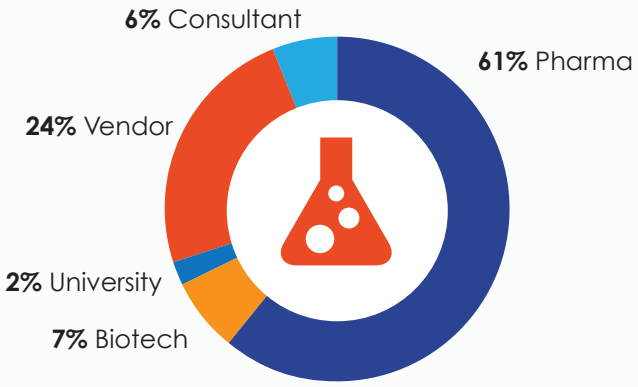

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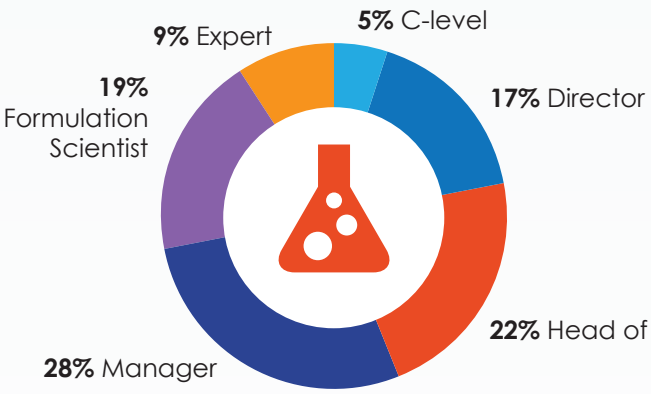

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Pre-Filled Syringes & Injectable Drug Devices
16th -17th January, London, UK

Pharmaceutical Microbiology
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21st - 22nd January, London, UK

FEBRUARY 2019

Parallel Trade
5th - 6th February, London, UK

3D Cell Culture
20th - 21st February, London, UK

RNA Therapeutics
20th - 21st February, London, UK

MARCH 2019

Superbugs & Superdrugs
18th - 19th March 2019, London, UK

Drug Discovery Chemistry
18th - 19th March 2019, London, UK

APRIL 2019

Adaptive Designs
1st - 2nd April 2019, London, UK

Pre-Filled Syringes East Coast
8th - 9th April 2019, Boston, USA

Microbiology East Coast
10th - 11th April 2019, Boston, USA

MAY 2019

Highly Potent Active Pharmaceutical Ingredients
13th - 14th May 2019, London, UK

Pain Therapeutics
13th - 14th May 2019, London, UK

Injectable Drug Delivery
15th - 16th May 2019, London, UK

JUNE 2019

Prefilled Syringes West Coast
3rd - 4th June 2019, San Diego, USA

Lyophilisation
3rd - 4th June 2019, London, UK

Microbiology West Coast
5th - 6th June 2019, San Diego, USA

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