

# #5 Highly Potent Active Pharmaceutical Ingredients Summit

#VL5HPAPI

EUROSTARS ROMA AETERNA, VIA CASILINA 125, 00176

## Key Practical Learning Points of the Summit:

- EMA requirements and considerations
- Latest containment technologies and handling
- Assuring regulatory compliance with the permitted daily exposure
- Avoiding major HPAPI project issues
- Hazard assessment classifications
- Reducing risk – by design
- Prevention of cross-contamination
- Defining exposure controls in the workplace
- Advanced therapies: are they HPAPI?

## Key Speakers:

### Chairman



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



**Dr. Ester Lovsin, CH**  
Head Product Stewardship and Health  
Takeda



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



**Andrea Messori, IT**  
Lead Process Engineer  
Process Service Srl



**Martyn Ryder, UK**  
Director  
Solo Containment



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



**Dr. Michael Wölfle, CH**  
Validation Expert  
Manufacturing Science & Technology  
Novartis



**Dr. Firelli Alonso, US**  
Senior Director, External Supply  
Pfizer, Inc



**Dr. Denis Croisat, FR**  
Director, CMC & Biologics Sourcing  
& External Business  
Chemical & Pharmaceutical Development  
Sanofi



**Toral Mehta, AT**  
Head Industrial Hygiene and Containment  
Novartis



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



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



**Scott Patterson, US**  
Vice President, Commercial Sales  
ILC DOVER



**Tomás Hopkins, IE**  
EHS Manager  
Helsinn Birex



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



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



**Marina Martinelli, IT**  
EHS Coordinator  
BSP Pharmaceuticals S.p.A.



## Sponsors



## Welcome to the 5<sup>th</sup> anniversary edition

of the **Highly Potent Active Pharmaceutical Ingredients Summit** on October 2-4, 2019, in Rome, Italy.

This event provides its participants access to other industry leaders and 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 and best manufacturing practices as well as regulatory updates. This year's instalment includes the 2-day summit and a **1-day workshop\* session, sponsored by FPS Food and Pharma Systems srl.**

We are excited to be hosting the 5<sup>th</sup> Annual Highly Potent Active Pharmaceutical Ingredients Summit and we look forward to meeting you in Rome!

## 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
- + Health, Safety & Environment (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

### \*WORKSHOP LIMITED CAPACITY WARNING

We remind you that in order to make sure that you have a place in the workshop session, it's necessary to **register in advance** and receive a confirmation from Vonlanthen Group.

Seats will be sold until the capacity is filled.


**Once tickets are sold out, access will not be granted.** Thank you.

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

OCCUPATIONAL TOXICOLOGY AND INDUSTRIAL HYGIENE

09:10  WORKSHOP

**Public potent API hazard data – Live!**




**DR. ESTER LOVSIN**  
Head Product Stewardship and Health  
Takeda

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**




**The sky is not the limit, HBELs are**

**DR. ESTER LOVSIN**  
Head Product Stewardship and Health  
Takeda

- What are HBELs?
- What value do they bring to manufacturing?
- How to use them to assure compliance

10:55  MORNING COFFEE AND NETWORKING BREAK

11:25 **CASE STUDY**



**Toxicological justification for worker safety assessment of DARPins**

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

- Introduction to DARPins
- Basic worker safety assessment in general (OHC, banding)
- Specific worker safety assessment for DARPins
- Exposure assessment
- Worker safety assessment for women of childbearing potential, pregnant women and breast-feeding women working with DARPins

QUALITY RISK MANAGEMENT AND CLEANING VALIDATION


12:00 **CASE STUDY**



**Cleaning validation as one driver to prevent cross-contamination**

**DR. MICHAEL WÖLFLE**  
Validation Expert  
Manufacturing Science & Technology  
Novartis

- Regulatory requirements
- Health-based exposure limits
- Case studies

12:35	<p><b>CASE STUDY</b></p> <p><b>Reducing risk – by design</b></p> <p><b>TORAL MEHTA</b> Head Industrial Hygiene and Containment Novartis</p>		<ul style="list-style-type: none"> <li>• Overview of risk assessment methods</li> <li>• Selection of risk reduction method</li> <li>• Designing for containment and controlling exposures</li> <li>• Selecting the adequate control technologies</li> <li>• Validating your risk reduction</li> </ul>
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**13:10**  **NETWORKING BUFFET LUNCH**

14:10	<p><b>CASE STUDY</b></p> <p><b>High containment compounds, OH strategy and NPI at AbbVie</b></p> <p><b>DR. OLINDO LAZZARO</b> Director, Global EHS Technical Operations AbbVie</p>		<ul style="list-style-type: none"> <li>• Containment targets and OH long-range plan</li> <li>• High containment compounds</li> <li>• Tracking of risk assessments and improvements projects/OH exposure assessment metrics</li> <li>• PiE</li> <li>• New product introduction and tech transfer EHS/OH at FEP – EHS/OH at TPMs</li> </ul>
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**EQUIPMENT AND FACILITY DESIGN**

14:45	<b> SPONSORED SPEAKING SLOT</b>		
	<p><b>Process equipment special design for HPAPI containment system integration</b></p> <p><b>STEFANO BUTTI</b> Technical Sales Director FPS Food and Pharma Systems srl</p>		<ul style="list-style-type: none"> <li>• Are all standard process equipment suitable to handle HPAPI in a safe way?</li> <li>• Process equipment critical analysis for containment system integration</li> <li>• Case studies</li> <li>• Conclusions</li> </ul>


15:15	<b> SPONSORED SPEAKING SLOT</b>		
	<p><b>HPAPI facilities design from the engineering point of view</b></p> <p><b>ANDREA MESSORI</b> Lead Process Engineer Process Service Srl</p>		<ul style="list-style-type: none"> <li>• What is “highly potent”?</li> <li>• Exposure risks and containment strategies – operator protection</li> <li>• Primary and secondary containments</li> <li>• Typical examples of HPAPI facilities</li> <li>• HPAPI engineering fundamental project milestones</li> <li>• Key considerations in new facilities conceptual design</li> </ul>

15:45  AFTERNOON COFFEE AND NETWORKING BREAK

16:15 **CASE STUDY**

**Evaluating a CMO's overall ability to safely handle potent APIs**

**MARTIN AXON**  
Principal Occupational Hygienist  
SafeBridge Europe



A systematic approach to review of a CMO's capability

- Management and resource for API safety
- System for evaluation of the hazard
- Techniques applied to exposure control
- Verifying controls; available data
- Design of the facility from an exposure control perspective
- Employee understanding of API safety


16:50 **CASE STUDY**

**From non-potent to potent in a pharmaceutical finishing plant**

**TOMÁS HOPKINS**  
EHS Manager  
Helsinn Birex



- What's in a name? Standardising terminology, rationalising the risk
- Staff engagement – bringing everyone along for the journey
- Risk review tools – some different approaches

17:25  **PANEL DISCUSSION**

**Moderated by Chairman**



1. The occupational exposure limit is a borderline:  
worker exposure below the line is safe, exposure above the line results in health effects
2. Containment performance data for a high containment solution demonstrates and guarantees that the exposure limit will not be exceeded

18:00  **CHAIRMAN'S CLOSING REMARKS AND END OF DAY ONE**




19:00  **BUSINESS DINNER - SPONSORED BY GFPS**  
21:00 **RESTAURANT VA.DO AL PIGNETO (VIA BRACCIO DA MONTONE, 56)**

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

NAVIGATING REGULATORY DEMANDS AND PROGRESS OF CONTAINMENT TECHNOLOGIES

<p>09:10</p>	<p><b>CASE STUDY</b></p> <p><b>GMP and containment</b></p> <p><b>RICHARD DENK</b> Head of Containment Group Skan AG, Switzerland</p>	 <ul style="list-style-type: none"> <li>• What are the regulatory authorities concerns?</li> <li>• EMA/FDA and occupational safety authorities' requirements; are they the same or what is the difference?</li> <li>• Manufacturing in shared facilities; what are the critical pharmaceutical process design criteria?</li> <li>• Cleaning and cross-contamination requirements, especially for non-product contact surfaces</li> </ul>
<p>09:45</p>	<p><b>CASE STUDY</b></p> <p><b>Is there a difference between occupational hygiene monitoring and assessing the containment performance target of technical measures?</b></p> <p><b>DR. FRIEDERIKE HERMANN</b> Head of Occupational Hygiene Lonza</p>	 <ul style="list-style-type: none"> <li>• The aim of occupational exposure monitoring</li> <li>• The basics of OH-monitoring</li> <li>• Strategy for testing compliance: EN 689 vs. SMEPAC-testing</li> <li>• Interpretation of monitoring results</li> <li>• Are OELs applicable for incidents?</li> <li>• Examples</li> </ul>

SUCCESSFUL IMPLEMENTATION OF OUTSOURCING STRATEGIES

<p>10:20</p>	<p><b>CASE STUDY</b></p> <p><b>Adapting outsourcing strategies to the evolving challenges of CMC and pharmaceutical development</b></p> <p><b>DR. DENIS CROISAT</b> Director, CMC &amp; Biologics Sourcing &amp; External Business Chemical &amp; Pharmaceutical Development Sanofi</p>	 <ul style="list-style-type: none"> <li>• What dominates the outsourcing today? Criteria, trends, etc.</li> <li>• Adapting outsourcing strategies to the evolving challenges of CMC and pharmaceutical development, including high potent compounds and biologics</li> <li>• How to deal with variability and uncertainty</li> <li>• Drug delivery technologies</li> <li>• Creating value through a preferred vendor and strategic partnering model</li> <li>• Considerations for the selection of CMOs</li> </ul>
<p>10:55  <b>MORNING COFFEE AND NETWORKING BREAK</b></p>		
<p>11:25</p>	<p><b>CASE STUDY</b></p> <p><b>Establishing robust ADC manufacturing and supply chains</b></p> <p><b>DR. FIRELLI ALONSO</b> Senior Director, External Supply Pfizer, Inc</p>	 <ul style="list-style-type: none"> <li>• Establishing guiding principles for externalisation to ensure the selection of the right CMOs for ADC outsourcing and technology transfer</li> <li>• Strategising the best outsourcing practices for producing and testing ADCs for use in clinical trials</li> <li>• Sizing appropriately of the ADC supply chain to expedite transition from clinical to commercial manufacturing</li> </ul>

12:00  SPONSORED SPEAKING SLOT

**Manufacturing of oncological products by a CDMO**



**MARINA MARTINELLI**  
EHS Coordinator  
BSP Pharmaceuticals S.p.A.

**FABIO ZENOBI**  
EHS Director & QP  
BSP Pharmaceuticals S.p.A.

- New product introduction: change control - risk assessment
- Case study: ADC manufacturing
- Waste and wastewater treatment
- Project phase out

12:20  NETWORKING BUFFET LUNCH

13:30  SPONSORED SPEAKING SLOT

**Single-use containment technology for solving challenges in multi-purpose facilities**



**SCOTT PATTERSON**  
Vice President, Commercial Sales  
ILC DOVER

- High containment powder transfer solutions handling HPAPI
- Single-use flexible isolators to contain at the source
- Production efficiency and cost benefits when using single-use containment technology

14:00  SPONSORED SPEAKING SLOT

**Fully disposable, single-use isolator system for HPAPI containment**




**MARTYN RYDER**  
Director  
Solo Containment

- ADC toxin linker compounding in a fully disposable system
- Changes and features of single-use flexible film containment
- Proven high containment results

14:20  PANEL DISCUSSION

**Moderated by Chairman**

1. Recent years have seen the evolution of innovative flexible containment solutions; how do you decide whether traditional stainless steel equipment or disposable flexible containment solutions should be applied to a project?
2. When selecting a CMO for the manufacture of potent pharmaceutical products, with respect to control of exposure there are hardware (facility and equipment) and software (management, knowledge, experience) elements to consider.
  - What weight do you place on a low score for software elements?
  - How would you view a CMO that has no industrial hygiene data to support their containment claims?

15:00  CHAIRMAN'S CLOSING REMARKS AND END OF SUMMIT

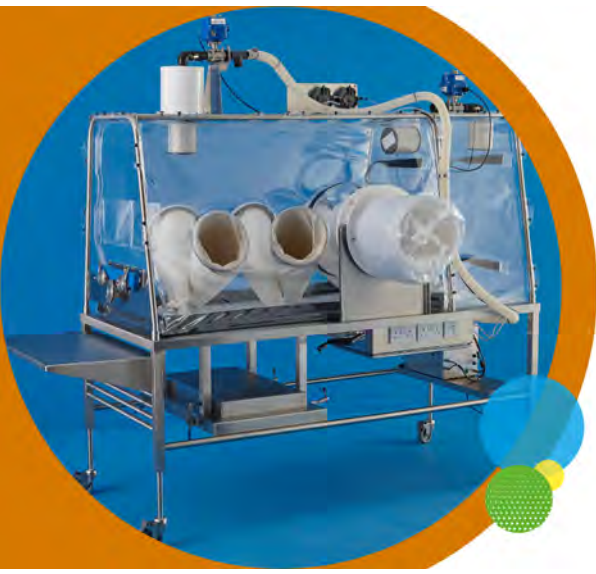
15:10  FAREWELL COFFEE AND NETWORKING BREAK

**High Potent APIs and ADC payloads**

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# Fully disposable, single use isolator system for HP API containment

Demonstrable high containment performance using the latest in flexible film technology

Listen to Martyn Ryder, our containment expert at 5th Annual HP API Summit, Rome



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# WORKSHOP

sponsored by  GFPS

Hotel Roma Aurelia Antica  
Via Degli Aldobrandeschi, 223 - 00163 Roma

09:00 Transfer from hotel to venue  
10:00 Registration and coffee break

## MORNING SESSION

- 10:30 Introduction of the day
- 10:45 Validation activities of high containment system
- 11:15 Containment performance test of equipment: method and results
- 11:45 High containment system routine and preventative maintenance
- 12:15 Question&Answers



## LUNCH BREAK

## AFTERNOON PRACTICAL SESSION

- 14:00
  - Demo on glove tester device functionality
  - "The evil is in the detail": isolators details that can make the difference (few isolator will be available to show these details)
  - Process equipment integrated into isolator: std. capsule filling machine vs. WIP version designed for Isolator integration
  - MicroNir spectrometer for Pharmaceutical application demo
- 15:45 Final notes
- 16:00 Transfer to hotel Eurostars Roma Aeterna / airport Fuimicino

## Our Upcoming Event:

**3rd Annual  
Aseptic Processing Summit**  
Vienna, Austria | November 20 – 21 2019





**Andrea Messori, IT**  
Lead Process Engineer  
Process Service Srl



Andrea Messori is leading process engineering design activities for pharmaceutical and fine chemicals at Process Service – an Italian engineering company. He has more than 20 years of expertise in API production facilities design starting from feasibility and conceptual design, basic design development and complete detailed engineering project management. He joined Process Service in 1997, and in those years he increased his knowledge developing many projects for pharma (API production facilities, HPAPI, fermentation and DSP biotechnologies, utility systems) and fine chemicals. In the last eight years he has managed HPAPI projects for more than six different main pharma companies in Italy and abroad dealing with HPAPI up to a few tens of nanograms CPT with investments ranging from a few million to many tens of millions, achieving a significant expertise in HPAPI facility design and containment strategies. Andrea graduated in chemical engineering in 1995 at Politecnico di Milano.



**Dr. Jörg Herbst, CH**  
Director of 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 has 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. In 2013, he joined 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 German Federal Institute for Risk Assessment.



**Toral Mehta, AT**  
Head Industrial Hygiene and Containment  
Novartis



Toral Mehta is EHS professional with more than 18 years of international experience in the core areas of occupational hygiene and occupational safety. She is a certified industrial hygienist (CIH) and certified safety professional (CSP) from American boards. In her professional tenure of 18-plus years, Toral worked with a large number of multinational pharmaceutical companies in more than 35 countries. Her contribution to the workplaces includes innovative methods of risk evaluations, prioritisation and controlling employee exposures with best containment technologies.



**Richard Denk, CH**  
Head of 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 Albstadt-Sigmaringen University of Applied Sciences in Germany. Richard works at SKAN AG, headquartered in Allschwil, as the head of sales containment. Eight years ago he founded the expert containment group of the ISPE D/A/CH, and in 2015 they published the Containment Manual. Richard has spent nearly 20 years with the production of highly active and highly hazardous substances and has developed the containment pyramid.



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



Fabio is responsible of Environment, Health and Safety at BSP Pharmaceuticals S.p.A., Latina Italy, a Contract Development and Manufacturing Organization focused on anticancer product, small molecules and ADC compounds. He is a Pharmaceutical Chemist and has over 20 years of experience in pharmaceutical industries as Serono, Bristol-Myers Squibb and Intervet, in Manufacturing, Quality Assurance, Technical Operations and EHS.



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- Powder weighing
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- Filter driers
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**Dr. Olindo Lazzaro, IT**  
Director,  
Global EHS Technical Operations  
**AbbVie**



Olindo Lazzaro is director of global EHS technical operations at AbbVie, responsible for global EHS technical centres of excellence at AbbVie supporting both R&D and manufacturing. Key areas are as follows: process safety management, loss prevention and fire protection, OH/containment, chemical safety and GHS, PiE, green chemistry/ecoefficiency, N2/inert gas handling, EHS new product introduction and EHS technical transfer. He's also responsible for AbbVie environmental and OH labs (both are ISO 17025 accredited), leads prevention of catastrophic incidents (PCI) strategy and is an EHS approver for AbbVie engineering standards. Olindo's a champion of manufacturing containment capital improvement long plan, OH/containment engineering community of practice and of the AbbVie pharma in the environment (PiE) team. He is EHS representative in the AbbVie operations pipeline teams. Olindo holds a master's degree with honours in environmental engineering with a specialisation in process safety management and major hazard control from the University of Roma La Sapienza and an EMBA in pharmaceutical administration from LUISS University Business School, Italy. He is registered as a professional engineer and fire protection expert in Italy. He is a certified occupational health and safety manager, construction safety manager and energy manager. Olindo is also qualified as an evaluator of environment management systems according to ISO14000 and EMAS rules and as internal auditor for the health and safety management system according to OHSAS 18001 and UNI 10617.



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



Martin Axon is principal occupational hygienist for SafeBridge Europe and is a chartered fellow of the faculty of occupational hygiene. He has degrees in industrial chemistry and environmental pollution science. He has over 25 years of experience working in the pharmaceutical industry in the UK and internationally, where, as an occupational hygienist for primary and secondary sites, he provided support for potent pharmaceutical product manufacture. During mid-career, he was course director for a postgraduate programme in occupational hygiene, health and safety, at London South Bank University. Martin joined SafeBridge in 2005. His current role includes managing SafeBridge's services in Europe and advising clients on the safe handling of potent pharmaceutical compounds in a range of environments, from laboratory scale through to secondary manufacture.



**Marina Martinelli, IT**  
EHS Coordinator  
**BSP Pharmaceuticals S.p.A.**



Marina has the responsibility to coordinate the Environment, Health and Safety department at BSP Pharmaceuticals S.p.A., Latina Italy, a Contract Development and Manufacturing Organization focused on anticancer product, small molecules and ADC compounds. She is an Environmental Engineer with several years of experience in the Pharmaceutical make sites, including multinational companies such as Janssen Cilag Spa, pharmaceutical branch owned by Johnson & Johnson.



**Dr. Firelli Alonso, US**  
Senior Director, External Supply  
**Pfizer, Inc**



Dr. Firelli Alonso is senior director of external supply at Pfizer, Inc. She heads the biotherapeutics and vaccines outsourcing group in worldwide research and development. Fi has 35 years of combined experience in research, development and cGMP production of biological products and vaccines, and 15 years of experience in outsourcing, project and contract management and technology transfer to qualified third parties. Her areas of expertise include viral vectors and viral vaccine development, recombinant proteins, vaccine process development and cGMP production, project management, technology transfer and outsourcing. She obtained her PhD in microbiology/virology from the University of Alabama in Birmingham, followed by postdoctoral research at the U.S. Army Medical Research Institute for Infectious Diseases, Sloan-Kettering Institute for Cancer Research and Rutgers University's Center for Advanced Biotechnology and Medicine. Prior to joining Wyeth/Pfizer in 1996, Fi worked at The Salk Institute/Government Services Division, a vaccine contract manufacturer for the U.S. Armed Forces.



**Dr. Denis Croisat, FR**  
Director, CMC & Biologics Sourcing  
& External Business  
Chemical & Pharmaceutical Development  
**Sanofi**



Deputy head of CMC licensing, sourcing and collaborations, Denis Croisat has more than 20 years of experience in the field of outsourcing and CMO management, technologies scouting and drug delivery technologies. After completing a PhD in organic chemistry at the University of Paris, in 1991 Denis joined Sanofi-Aventis and held different positions in process development and industrial affairs. Denis is managing the sourcing and outsourcing related activities within research and development. In his role, Denis is responsible for all sourcing related activities, encompassing sourcing and outsourcing activities within CMC departments: chemical and process development departments, biotechnology department, pharmaceutical sciences development department and analytical sciences development department.



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



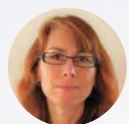
Stefano Butti studied mechanical engineering at the University of Milan and graduated in 2000. He has been an ISPE member since 2002. He has participated as a speaker at different congresses and seminars on containment and micronisation; topics have been for both HPAPI and sterile application. Adding to that, he has published different articles in technical newspapers. Stefano worked as a project and process manager in the chemical and pharmaceutical business following containment and micronisation system installation worldwide. He 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, spending close to 18 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.



**Scott Patterson, US**  
Vice President, Commercial Sales  
**ILC DOVER**



Scott Patterson is a subject matter expert for containment of pharmaceutical manufacturing processes as well as powder handling in upstream biopharmaceutical manufacturing. He has been supporting the global marketplace with ILC Dover for the past 14 years and has a total of 21 years of experience in the life sciences market. He has led innovative advancements using single use products to demonstrate the performance capabilities and value proposition. With a mechanical engineering education at Youngstown State University he is now starting year 41 of experience in a wide range of markets including plastics, pulp and paper, packaging and inspection equipment, as well as expertise in milling and roller compaction.



**Dr. Ester Lovsin, CH**  
Head Product Stewardship and Health  
**Takeda**



Ester Lovsin Barle, DVM, MSc, PhD, MScTox is the Head of Product Stewardship and Health at Takeda. Previously she has held corporate positions at Lonza and Novartis. Her responsibilities include regulatory and SDS related topics, scientific development and cross-organizational implementation of health based exposure limits (HBEL), compiling global policy product stewardship related process in support of manufacturing in Takeda globally, as well as global implementation of industrial hygiene. She received her PhD in veterinary sciences from University of Ljubljana, Slovenia and a second masters degree in toxicology and risk assessment from Medical University in Vienna. Dr. Lovsin Barle is author/co-author of over 70 publications including peer-reviewed articles and book chapters. She is a member of several pharma industry and toxicological associations and boards and has served as the president of the Slovenian Society of toxicology. She lectures at several universities. Privately she is a mother of two and is enthusiastic about balanced and healthy lifestyle which includes components of triathlon, mountain hiking and good food.



**Dr. Michael Wölfle, CH**  
Validation Expert  
Manufacturing Science & Technology  
**Novartis**



Martyn Ryder is director of Solo Containment, based in Greater Manchester, UK. Since establishing Extract Technology in 1981, Martyn has worked across the pharmaceutical containment industry but has focussed his expertise to single-use, flexible film containment since launching Solo in 2011. Across his career, Martyn has been involved in developing HPLC surrogate API containment test methodology and co-authored the IchemE Containment Design Guide in 1999. Part of the remit of Solo Containment is to push the capabilities of flexible film containment and as such, Martyn developed the first ADC compounding isolator in 2016.



**Tomás Hopkins, IE**  
EHS Manager  
**Helsinn Birex**



Tomás Hopkins has worked in the arena of pharmaceutical EHS for 20 years. His primary role covers the risk management of site operations in multiple fields such as safety, energy, environmental and wellbeing. The majority of Tomás's tenure has been with Helsinn Birex Pharmaceuticals Ltd., operating out of Dublin as part of the Swiss based Helsinn Group. Over the past number of years Helsinn has moved from cancer supportive care into cancer therapeutic care. This progression led to the introduction of potent materials and Tomás has played a key part in delivering this important change to site operations.



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



Dr. Friederike Hermann is Head of Occupational Hygiene at Lonza Visp. She obtained her doctorate in the field of Analytical Chemistry with an emphasis on Element Speciation. In 2001, Dr. Hermann started as an Analytical Chemist in the Environmental Department and eventually transitioned into the field of Occupational Hygiene. She was significantly involved in the setup of high potent compound production at Lonza. She completed her Master of Advanced Studies (MAS) degree on Work and Health at the ETH Zürich and the University of Lausanne. Dr. Hermann is a certified hygienist through the Swiss Society of Occupational Hygiene. She is a member of the steering committee of COP Containment ISPE Affiliate DACH. She is also a member of the MAK Commission Switzerland and actively participates in a network of Occupational Hygienists, Physicians and Toxicologists, which form the Basel Chemical Industry (BCI). She is also a member of the Health Commission for the Lonza Visp site, which has over 3,000 employees. She lives in Wallis, Switzerland, where she enjoys running, cycling and hiking.



**Martyn Ryder, UK**  
Director  
**Solo Containment**



Martyn Ryder is director of Solo Containment, based in Greater Manchester, UK. Since establishing Extract Technology in 1981, Martyn has worked across the pharmaceutical containment industry but has focussed his expertise to single-use, flexible film containment since launching Solo in 2011. Across his career, Martyn has been involved in developing HPLC surrogate API containment test methodology and co-authored the IchemE Containment Design Guide in 1999. Part of the remit of Solo Containment is to push the capabilities of flexible film containment and as such, Martyn developed the first ADC compounding isolator in 2016.