# 4th Annual HIGHLY POTENT ACTIVE PHARMACEUTICAL INGREDIENTS Summit

#4HPAPI18

MILAN, ITALY | OCTOBER 17 - 19, 2018

LEONARDO HOTEL MILAN CITY CENTER | VIA MESSINA, 10 | 20154 MILAN, ITALY

Sponsors:

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Key Speakers:

Sponsorship-related questions to: register@vonlanthengroup.com

**Chairman:**

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

**Richard Denk, CH**
Head Containment Group
**Skan AG, Switzerland**

**Stefano Butti, IT**
Technical Sales Director
**FPS Food and Pharma Systems srl.**

**Chris Seaman, UK**
Managing Toxicologist
**SafeBridge Consultants, Inc.**

**Graham Box, UK**
Head of Mammalian & Early Phase
Microbial Programme Management
**Fujifilm Diosynth Biotechnologies**

**Jessica Redmer, DE**
Expert Pharmaceutical Development
**AiCuris Anti-infective Cures GmbH**

**Dr. Ulrich Scholz, DE**
Head of Scale-up & Processing
**Bayer AG**

**Paolo Moretti, IT**
Global EHS,
Environmental Director
**TAPI / TEVA**

**Andreia Ferreira, PT**
Head of HSEE
Management Systems
**Hovione**

**Steve Marnach, NE**
EMEA Critical Environments
Specialist
**DuPont**

**Dr. Reinhold Maeck, DE**
Head of Corp EHS Regulatory
Intelligence
**Boehringer Ingelheim GmbH**

**Dr. Friederike Hermann, CH**
Head of Occupational Hygiene
**Lonza AG**

**Timo Rosvall, SE**
Senior Containment engineer
**AstraZeneca**

**Dr. Ulrich Rümenapp, DE**
Head of Launch Preparation
& Coordination
**Bayer AG**

**Dr. Ildikó Ziegler, HU**
Distinguished Validation Expert
**Richter Gedeon Plc**

**Dr. Jörg Herbst, CH**
Director Toxicology
**Molecular Partners AG**

**Silke Büchl, CH**
Occupational Hygienist
**Praevena AG**

**Claudio Salvagnini, BE**
Sales Director
**MINAKEM**

**João Reis, PT**
Senior Engineer
**Hovione**

Sponsors:

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VONLANTHEN CONFERENCES

# 4th Annual HIGHLY POTENT ACTIVE PHARMACEUTICAL INGREDIENTS Summit

Day One
October 17 - 19, 2018

## We would like to

*welcome you to the **4th Annual Highly Potent Active Pharmaceutical Ingredients Summit** between the **17th and 19th of October 2018** in **Milan, Italy**.*

*This event provides its participants and industry leaders an environment to discuss process innovation and technology and safety perspectives for both Highly Potent Active Pharmaceutical Ingredient (HPAPI) manufacturers and outsourcers.*

*This Summit will focus on current market trends for HPAPIs including process development and scale-up, cost-effective production, containment innovations, best manufacturing practices, as well as regulatory updates.*

*This year's instalment includes the 2-day summit and a day visit to the facility in Fiorenzuola d'Arda with a workshop session, sponsored by **FPS Food and Pharma Systems srl**.*

*We are excited to be hosting the 4th edition of our Highly Potent Active Pharmaceutical Ingredients Summit and look forward to meeting you in Milan!*

## Key Practical Learning Points of the Summit:

- How to improve safety and maximise manufacturing efficiencies for highly potent medicines
- Latest containment technologies and handling
- New requirements and considerations from the EMA guidelines
- Assuring regulatory compliance with the permitted daily exposure
- Hazard assessment classifications
- Occupational hygiene: past, present, and future
- Prevention of cross-contamination
- Strategies for CMO selection: insights from the industry
- Challenges and opportunities for ADC business

## Who Should Attend:

***Chief Executives, Vice Presidents, Directors, Department Heads, Leaders, Senior Managers, Principal Scientists, Principal Toxicologists, Fellows and Investigators specialising in:***

- *Business Development*
- *Engineering*
- *Environmental, Health & Safety (HSE)*
- *External Supply*
- *Formulation Development*
- *Industrial Hygiene*
- *Laboratory Services*
- *Manufacturing*
- *New Products*
- *New Technologies*
- *Occupational Toxicology*
- *Outsourcing*
- *Process Development*
- *Product Quality*
- *Regulatory*
- *Research & Development*
- *Risk Assessments*
- *Sales Development*
- *Strategic Development*
- *Validation*

Sponsors:

*Company Profile **Dishman Carbogen Amcis Limited** is a global outsourcing partner for the pharmaceutical industry, offering a portfolio of development, scale-up and manufacturing services. We improve our customers' businesses by providing a range of development and manufacturing solutions at various locations across Europe and in India. We are committed to delivering high value added solutions with technical excellence and to be a reliable partner to our customers, protecting their interests as if they are own.*

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VONLANTHEN CONFERENCES

# 4th Annual HIGHLY POTENT ACTIVE PHARMACEUTICAL INGREDIENTS Summit

Day One
October 17, 2018

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**08:30** Registration and Welcome Coffee
**09:00** Opening Address from the Chairman

## NAVIGATING REGULATORY LANDSCAPE

**09:10**

**CASE STUDY**

**EMA requirements and their impact on PDE evaluations and OEL settings**

**DR. REINHOLD MAECK**
Head of Corp EHS Regulatory Intelligence
Boehringer Ingelheim GmbH

- New requirements based on EU-GMP regulations and Q&A of EMA
- How GMP and occupational health can lead to a harmonized approach
- First ideas and possible orientation of surface limits to cover GMP and occupational health aspects
- Discussion of the model: how to establish limits for non –product contact surfaces in and outside of the isolator

**09:45** **SPEED NETWORKING**

An innovative approach to maximize networking capabilities through two minute periods, where delegates can meet their peers and exchange business cards before rotating to the next company representative.

**10:20**

**CASE STUDY**

**Cleaning and cross contamination requirements for HPAPI**

**RICHARD DENK**
Head Containment Group
Skan AG, Switzerland

- GMP and containment: new requirements based on GMP regulations
- Cleaning and cross contamination requirements based on PDE (Permitted Daily Exposure)
- Cleaning requirements for none product contact surfaces based on the PDE

**11:55** **MORNING COFFEE AND NETWORKING BREAK**

## OCCUPATIONAL TOXICOLOGY AND INDUSTRIAL HYGIENE

**11:25**

**CASE STUDY**

**Linking PDEs, OELs, and banding**

**CHRIS SEAMAN**
Managing Toxicologist
SafeBridge Consultants, Inc.

- Background – same hazards, different populations
- Establishing the values – what is common, what is different?
- Application

**12:00**

**CASE STUDY**

**DARPins / DARPin-Toxin-Conjugates: hazard assessment and worker safety assessment**

**DR. JÖRG HERBST**
Director Toxicology
Molecular Partners AG

- Introduction to DARPins
- Basic hazard assessment and worker safety assessment for DARPins in general (ADE/OEL, banding)
- Hazard assessment of targets therapies
- Hazard assessment, worker safety assessment and OHC for MP0250, a bispecific DARPin
- Hazard assessment, worker safety assessment and OHC for a DARPin-toxin fusion candidate (Pseudomonas exotoxin conjugate)

**12:35**

**CASE STUDY**

**Managing ultrapotent APIs in ADC projects**

**JUSTIN MASON-HOME**
Director
HPAPI Project Services Limited

- ADC toxins, potencies, and toxicities
- Linking hazard to control – risk assessment
- HPAPI facility design elements - antibodies, drugs, and conjugates
- Investing in, managing, and determining control/containment

**13:10** BUSINESS LUNCH

**14:10**

CASE STUDY

**Exposure profile of different pharmaceutical equipment**

**SILKE BÜCHL**
Occupational Hygienist
Praevena AG

- Expected exposure due to technical layout
- Challenges to organize reliable exposure monitoring
- Challenges during handling of pharmaceutical equipment
- Exposure in reality during normal operation and cleaning of pharmaceutical equipment

## MANUFACTURING AND PROCESS DEVELOPMENT

**14:45**

CASE STUDY

**Manufacturing of highly potent antibody-drug-conjugates in a multi-purpose facility – challenges and solutions**

**DR. ULRICH RÜMENAPP**
Head of Launch Preparation & Coordination
Bayer AG

- Antibody-drug-conjugates (ADCs) – linking antibodies to small molecule toxins
- Manufacture of ADCs - challenges and solutions
- Bayer's production concept using HPAPIs

**15:20** SPONSORED SPEAKING SLOT

**HPAPI Handling and processing in aseptic condition**

**STEFANO BUTTI**
Technical Sales Director
FPS Food and Pharma Systems srl.

- General introduction about HPAPI handling in aseptic condition
- Process vessel charging
- Process vessels discharging
- Milling and micronisation
- Final dispensing

**15:50** AFTERNOON COFFEE AND NETWORKING BREAK

**16:20**

CASE STUDY

**HPAPI Handling from lab bench to pilot plant**

**DR. ULRICH SCHOLZ**
Head of Scale-up & Processing
Bayer AG

- Alignment of SHE requirements with accelerated development timelines
- Handling of high potent compounds following shared facility requirements
- Systematic approach to avoidance of cross contamination and upgrade of existing equipment
- Handling potential HPAPIs in development laboratories
- Handling lower rater HPAPIs in process technology laboratories
- Handling HPAPIs in kg-lab and pilot plant

**16:55**

CASE STUDY

**TEVA TAPI HPAPI control strategy and program: case study applied to the implementation of a new HPAPI manufacturing line**

**PAOLO MORETTI**
Global EHS, Environmental Director
TAPI/TEVA

- TEVA occupational health and management of employee exposures (including banding structure)
- Occupational control strategy (containments to be applied for HPAPI)
- Design of the new HPAPI manufacturing line (facilities, engineering controls, ...)

**17:30** PANEL DISCUSSION - MODERATED BY CHAIRMAN

**Definitions and labels: application, understanding, and translation into practical action**

- Potent and highly potent? Are there any non-potent drugs?
- Hazard definitions - Occupational Exposure Limit (OEL), Acceptable Daily Exposure (ADE), Banding - Occupational Exposure Band (OEB), Occupational Health Categorisation (OHC), etc
- Risk assessment
- Project and design definitions – Design Exposure Limit (DEL), Containment Performance Target (CPT)
- Control or containment?

**17:50** CHAIRMAN'S CLOSING REMARKS AND END OF DAY ONE

**19:00** BUSINESS DINNER (SPONSORED BY FPS FOOD AND PHARMA SYSTEMS SRL.)

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- *Webinars, podcasts, virtual conferences and short videos to generate leads, produce branded content and share your expertise*
- *Using customer insights and feedback from social media to enhance product and service offerings.*

***All our sponsorship opportunities are*** *bespoke and developed to enhance value for both our partners and Vonlanthen's network of business leaders.*

Sponsorship-related questions to:
**register@vonlanthengroup.com**

**08:30** Registration and Welcome Coffee
**09:00** Opening Address from the Chairman

## PROGRESS OF CONTAINMENT TECHNOLOGIES

**09:10**

CASE STUDY

**Handling of toxic and flammable liquids**

**TIMO ROSVALL**
Senior Containment engineer
AstraZeneca

- Activities in the early project phase
- Handling of liquid
- Create a safe environment for liquid
- Cleaning of process pipes
- Cleaning of drums
- Experiences

**09:45**

CASE STUDY

**Do containment solutions achieve the guaranteed OEL? A reality check!**

**DR. FRIEDERIKE HERMANN**
Head of Occupational Hygiene
Lonza AG

- The difference between containment verification and occupational hygiene monitoring
- Interpretation of results
- Occupational hygiene monitoring results for various containment solutions
- Impact of differing work practices on sampling results

**10:20**

CASE STUDY

**Cross contamination risk assessment in parenteral product and HPAPI manufacturing**

**DR. ILDIKÓ ZIEGLER**
Distinguished Validation Expert
Richter Gedeon Plc

- EU guidelines regarding cross contamination and toxicological approach
- Complexity in risk analysis of cross contamination and some measures
- Case studies: manufacturing parenteral products, and HPAPIs exhibiting hormonal activity

**10:55** MORNING COFFEE AND NETWORKING BREAK

**11:25** SPONSORED SPEAKING SLOT

**Containment Approaches and Application at Hovione R&D Pilot Plant Operations**

**ANDREIA FERREIRA, PT**
Head of HSEE
Management Systems
Hovione

**JOÃO REIS, PT**
Senior Engineer
Hovione

- Containment approach at Hovione
- Step-Wise Risk Assessment
- Practical Examples of Containment Strategies at Pilot Plant

**11:55**

CASE STUDY

**The overview of risk assessments methods with examples of topic containment. How can risk for safety and cross contamination be handled in one document**

**JESSICA REDMER**
Expert Pharmaceutical Development
AiCuris Anti-infective Cures GmbH

- General topics (when, how, which people takes part...)
- How to narrow down the topics of the risk assessment
- Methods of risk assessments with real examples

**12:30** BUSINESS LUNCH

## CMO STRATEGIES AND OUTSOURCING

**13:30**

**CASE STUDY**

**HPAPI biologics: opportunities, challenges, and solutions for outsourcing**

**GRAHAM BOX**
Head of Mammalian & Early Phase Microbial Programme Management
Fujifilm Diosynth Biotechnologies

- HPAPI biologics - an increasingly important class of therapeutics
- Process development for HPAPI biologics
- GMP facility design and operational controls for HPAPI biologics
- Selecting a CDMO partner for HPAPI biologics

**14:05** SPONSORED SPEAKING SLOT

**Implementing preparative HPLC under containment**

**CLAUDIO SALVAGNINI**
Sales Director
MINAKEM

- Building concept and design
- Considerations on de-packing and cleaning of small pieces of equipment in safe conditions
- Purification from lab (mg to 10s g) up to industrial scale (100s kg)

**14:40** SPONSORED SPEAKING SLOT

**Garment selection criteria for the safe handling of HPAPI**

**STEVE MARNACH**
EMEA Critical Environments Specialist
**DuPont**

- Assessing performance properties of chemical protective clothing
- Protecting operators in GMP B and C/D environments
- Role of garments in the contamination control strategy

**15:10** AFTERNOON COFFEE AND NETWORKING BREAK

**15:40** PANEL DISCUSSION - MODERATED BY CHAIRMAN

**Verification of engineering control and containment performance**

- Risk algorithms
- Control matrices and containment guides
- Quality of occupational hygiene data

**16:10** CHAIRMAN'S CLOSING REMARKS AND END OF SUMMIT

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

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 multiple ADC projects and specialises in technically complex and strategic projects, including unique experience in managing sensitive highly potent and toxic biopharmaceutical compound matters.

**Richard Denk, CH**
Head Containment Group
**Skan AG, Switzerland**

Richard Denk has studied mechanical engineering and did an examination on experts of GMP, qualification and validation, pharmaceutical auditing, pharmaceutical engineering, and quality control at the University of Applied Sciences in Albstadt/Sigmaringen Germany. Richard Denk works at SKAN AG, headquartered in Allschwil, as the head of sales containment. Mr. Denk founded the expert Containment group of the ISPE DACH eight years ago. The Containment Group published the Containment Manual in September 2015. Mr. Denk has spent nearly 20 years with the subject production of highly active and highly hazardous substances and has developed the containment pyramid.

**Stefano Butti, IT**
Technical Sales Director
**FPS Food and Pharma Systems srl.**

Stefano Butti studied mechanical engineering at the University of Milan and graduated in 2000. He has been an ISPE member since 2002. He has participated as a speaker at different congresses and seminars on containment and micronisation; topics have been for both HPAPI and sterile application. Adding to that, he has published different articles in technical newspapers. He worked as a project and process manager in the chemical and pharmaceutical business following containment and micronisation system installation worldwide. He also took a direct role in the definition of containment system upgrade and optimisation for the handling of products with OEL down to ng level with successful results. He also worked on a few projects where the combination of sterile and toxic compound handling was successfully coordinated. He spent close to 15 years in this business area. He joined FPS in 2008, starting as technical sales manager and he is now the head of the sales group for the company's containment and micronisation system that is provided worldwide.

**Timo Rosvall, SE**
Senior Containment engineer
**AstraZeneca**

Timo Rosvall is an experienced engineer and project manager with 25 years of experience in the manufacturing industry and service companies. He has been responsible for a number of containment projects in API, R&D, and formulation. Timo is currently working as senior containment engineer for AstraZeneca.

**Claudio Salvagnini, BE**
Sales Director
**MINAKEM**

Claudio Salvagnini has a PhD in organic chemistry from Louvain University in Belgium. He has worked for several fine chemicals companies in business development and sales roles in the pharmaceutical field having recently joined Minakem in 2015 as the head of the Sales and Marketing Department for the high potent API and custom development and manufacturing markets.

**Dr. Reinhold Maeck, DE**
Head of Corp EHS Regulatory Intelligence
**Boehringer Ingelheim GmbH**

Dr. Reinhold Maeck is the head of corp EHS regulatory intelligence at Boehringer Ingelheim Germany. He has more than 20 years of experience in the pharmaceutical industry with key functions in chemical production as well as EHS and has worked many years in China and US.

**Dr. Friederike Hermann, CH**
Head of Occupational Hygiene
**Lonza AG**

Dr. Friederike Hermann is head of occupational hygiene at Lonza Site Visp. Since 2001, Dr. Hermann works at Lonza AG, where she initially worked in the environmental department, now in the field of occupational hygiene. She was significantly involved in the setup of high potent compound production at Lonza. Following graduation, she obtained a doctorate in the field of analytical chemistry with an emphasis on element speciation. She graduated from ETH Zürich and the University of Lausanne with a master's degree in advanced studies on work and health. Dr. Friederike Hermann received her occupational hygiene certification from the Swiss Society of Occupational Hygiene. She is a member of the steering committee of COP Containment ISPE Affiliate DACH.

**Dr. Ulrich Scholz, DE**
Head of Scale-up & Processing
**Bayer AG**

Ulrich is currently in the position as the head of scale up and processing in the chemical development department of the pharmaceutical business unit of Bayer AG. He is responsible for the pilot plant, GMP kg labs, technical labs and process technology labs; all capable of handling high potent APIs. Ulrich has a total of 17 years of industrial experience in various companies as well as various countries and holds a Ph.D. degree in synthetic organic chemistry from the University of Hannover in Germany. With growing regulatory and safety demands in the handling of high potent active ingredients, clear trends in pharmaceutical research to develop candidates with high potency and portfolio strategies to engage in breakthrough designation therapies, many challenges of these trends have to be taken care of in the scale up and late development stage phase. How these challenges are coped with inside the Bayer AG will be subject of the talk.

**Andreia Ferreira, PT**
Head of HSEE Management Systems
**Hovione**

Andreia Ferreira graduated with a degree in chemical engineering from Instituto Superior Técnico, Universidade de Lisboa and has a diploma in health and safety management. Andreia joined Hovione in 2011 as an HSEE technical expert. A year later she was appointed as head of the HSEE area being responsible for the HSE management systems, the operational safety of the site, training, and HSEE assessments for new processes and installations. Since 2015, Andreia assumed the role of head of HSEE management systems at Hovione being responsible for the Health, Safety, and Environmental Certification of the site as well as the occupational hygiene monitoring.

**João Reis, PT**
Senior Engineer
**Hovione**

João Reis, MsC, is a senior engineer at the Tech Transfer Group of R&D Pilot Plant Operations, at Hovione FarmaCiencia SA. João joined Hovione in 2010 and, since then, has worked as a process engineer in different sites (Loures, Portugal and New Jersey, US). He received his degree in chemical engineering from the University of Coimbra, Portugal. Currently, he handles the startup of operations in new equipment/buildings, introduction of new technologies, and enhancement of containment solutions across a wide range of manufacturing processes (API Synthesis, Intermediate Drug Product, and Final Dosage Forms).

**Dr. Ulrich Rümenapp, DE**
Head of Launch Preparation & Coordination
**Bayer AG**

Dr. Rümenapp is based in Wuppertal, Germany and works within the Biological Development Organisation of Bayer AG, where he is responsible for the transfer of Bayer's pipeline candidates (antibodies and antibody drug conjugates) to external manufacturing partners and regulatory submission and launch preparations. Prior to working in development, Dr. Rümenapp was head of biotech projects in Product Supply Biotech at Bayer, where he was responsible for contract manufacturing partnerships in the field of biotechnological drug substances, drug products, and interdisciplinary project management with the goal to ensure market supply. Before it was acquired by Bayer, Dr. Rümenapp held a similar position at Schering AG, and before that, he worked in the production & logistics department of Schering, where he was responsible for production aspects of in-and-out-licensing deals, due diligences, and product acquisitions of small molecule products and biologics. Dr. Rümenapp studied chemistry and holds a Ph.D. in biosciences. He has several years of experience in academic research in the field of signal transduction and as an assistant teacher in the field of general pharmacology. Currently, Dr. Rümenapp's area of expertise is the set-up and management of external relationships for the development and supply of bio-pharmaceutical products. He has more than 15 years of experience in the bio-pharmaceutical industry.

**Dr. Ildikó Ziegler, HU**
Distinguished Validation Expert
**Richter Gedeon Plc**

Dr. Ildiko Ziegler has been a professional at Gedeon Richter for 14 years and has been leading different projects in her field for 4 years. She has been a distinguished validation expert since January 2014, specialising in cleaning validation and quality risk assessment in the pharma industry. Ildiko obtained a M.Sc. in chemical engineering at the Budapest University of Technology and Economics (BUTE) in 1996. She received a licentiate degree at the Luleå University of Technology (Sweden) in 2000. She defendedher Ph. D. at the BUTE in 2000 and obtained the Géza Schay Award for her achievements in the field of physical and theoretical chemistry.

**Chris Seaman, UK**
Managing Toxicologist
**SafeBridge Consultants, Inc.**

Chris Seaman is a European-registered toxicologist with over 40 years of experience in the pharmaceutical industry. He provides services for toxicological hazard assessment and communication, particularly with respect toxicological risk assessment contributing to articles on derivation of Occupational Exposure Limits (OELs) and Occupational Exposure Bands (OEBs), and Acceptable Daily Exposure (ADE)/Permissible Daily Exposure (PDE) values for cross-contamination. He has considerable experience in classification and labelling, SDS production, and toxicity testing including replacement, reduction, and refinement of animal tests.

**Graham Box, UK**
Head of Mammalian & Early Phase Microbial Programme Management
**Fujifilm Diosynth Biotechnologies**

Graham Box is the head of mammalian & early phase microbial programme management at Fujifilm Diosynth Biotechnologies, Billingham, UK site. He has received a B.S. in pharmacology and B.A. in business management from the University of Sunderland. Graham has over 20 years' experience in pharmaceuticals encompassing an expansive set of roles ranging from QA, QC to manufacturing, project and capital management, and GMP facility installation. He has delivered GMP operational HPAPI GMP ready facilities for multiple biologic derived therapeutics at Fujifilm. His current role involves managing the delivery of programmes in Fujifilm's Mammalian and Early Phase Biologics GMP facilities meeting the needs of clients requiring a contact development and manufacturing organisation.

**Jessica Redmer, DE**
Expert Pharmaceutical Development
**AiCuris Anti-infective Cures GmbH**

Jessica Redmer is an expert for pharmaceutical development, specifically cGMP, at AiCuris since 2017. In this position, she is responsible for the CMC, managing relationships with partners CROs/CMOs and oversight of drug development process. Jessica Redmer has more than 15 years of experience in the pharmaceutical industry. At Cordenpharma, she established a new GMP system for the development department and planned and launched a new development area for high potent substances. Jessica Redmer is part of the expert containment group ISPE DACH.

**Silke Büchl, CH**
Occupational Hygienist
**Praevena AG**

Silke Büchl is an experienced IOHA certified occupational hygienist with about 20 years of experience in occupational hygiene. She received her IOHA certification after completing her postgraduate studies in work and health at ETH Zürich and the University of Lausanne in 2003. Before working as a occupational hygienist and deputy of the managing director at Praevena in 2014, she gained experiences in the different fields of occupational hygiene, safety data sheets, hazard communication as well as participating in the internal board of Occupational Exposure Limits at Novartis.

**Paolo Moretti, IT**
Global EHS,
Environmental Director
**TAPI / TEVA**

Paolo Moretti is an organic chemist with extensive environmental, health, and safety experience within international pharmaceutical companies. In his carrier he conducted multiple studies or coordination of EHS projects. After moving to global roles in EHS technical support in 2006, he was part of the drug handling committee looking after EHS aspects during HPAPI technology product transfer projects, including minimization of potential environmental impacts. In his current role as environmental TAPI director, he is involved in multiple projects aiming to reduce TEVA environmental footprint and improve EHS performance.

**Dr. Jörg Herbst, CH**
Director Toxicology
**Molecular Partners AG**

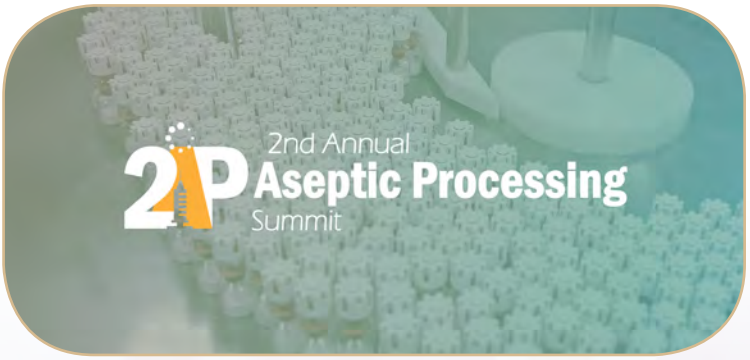
Jörg Herbst is a board-certified toxicologist (DABT and ERT) and biopharmaceutical manager with nearly 20 years of industry experience. He worked for a range of biotech companies as an expert in the field of non-clinical development and safety evaluation of biopharmaceuticals and small molecules. Jörg has considerable experience in development and execution of non-clinical safety risk assessment strategies, including regulatory considerations, selection of appropriately skilled CROs, and proposing program budgets and timing of toxicology studies in support of clinical programs in a broad range of indications. He is experienced in designing, outsourcing and monitoring toxicology studies at CROs, reviewing and interpreting toxicology data and study reports, preparation of domestic and international regulatory filings, preparation of worker safety assessments, collaborating with industry consultants and partner pharmaceutical companies, and defending his evaluations during meeting with regulatory bodies. In 2013, Jörg joined the biopharmaceutical company, Molecular Partners, located in Zurich, Switzerland as their director of toxicology. Molecular Partners is pioneering the development of a novel class of targeted protein therapeutics termed DARPins. Jörg holds a diploma in chemistry and received his PhD in toxicology from the Institute of Toxicology at the University of Würzburg. Since 2008, he has been a full member of the Advisory Committee for pharmacologically active substances and veterinary drugs of the Federal Institute for Risk Assessment of Germany.

**Steve Marnach, NE**
EMEA Critical Environments Specialist
**DuPont**

Steve has a Masters' degree in Business Administration and has joined DuPont in 1995. After having held various positions within the company, he is currently the EMEA Training Manager and critical environments marketing and specialist for DuPont Personal Protection, the chemical protective garments business that Steve has been working for since 2003. In his current role, Steve is providing training sessions on the selection and safe handling of chemical protective garments used in, amongst others, pharmaceutical production and GMP grade B, C and D cleanroom operations as well as giving technical support to health and safety specialists.

## Our Upcoming Events:

**2nd Annual Aseptic Processing Summit**
Berlin, Germany | November 8 - 9, 2018



# Tailor-made containment systems

## FPS workshop
## Fiorenzuola d'Arda - 19th October 2018

**FPS Food and Pharma Systems** is an Italian company specialized in design and manufacture of fine grinding, and micronization and containment solutions (both for toxic and sterile products). Flexibility and attention to customer needs drive all stages of the process and ensures high standards of quality and safety for the operator, the product and the environment.

**FPS**, in partnership with **Vonlanthen Group of Companies**, for the first time organises a workshop dedicated to the Containment world. It will be on 19th October at the "Training Area" on the production plant in Fiorenzuola d'Arda (PC). During the event **FPS** expert team will be at your disposal to show and play with the innovative solutions in containment.
The goal of the workshop is to share and deepen the latest solutions about process equipment integration in containment systems with expert technicians of the sector. In the afternoon the attendees will be split in small groups to "play" with **FPS** equipment and visit the R&D and Test Center.

**FPS** designed containment systems are based on end-user specific requirements and safety standards by authorities. The isolators are engineered to contain the entire production process. **FPS** designs containment units for a variety of chemical and pharmaceutical applications: powder loading, powder drying, sampling activities, powder grinding and jet milling, liquid and powder filling, tableting, dispensing, final discharge and packaging, process control and recording, for the protection of the environment/operator as well as for sterile applications.

## Program

| | |
|---|---|
| 09:00 - 10.30 | Transfer from Hotel to FPS plant |
| 10:30 - 10:45 | Registration and coffee break |
| 10:45 - 11:00 | Welcome introduction |
| 11:00 - 11:45 | **SESSION 1**: Process equipment integration into containment systems |
| 12:00 - 12:45 | **SESSION 2:** Containment performance verification |
| 13:00 - 14:00 | Lunch break / buffet |
| 14:00 - 15:30 | **SESSION 3:** Guided Tour<br>- Detailed engineering<br>- Mock-up<br>- Assembling area<br>- Test Center |
| 15:30 - 15:45 | Final notes |
| 15:45 - 17:00 | Transfer from FPS plant to Hotel |