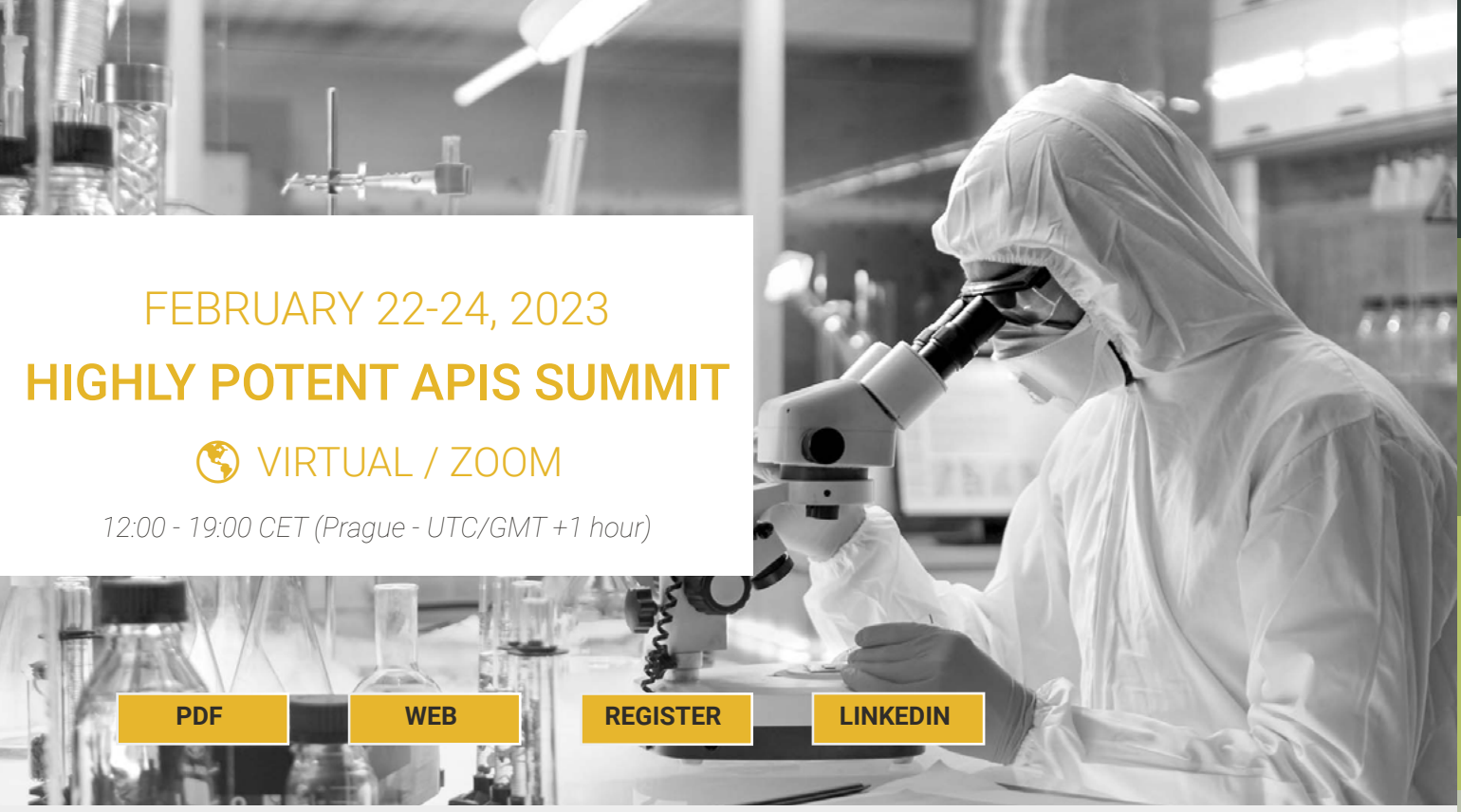

FEBRUARY 22-24, 2023

HIGHLY POTENT APIS SUMMIT

VIRTUAL / ZOOM

12:00 - 19:00 CET (Prague - UTC/GMT +1 hour)

PDF | WEB | REGISTER | LINKEDIN

SPEAKERS BOARD

PARTNER

SCHEDIO
The Power of Together

Presented by:

Mattia Wiedemeier
Commercial Director
Schedio SA, CH

Milko Leone
CEO and Technical Director
Schedio SA, CH

Schedio Aftersales Program

Schedio Company Brochure

White paper "What are some hidden risks associated with isolators?"

White paper "Reducin gas consumption by 20% during the micronization process with the coaxial jet mill"

Schedio was born from a group of passionate and experienced specialists from the pharmaceutical industry who launched the company and created something new and unique established on specific core values and commitments including equality and diversity, work-life balance, entrepreneurship and continuous learning, among others.

Dr. Claudia Sehner
Senior Toxicologist
Boehringer Ingelheim, DE

Douglas E. Kiehl
Senior Director
Spectroscopy, Elemental Impurities, Extractables & Leachables
Eli Lilly & Company, USA

Dr. Thomas Adam
Head of GQA Chemical APIs
Bayer AG, DE

Jay L. Brown
Associate Director of EHS
Piramal Pharma Solutions, USA

Olindo Lazzaro
Head, Global EHS by Design
CSL Behring, CH

Andreas Schreiner
Director of Validation, Manufacturing Science and Technology
Novartis, CH

SPEAKERS BOARD

Andrea Guytingco, MPH, CIH
Sr. EHS Business Partner
Takeda Pharmaceutical Company Limited USA

Jeremy Justin Mason-Home, BSc (Hons), FRSC
Director
HPAPI Project Services Limited, UK

Nancy M. McClellan, M.P.H., CIH, CHMM
Principal Industrial Hygiene Expert & CEO
Occupational Health Management, PLLC, USA

Lisa Wiesner
Sr. Manager, Toxicologist – Nonclincial Safety Assessment
Takeda, CH

Silke Buechl
Deputy Managing Director, Occupational Hygienist
Praevena AG, CH

Thomas Weingartner
Managing Director
Lugaia Deutschland GmbH, DE

Dr. Greg Erexson, PhD, DABT, FATS, FRSB, ERT
AbbVie Retiree
Greg Erexson Toxicology Consulting, LLC

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

Dr. Ildikó Ziegler
Director Of Quality
Vanessa Research, HU

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

Sean Keenan
Pilot Plant Manager
CONTINUUS Pharmaceuticals, Inc., USA

Steve Marnach
EMEA Training Specialist & Pharma Specialist
DuPont Personal Protection LU

Dr. Friederike Hermann
Head of Occupational Hygiene
Lonza, CH

Dr. Jürgen Schnaubelt
Director Early Drug Substance Development
Boehringer Ingelheim Pharma GmbH & Co. KG, DE

Richard Denk
Senior Consultant, Aseptic Processing & Containment
Skan AG, CH

Richard Arnett
Manager, Industrial Hygiene & Toxicology
Pharmascience Inc., CA

Andrew Walsh
President
Center for Pharmaceutical Cleaning Innovation (CPCI™), USA

Dr. Martin Kohan PhD, ERT, DABT
Managing Toxicologist
SafeBridge Europe, Ltd., UK

Christopher Lippelt
Manager, Pharmaceutical Project Management
Eli Lilly and Company, USA

Martin William Axon
Senior Scientific Advisor
SafeBridge Europe, UK

SCHEDIO
The Power of Together

Containing the HPAPI of the future

Tailored solutions for unparalleled safety

As the demand for high potent API (HPAPI) continues to grow, so does the need for reliable and effective containment solutions. Micronization, in particular, can be a challenging process to contain due to the heavy creation of ultra-fine particles. But at Schedio, we understand the importance of protecting operators from operative exposure levels (OEL) that become more and more challenging each year.

That's why we've developed a range of innovative technologies and expertise to help us create fully tailored and top-tier containment solutions. Whether you're dealing with jet mills or reactor loading, our solutions are specifically designed to meet the unique needs of your process and product.

Thanks to our cutting-edge technology, we're able to provide contained processes with an OEL of up to 1 nanogram/m³ (0.001 microgram/m3). With our solutions, you can rest assured that your operators are protected and your HPAPI is handled safely.

www.schedio.ch

SNAPSHOT OF ATTENDEES - 2nd Annual Highly Potent APIs Summit 2020

https://qepler.com/events/hpapi20.html
https://qepler.com/pdf/hpapi20.pdf

AbbVie • Acino Pharma AG • Affygility Solutions, LLC • Allergan plc • AMRI ITALY SRL • Andreas Flueckiger Consulting • Angelini Pharma S.p.A. • Bayer AG • Boehringer Ingelheim Pharma GmbH & Co. KG • F. Hoffmann-La Roche AG • Ferring International Center SA • Ferring Pharmaceuticals • Fresenius Kabi Austria GmbH • FUJIFILM Diosynth • GEA Process Engineering nv • Gedeon Richter Plc. • Hebeler Process Solutions LLC • Heraeus Deutschland GmbH & Co. KG • HPAPI Project Services Limited • ILC Dover • Lonza Pharma & Biotech • Merck & Cie • Merck Group • Merck Healthcare KGaA • Merck Performance Materials KGaA • Minakem High Potent • oncomed manufacturing a.s. • Pfizer CentreOne • Pharmacare Premium • Praevena AG • Quinta-Analytica • Raybow Pharmaceutical • SafeBridge Europe, Ltd. • Seqens R&D SERVICES • Servier • Synthon • Takeda • University of Oxford • Vanessa Research Magyarország Kft. • Vetter Pharma-Fertigung GmbH & Co. KG • Zentiva k.s. • Zhejiang Juli Electric Tools Co., Ltd • others.

SNAPSHOT OF ATTENDEES - Highly Potent APIs Summit 2019

https://qepler.com/events/hpapi19.html
https://qepler.com/pdf/hpapi19.pdf

Affygility Solutions • Ardena • ARTeSYN Biosolutions • Bayer AG • Bayer Consumer Care AG • Biocon • Bristol Myers Squibb • Celgene • ChargePoint Technology Ltd • EVER Pharma Jena GmbH • Gedeon Richter • GlaxoSmithKline • Guido Maik Consulting • Hebeler Process Solution LLC • HPAPI Project Services Limited • ILC Dover • Ipsen • JLS International Germany • Krka, d.d., Novo mesto • Leeds Beckett University • Lonza • Lonza Pharma & Biotech • Lusochimica SpA • Merck Group • Minaken • Mitsui & Co. Italia S.P.A. • MSD • Novartis • Novasep • Oriento SA • Patheon, part of Thermo Fisher Scientific • Piramal Pharma Solutions • Pliva Croatia Ltd, TAPI Croatia • Praevena AG • Regeneron Pharmaceuticals, Inc • Skan AG • Takeda Ireland Limited • Umicore AG & Co KG • others.

DIVISIONS

- API, HPAPI & Impurities
- Environmental, Health & Safety
- Industrial Hygiene
- Occupational Toxicology
- Risk Assessment, Evaluation & Mitigation
- Hazard Assessments
- ADE, PDE, OELs, OEBs
- Quality Control & Assurance
- Aseptic Processing
- ADC & New Molecules
- CMC
- Chemical Manufacturing, Processes & Synthesis
- Compounds Manufacturing
- Contamination
- Containment
- Drug Process Development
- Extraction
- Isolation
- Formulation Development
- Laboratory Services
- Manufacturing
- Materials Management
- New Technologies
- Plant & Site Management
- Facility Design & Equipment Selection
- Cleanrooms
- Process Chemistry
- Process Development & Engineering
- Raw Materials
- Regulatory
- Research & Development
- Toxicology
- Validation
- Corporate & Business Development
- External Supply
- Marketing
- Outsourcing
- Partnerships & Alliances
- Sales Development
- Strategic Development

February 22, 2023 | 1st DAY

Central European Time (CET, Prague, UTC/GMT +1 hour)

11:20 Opening Address

11:30 **HPAPI Process Design and Project Implementation [REC] [SLIDES]**

- *Potent drug safety in R&D and Scale-Up environments*
- *Exposure risk in the Laboratory Setting*
- *HPAPI Process Design (influencing potent drug safety early in the project timeline)*
- *HPAPI Process Transfer and Scale-up*

Jeremy Justin Mason-Home, BSc (Hons), FRSC | Director | HPAPI Project Services Limited, UK

12:10 **Manufacturing of Oncological Products by a CDMO [REC] [SLIDES]**

- *New Product Introduction: Change Control - Risk Assessment*
- *Case Study: ADC Manufacturing*
- *Waste & Wastewater treatment*

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

12:50 **Garment selection criteria for the safe handling of HPAPI [REC] [SLIDES]**

Based on the manufacturing environment and the workplace risk assessments, it is important to select the right protective garments to protect the workers from getting contaminated with HPAPI without risking to contaminate the HPAPI that are handled or produced.
This presentation will highlight the most important aspects to be taken into consideration when selecting the appropriate protective garments in grade A-D pharmaceutical cleanrooms.

- *The role of PPE in the containment strategy*
- *Risk assessment*
- *Understanding permeation & penetration*
- *Which garments to use in grade A-D pharmaceutical cleanrooms?*

Steve Marnach | EMEA Training Specialist & Pharma Specialist | DuPont Personal Protection, LU

13:30 Break

13:50 **HPAPI manufacturing in early Chemical Development [REC] [SLIDES]**

- *Case study on small scale production*
- *Feasibility study of new lab facility*

Dr. Jürgen Schnaubelt | Director Early Drug Substance Development | Boehringer Ingelheim Pharma GmbH & Co. KG, DE

14:30 **How to handle HPAPIs within Chemical Development (case studies) [REC] [SLIDES]**

- *GMP-Compliance and Regulatory Environment*
- *Prevention of Cross-Contamination in HPAIs Shared Facilities*
- *Cleaning of Equipment in the Manufacturing of HPAIs*

Dr. Thomas Adam | Head of GQA Chemical APIs | Bayer AG, DE

PRESENTER PARTNER

15:10 **What are some hidden risks associated with isolators?**

Pharmaceutical and fine chemical entities may not fully consider potential hazards associated with the usage of glove boxes and isolators when conducting operations with hazardous materials. To ensure optimal safety protocols, it is imperative to prioritize operator safety and minimize the probability of incidents or suboptimal product development.

This presentation will uncover the hidden risks associated with isolators and discover the Schedio approach of putting safety first.

Mattia Wiedemeier | Commercial Director | Schedio SA, CH
Milko Leone | CEO and Technical Director | Schedio SA, CH

February 22, 2023 | 1st DAY

Central European Time (CET, Prague, UTC/GMT +1 hour)

15:50 Break

16:10 **Case Study: How to develop a high potent Antibody Drug Conjugate ADC production suite**

[REC] [SLIDES]

- *How to design the Containment from inside to the outside*
- *Design criteria for high potent Aseptic Manufacturing*
- *Cleaning requirements to prevent Contamination and Cross Contamination*

Richard Denk | Senior Consultant, Aseptic Processing & Containment | Skan AG, CH

16:50 **A Systematic Approach to the Safe Handling of Potent Active Pharmaceutical Ingredients**

[REC] [SLIDES]

Potent APIs can produce adverse health effects in pharmaceutical production workers or scientists, even if exposed to airborne concentrations that are not visible. Organisations handling potent APIs should employ a systematic approach to safe handling, so that appropriate facility design, and controls at source, are selected for each work environment. An essential element of the approach is to demonstrate that controls are effective.

Martin William Axon | Senior Scientific Advisor | SafeBridge Europe, UK

17:30 **Panel Discussion: Looking Beyond Pharma 4.0: Future Initiatives and Advanced Manufacturing Approaches**

- *FDA is driving advanced manufacturing as a strategic and technical priority via the FRAME initiative. This includes:*
  - *continuous end-to-end manufacturing*
  - *point of care manufacturing*
  - *distributed manufacturing*
  - *agile modular/reconfigurable manufacturing*
  - *application of AI/ML across manufacturing processes*

Given this, how do we reconcile the FRAME manufacturing initiatives and Pharma 4.0 with HPAPI requirements?

- *A primary tool for Pharma 4.0 implementation is digital and virtual twin technologies. Is this an enabler for digital transformation for HPAPI processes?*
- *Does digital enablement (e.g., digital or virtual twins) simplify and speed validation?*
- *What challenges exist with HPAPI containment and scale?*
- *What challenges exist with plant safety inspections HSE concerns?*
- *Is there implementation of remote interaction with process operations to minimize human intervention (e.g., virtual/augmented reality)?*
- *How about remote interactive evaluation (REI) for regulatory inspections (e.g., PAI)?*
- *What challenges exist with supply chain integrity and security?*

[Moderator] Douglas E. Kiehl | Senior Director Spectroscopy, Elemental Impurities, Extractables & Leachables | Eli Lilly & Company, USA
Martin William Axon | Senior Scientific Advisor | SafeBridge Europe, UK
Christopher Lippelt | Manager, Pharmaceutical Project Management | Eli Lilly and Company, USA
Nancy M. McClellan, M.P.H., CIH, CHMM | Principal Industrial Hygiene Expert & CEO | Occupational Health Management, PLLC, USA
Dr. Ildikó Ziegler | Director Of Quality | Vanessa Research, HU
Andreas Schreiner | Director of Validation, Manufacturing Science and Technology | Novartis, CH
Jeremy Justin Mason-Home, BSc (Hons), FRSC | Director | HPAPI Project Services Limited, UK
Richard Denk | Senior Consultant, Aseptic Processing & Containment | Skan AG, CH
Sean Keenan | Pilot Plant Manager | CONTINUUS Pharmaceuticals, Inc., USA

18:30 Closssing remark

February 23, 2023 | 2nd DAY

Central European Time (CET, Prague, UTC/GMT +1 hour)

11:40 Opening Address

11:50 Sources of cross-contamination risk in solid dosage form manufacturing [REC] [SLIDES]

- *Guidelines regarding cross contamination and toxicological approach*
- *Complexity in risk analysis of cross contamination*
- *Case study - a tabletting plant*

Dr. Ildikó Ziegler | Director Of Quality | Vanessa Research, HU

12:30 Cleaning validation – Enhanced approach required for Highly Potent APIs? [REC] [SLIDES]

- *Health Authority Requirements*
- *Case Studies*
- *Cleaning Process Design Phase*

Andreas Schreiner | Director of Validation, Manufacturing Science and Technology | Novartis, CH

13:10 Break

13:30 EHS Integration in Capital Projects and Tech Transfer ~~[REC]~~ [SLIDES]

- *Risk Reduction and EHS Management Elements*
- *Proactive approach for EHS review and input during TT and Capital planning process*
- *How to Address EHS issues early during the design phase.*
- *EHS deliverables during the planning, design and installation of processes, equipment and facilities to support TT*
- *Verification: FAT/SAT/PSSR*

Olindo Lazzaro | Head, Global EHS by Design | CSL Behring, CH

14:10 Integrating EHS into the RFP Process for HPAPIs [REC] [SLIDES]

- *Integrate EHS as early in the process as possible*
- *Having the right team F2F with customers/clients*
- *Information needs to ensure a smooth scoping process*
- *Resolving OEB and/or OEL disagreements with customers/clients quickly*
- *Determine who pays for containment, risk assessments, and waste costs*

Jay L. Brown | Associate Director of EHS | Piramal Pharma Solutions, USA

14:50 Quantitative Measurement of Risk in Cleaning using ASTM Standards [REC] ~~[SLIDES]~~

- *Why do we Need to Measure Risk in Cleaning?*
- *What are the ASTM Cleaning Standards?*
- *What are the Components of Risk in Cleaning?*
- *What are the Toxicity, Process Capability and Detectability Scales?*
- *What is the Shirokizawa Matrix?*

Andrew Walsh | President | Center for Pharmaceutical Cleaning Innovation (CPCI™), USA

February 23, 2023 | 2nd DAY

Central European Time (CET, Prague, UTC/GMT +1 hour)

15:50 Break

16:10 **Occupational Hygiene Programs and Practice Standards of Care [REC] [SLIDES]**

- *The Future Benchmark for Occupational/Industrial Hygiene Programs*
- *What Might a Pharma Mercedes Benz Look Like?*
- *Free OH Program Development & Management Tools*
- *Who Are Your Critical Team Players?*

Nancy M. McClellan, M.P.H., CIH, CHMM | Principal Industrial Hygiene Expert & CEO | Occupational Health Management, PLLC, USA

16:50 **The Ongoing Significant Toxicological Challenges in Developing Efficacious Antibody Drug Conjugates (ADCs) [REC] [SLIDES]**

- *History of ADCs*
- *Monoclonal Antibody (or Antibodies Selection)*
- *Linker Technology*
- *Payload/Warhead/Small Molecule Selection*
- *Approved/Marketed ADCs and Efficacy*
- *Containment Requirements*

Dr. Greg Erexson, PhD, DABT, FATS, FRSB, ERT | AbbVie Retiree | Greg Erexson Toxicology Consulting, LLC, USA

GREG EREXSON Toxicology Consulting, LLC

17:30 **Exposure Assessment Challenges for New Modality Potent Compounds in R&D [REC] [SLIDES]**

As the shift in the pharmaceutical R&D environment goes from small molecule, solid, powder handling transitions to large molecule, liquid handling, how does Industrial Hygiene and the greater EHS team adapt to new methods of risk assessment and control? This presentations addresses:

- *The partnership of Industrial Hygiene and Biosafety practices to mitigate employee exposure to pharmaceutical ingredients that have both biological and chemical components or require additional employee protection.*
- *Understanding that traditional Industrial Hygiene risk assessments can be difficult when there is limited knowledge or data on the API being handed. How do we make our best educated recommendation on controls that's not overly conservative?*
- *Designing spaces for adaptability and flexibility.*
- *Case studies highlighting the challenges of controlling for new modality potent compounds in an R&D setting.*

Takeda

Andrea Guytingco, MPH, CIH | Sr. EHS Business Partner | Takeda Pharmaceutical Company Limited, USA

18:10 Closssing remark

February 24, 2023 | 3rd DAY

Central European Time (CET, Prague, UTC/GMT +1 hour)

11:20 Opening Address

11:30 **Flexible Isolator- Occupational Hygiene Experience [REC] [SLIDES]**

- *technical details and design of a flexible isolator by lugaja,*
- *results of exposure monitoring at the flexible isolator*
- *Results of exposure monitoring of the operator*
- *scope and challenges between monitoring of operator exposure according to EN689 and monitoring of containment performance according to SMEPAC*

Silke Buechl | Deputy Managing Director, Occupational Hygienist | Praevena AG, CH
Thomas Weingartner | Managing Director | Lugaia Deutschland GmbH, DE

12:30 **Occupational Exposure Bands (OEBs) [REC] [SLIDES]**

- *What are OEBs?*
- *History of OEBs*
- *Use and communication of OEBs*
- *Case studies - OEBs for compounds with limited data*

Dr. Martin Kohan PhD, ERT, DABT | Managing Toxicologist | SafeBridge Europe, Ltd., UK

13:10 **Health-based exposure limits (HBELs) for biotechnological products ~~[REC]~~ [SLIDES]**

- *HBELs (OELs and PDEs): Why are they needed?*
- *Principles for the calculation of OELs and PDEs*
- *Are OELs and PDEs required for biotechnological products/new modalities?*
- *Particularities e.g., for protein- and RNA/DNA-based therapeutics*
- *Considerations for implementation*

Dr. Claudia Sehner | Senior Toxicologist | Boehringer Ingelheim, DE

13:50 Break

14:10 **How to derive health-based exposure limits (HBEL) for ADCs [REC] ~~[SLIDES]~~**

- *Example of an Antibody-Drug-Conjugate (ADCs) at Takeda*
- *What are health-based Exposure Limits (HBEL)?*
- *Default HBEL for ADCs*
- *HBEL calculation methods for ADCs*

Lisa Wiesner | Sr. Manager, Toxicologist – Nonclincial Safety Assessment | Takeda, CH

February 24, 2023 | 3rd DAY

Central European Time (CET, Prague, UTC/GMT +1 hour)

14:50 **HBEL - containment and occupational hygiene monitoring.** ~~[REC]~~ [SLIDES]

- *Assessing the risk of exposure*
- *Defining the needed containment*
- *Occupational Hygiene Monitoring*

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

15:30 **Antibody-Drug Conjugates – antibodies meeting HPAPIs for specific and efficient bio-pharmaceutical drugs.** ~~[REC]~~ [SLIDES]

- *The development and manufacture of ADCs - challenges and solutions*
- *The make-or-buy question – what to outsource and what to do in-house?*
- *Bayer's ADC production concept*
- *Best practices for CDMO selection and outsourcing*
- *Understanding the success factors, risks and mitigations*

Dr. Ulrich Rümenapp | Head of Launch Preparation and Coordination | Bayer AG, DE

16:10 Break

16:30 **Ensuring product & worker safety in multi-product GMP facilities** [REC] [SLIDES]

- *Identifying the 'must haves' vs the 'nice to haves'*
- *Ensuring safety and acceptable risk without 'over-engineering'*
- *Leveraging HBELs to achieve the required standard*
- *Choosing between flexible/disposable and rigid containment solutions*

Richard Arnett | Manager, Industrial Hygiene & Toxicology | Pharmascience Inc., CA

17:10 **Continuous Processing as a Tool for HPAPI Development and Manufacturing** ~~[REC]~~ [SLIDES]

Continuous "flow" processing is a maturing technology that is rapidly gaining interest and adoption thanks to the benefits that it can offer for the synthesis of API. HPAPI synthesis may uniquely benefit from the advantages of continuous processing, especially in regards to containment and process economics.
This talk will offer an introduction to the benefits of continuous processing, review common types of continuous reactors and process analytical technology, and propose scenarios for when and how to apply continuous processing to synthesis of HPAPIs.

Christopher Lippelt | Manager, Pharmaceutical Project Management | Eli Lilly and Company, USA

17:50 **Design Considerations for the Buildout of a New Small Molecule HPAPI R&D Laboratory**

CONTINUUS Pharmaceuticals recently completed the opening of a new OEB4 Highly Potent API R&D laboratory earlier this year within 6 months from building occupancy.
This talk will touch on the comprehensive safety programs developed and the cross functional approach used to manage the buildout, focusing on the implementation of the hierarchy of controls.
Risk-based safety procedures, engineering controls equipment, and industrial hygiene practices used in the safe operation of this R&D laboratory will all be discussed.

Sean Keenan | Pilot Plant Manager | CONTINUUS Pharmaceuticals, Inc., USA

18:30 Closssing remark

Silke Buechl | Deputy Managing Director, Occupational Hygienist | Praevena AG, CH

Silke Büchl is an experienced IOHA certified Occupational hygienist with about 20 years of experience in occupational hygiene.
She received the IOHA certified Occupational Hygienist after the postgraduate studies for work and health at ETH Zürich and Uni Lausanne in 2003.
Bevor she started as 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 with the focus on occupational hygiene topics as well as participation in the internal board to define of Occupational Exposure Limits at Novartis.

Praevena is a company which provides services in all topics of Occupational Hygiene as well as exposure monitoring.

Thomas Weingartner | Managing Director | Lugaia Deutschland GmbH, DE

Thomas Weingartner is the managing director of Lugaia Deutschland GmbH, he held managerial positions in powder handling companies and is active in the field of containment for more than 20 years. Thomas Weingartner develops customer specific containment solutions on the basis of high quality film materials. His experience includes pharmaceutical industrial hygiene and safety for other industries such as lifescience and finechemistry. Thomas has a wealth of experience in providing and installing containment solutions to minimize the risk of contamination.

The core competence of Lugaia lies in the market-ready products based on film, which customers use as single-use solutions in hygiene process technology. The film systems manufactured in clean rooms are used once and then disposed of. This eliminates the need for expensive and time-consuming cleaning processes for the systems and the costly qualification procedures that go with them.

Jeremy Justin Mason-Home, BSc (Hons), FRSC | Director | HPAPI Project Services Limited, UK

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

Dr. Thomas Adam | Head of GQA Chemical APIs | Bayer AG, DE

Thomas Adam is currently the head of global quality assurance chemical APIs in the chemical development department of the pharmaceutical business unit of Bayer.
He is responsible for the release of chemical APIs for clinical trials, the GMP-Quality system and the QA-oversight of the pilot plants and analytical development laboratories.

Thomas holds a PhD in analytical chemistry from the University of Mainz in Germany.
He has about 20 years of industrial experience at Bayer in different QC/QA-functions and a two years Post-Doc experience at Novartis, Switzerland.
He is and was involved in many technical (transfer)-projects so as the planning and launching of the new GMP-kg lab for highly potent APIs and establishing a cleaning concept for the chemical development department.

Dr. Ulrich Rümenapp | Head of Launch Preparation and Coordination | Bayer AG, DE

Dr. Rümenapp is based in Wuppertal, Germany and works within the Product Supply Biotech organization of Bayer AG, where he is responsible for product development of late stage assets and launch preparations including the transfer of Bayer's pipeline candidates (proteins, antibodies and antibody-drug-conjugates) to external manufacturing partners, as well as strategic projects.

Prior to that, Dr. Rümenapp worked in Biologics Development, and he was Head of Projects in Biotech Contract Manufacturing, where he was responsible for contract manufacturing partnerships for drug substances and drug products and interdisciplinary project management to ensure market supply. Before it was acquired by Bayer, Dr. Rümenapp held a similar position at Schering AG, and he started his career 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 worked several years in academic research and as an assistant teacher in 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 20 years of experience in the biopharmaceutical industry.

Martin William Axon | Senior Scientific Advisor | SafeBridge Europe, UK

Martin Axon is Senior Principal Occupational Hygienist for SafeBridge and is a Chartered Fellow of the Faculty of Occupational has degrees in Industrial Chemistry and Environmental Pollution Science. He spent the majority of his 35-year career in the pharmaceutical industry and has worked in both primary and secondary production environments at facilities in the UK, the USA and the Bahamas. During mid-career, Martin was a Course Director, for several years, responsible for a postgraduate program in Occupational Hygiene, Health and Safety, at London South Bank University.
Martin joined SafeBridge Europe in 2005 and has, for the past 17 years, focused exclusively on the safe handling of potent pharmaceuticals supporting clients in Europe and the UK. Martin is a senior assessor for the SafeBridge Potent Compound Safety Certification Program.

Dr. Claudia Sehner | Senior Toxicologist | Boehringer Ingelheim, DE

Dr. Claudia Sehner is Senior Toxicologist at Boehringer Ingelheim Pharma GmbH & Co. KG in Biberach (Germany). She is responsible for Occupational Exposure Limits (OELs) and Permitted Daily Exposure Limits (PDEs) setting and leads the respective committee at Boehringer Ingelheim. She is (co-) author of several scientific publications on health-based exposure limits. Besides >15 years of experience in toxicological risk assessment/limit setting, Claudia Sehner has expertise as project toxicologist and in the fields of in vitro toxicology and toxicogenomics. Claudia Sehner graduated with a Diploma in Chemistry from the Johannes Gutenberg University, Mainz, earned her doctorate at the Institute of Toxicology (Mainz), and is a board certified toxicologist (DGPT).

Lisa Wiesner | Sr. Manager, Toxicologist – Nonclincial Safety Assessment | Takeda, CH

Lisa Wiesner (ERT) is an experienced Toxicologist currently working in the Drug Safety Research and Evaluation (DSRE) Department of Takeda. In her role, she supports safety assessments for patient and worker population, and is skilled in setting Health-based Exposure Limits (HBEL) including Occupational Exposure Limits (OEL) and Permitted Daily Exposure (PDE). Lisa completed her studies in Biology and Environmental Science (M.Sc.) at the Goethe University in Frankfurt/Main, as well as her studies in Toxicology (MAS) at the University of Geneva, and gained expertise in the field of Occupational Toxicology, Environmental Toxicology and Public Health, through previous work affiliations with Lonza, Novartis and the Swiss Tropical and Public Health Institute. She is a current member of the Society of Toxicology (SOT) and Swiss Society of Toxicology (SST).

Douglas E. Kiehl | Senior Director Spectroscopy, Elemental Impurities, Extractables & Leachables | Eli Lilly & Company, USA

Douglas Kiehl has over 39 years' experience with application of advanced mass spectrometry in characterization of diverse chemical entities. He is a member of the USP Packaging and Distribution Expert Committee, Chair for the PQRI (Product Quality Research Institute) Development Technical Committee, PhRMA Topic Lead for the ICH Q3E Expert Working Group, Board of Directors for the ELSIE (Extractables/ Leachables Safety Information Exchange) Consortium, and Chair for the SPIE Defense and Commercial Sensing Conference. His research interests include exploring MS-based visualization techniques for rapid, comprehensive characterization of complex mixtures of structurally and compositionally diverse chemical entities. He leads efforts to advance threat detection and ultrarapid development and deployment of pharmaceutical countermeasures for catastrophic and unanticipated medical needs and point-of-use patient therapies.

Andreas Schreiner | Director of Validation, Manufacturing Science and Technology | Novartis, CH

Andreas Schreiner graduated from the University Erlangen, Germany in 1996 in Chemical Engineering. After a Ph.D. and a scholarship at the University College London he joint Roche Vitamins as Head of Solids Processing; since 2006 Andreas Schreiner worked for Novartis in various departments with increasing responsibilities from project leader to global technology platform leader; currently he is heading the validation activities for pharmaceutical production of solid dosage forms.Since 2013 he works for the Manufacturing Science & Technology Department as Validation Head for Solid Dosage Forms.
Andreas Schreiner is appointed board member at various scientific organisations (Executive Board of European Federation of Chemical Engineers (EFCE), Swiss Society for Process Engineers (SGVC), Industrial Society for Pharmaceutical Engineering (ISPE), Swiss Laboratory of Material Science and Technology (EMPA)).
Since 2013 he works for the Manufacturing Science & Technology Department as Validation Head for Solid Dosage Forms.

Dr. Greg Erexson, PhD, DABT, FATS, FRSB, ERT | AbbVie Retiree | Greg Erexson Toxicology Consulting, LLC, USA

Globally boarded (DABT, ATS, ERT) toxicology consultant with over 43 years of fulltime work experience. I have an extensive background in all four general employment areas of the toxicology discipline: academia, government, contract and pharmaceutical industry environments. Consulting services are provided in multiple areas of toxicology including, but not limited to general toxicology, occupational toxicology, assessments of extraneous matter, extractables and leachables, solvents, impurities, degradants, excipients, trace elements, metals, biocompatibility, genetic toxicology, finished product medical devices and combination products as well as their individual components in addition to manufacturing components that are used in the process stream (e.g., filters, tubing, bioreactor liners, containers, films, coatings, inks/pigments, etc.). Experience as an expert toxicologist in litigation events.

Olindo Lazzaro | Head, Global EHS by Design | CSL Behring, CH

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Olindo Lazzaro is the Global Head EHS By Design at CSL Behring, in charge of key technical Environmental, Health and Safety and Sustainability (EHS) programs across the CSL Behring global organization.
His main areas of focus are:

- *Major Hazard Identification, Risk Assessment and Control,*
- *Process Safety Management (PSM) and auditing of PSM Systems,*
- *Serious Injury and Fatalities (SI)F prevention,*
- *EHS in Capital Project and Technology Transfer*
- *Loss Prevention and Fire Protection,*

Olindo has more than 25 years of experience in EHS and Pharmaceutical & Chemical Operations, including international experience in EHS management, Technical Transfer, EHS by Design, network optimization and post M&A EHS integration.

He holds a Master Degree with Honors in Environmental Engineering from the Faculty of Engineering, University of Rome "La Sapienza", a Specialization in Process Safety and Major Hazard Control from the School of Industrial Safety and Protection, University of Rome "La Sapienza" and an EMBA in Pharmaceutical Administration from LUISS University Business School, Rome, Italy.

Jay L. Brown | Associate Director of EHS | Piramal Pharma Solutions, USA

Piramal Pharma Solutions

Jay is the Associate Director of EHS for Piramal Pharma Solutions (PPS). He oversees the design, installation, & evaluation of HPAPI containment systems at PPS. He has 35 years of global EHS experience with 11 years handling potent compounds. He has an MS Degree in Occupational Health and is a Certified Industrial Hygienist (CIH) and Certified Pharmaceutical Industry Professional (CPIP).
Jay is a global SME in the design and construction of high containment facilities producing OEB 5 drugs. He has conducted numerous surrogate particulate emission studies of pharmaceutical equipment per ISPE guidelines and has authored book chapters & peer reviewed journal articles in industrial hygiene & occupational medicine. He is an Adjunct Professor of Industrial Hygiene at Columbus State Community College.

Dr. Ildikó Ziegler | Director Of Quality | Vanessa Research, HU

Vanessa Biotech

Dr. Ildiko Ziegler has been a professional for more than 15 years in the pharmaceutical industry, has extensive experience in QA, fulfills the QA manager role at Vanessa Research. She has been a validation and quality risk expert for almost 10 years. Ildiko obtained M.Sc. in chemical engineering at the Budapest University of Technology and Economics (BUTE) in 1996. She recieved licentiate degree at the Luleå University of Technology (Sweden) in 2000. She defended Ph. D. at the BUTE in 2000 and obtained the Géza Schay Award for the achievments in the field of physical and theoretical chemistry.

Dr. Martin Kohan PhD, ERT, DABT | Managing Toxicologist | SafeBridge Europe, Ltd., UK

SafeBridge®

Martin Kohan is a managing toxicologist for SafeBridge Regulatory and Life Sciences Group. He has a BSc and MSc in biochemistry from La Plata National University, Argentina, as well as an MSc in pharmacology and PhD in medical sciences from the Hebrew University of Jerusalem, Israel. Martin has over 11 years of industry experience in the field of toxicology conducting and managing over 1,000 hazard and risk assessments, including calculation of exposure limits and/or determination of exposure control bands for drug substances and isolated intermediates and quality deviations (impurities and extractables and leachables) for Teva (2010-18) and AstraZeneca (2018-22). He's a Diplomate of the American Board of Toxicology (DABT), a European Registered Toxicologist (ERT), and a member of the UK Register of Toxicologists and the British Toxicology Society.

Christopher Lippelt | Manager, Pharmaceutical Project Management | Eli Lilly and Company USA

Lilly

Chris Lippelt is a chemical engineer and pharmaceutical project manager at Eli Lilly and Company. The bulk of his career has been spent in design and development of continuous flow processes for API synthesis. Use of continuous flow processing enables unique solutions to enhance containment and process safety, especially for HPAPI synthesis.

Andrea Guytingco, MPH, CIH | Sr. EHS Business Partner | Takeda Pharmaceutical Company Limited, USA

Takeda

Andrea Guytingco, MPH, CIH, is a Senior Environment, Health & Safety Business Partner for Takeda Pharmaceuticals in Cambridge, MA. She received her BS in Movement Science (Kinesiology) and MPH in Environmental Health Sciences - Industrial Hygiene/Exposure Science with certificates in Risk Science and Human Health and Global Public Health from the University of Michigan. Her current role includes managing and providing technical guidance for EHS programs with focus on active pharmaceutical ingredients, drug development compounds, biological materials, and animal allergens. She also is leading and managing the Industrial Hygiene program at the Cambridge R&D sites with focus on creating hazardous exposure monitoring plans, performing exposure assessments, and providing support for ventilation optimization, chemical monitoring, and respiratory protection.

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

Dr. Friederike Hermann Head of Occupational Hygiene Lonza, CH

Dr. Friederike Hermann is Head of Occupational Hygiene at Lonza Visp. She ob¬tained 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 Stud¬ies (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 Con¬tainment 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 run-ning, cycling and hiking.

Steve Marnach | EMEA Training Specialist & Pharma Specialist | DuPont Personal Protection, LU

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 & cleanroom 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 A/B, C/D cleanroom operations as well as giving technical support to health and safety specialists.

Richard Denk | Senior Consultant, Aseptic Processing & Containment | Skan AG, CH

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

Dr. Jürgen Schnaubelt | Director Early Drug Substance Development | Boehringer Ingelheim Pharma GmbH & Co. KG, DE

Jürgen Schnaubelt graduated in chemistry from the Technical University of Darmstadt and received his PhD in organic chemistry from the Technical University of Dresden. After a postdoctoral stay at the University of Cambridge, he joined Boehringer Ingelheim.
At Boehringer Ingelheim, he held various positions, including process development and R&D project management. In 2021, he was appointed Director Early Drug Substance Development.
Juergen has more than 25 years of professional experience, including HPAPI handling and manufacturing.

Richard Arnett | Manager, Industrial Hygiene & Toxicology | Pharmascience Inc., CA

Currently Manager, Industrial Hygiene & Toxicology at Pharmascience Inc., Rich leads a team tasked with determining HBEL's and collaborating with the various functional areas to ensure safe product manipulation. Prior to joining Pharmascience, Rich held different roles in IH and Production management for solid dose & injectable products at Uman Pharma.
Rich began his career at Merck Frosst Canada in 1998 supporting the formulation/ process development, scale-up and tech-transfer of numerous dosage forms while executing the manufacture of worldwide clinical supplies for various Merck programs. While at Merck, Rich held several positions of increasing responsibility, including leading the Canadian GMP Pilot Plant Operations.

Andrew Walsh | President | Center for Pharmaceutical Cleaning Innovation (CPCI™), USA

Andrew Walsh is President of the Center for Pharmaceutical Cleaning Innovation (CPCI™) a not-for-profit research and educational organization and laboratory whose purpose is to support companies in the implementation of new ASTM Pharmaceutical Cleaning Standards. CPCI™ supports companies through research into new technologies (2 patents), educational offerings and internship opportunities for students.
Andrew teaches Cleaning Validation at the Temple University School of Pharmacy Regulatory Affairs and Quality Assurance Program. Andrew recently published a textbook "Cleaning Validation: Science, Risk and Statistics-based Approaches".
Andrew is very active in developing industry consensus standards with ASTM International and has led teams writing or updating 5 Pharmaceutical cleaning standards.

Sean Keenan | Pilot Plant Manager | CONTINUUS Pharmaceuticals, Inc., USA

Sean Keenan, MScEng, is a process engineer with experience working for CDMOs in Ireland, North Carolina, and Boston. He holds a BSc in Chemical and Biomolecular Engineering from the University of Notre Dame and a Master's in Biopharmaceutical Engineering from University College Dublin. His projects have involved working with big pharmaceutical clients from around the world to develop, optimize, and scale-up novel pharmaceutical processes from the gram to the kilo scale, specializing in small molecule flow chemistry. Most recently, Sean has developed potent compound expertise in his roles at CONTINUUS Pharmaceuticals as Laboratory Operations Manager and Pilot Plant Manager. As Laboratory Operations Manager, he oversaw the rapid buildout of new HPAPI R&D laboratory and managed the development of a new potent compound safety program. His current role is focused on the buildout of a modular, flexible, and automated kilo-scale continuous pilot facility, which will be used to tech transfer R&D processes to the CONTINUUS manufacturing plant.

Mattia Wiedemeier | Commercial Director | Schedio SA, CH

Mattia Wiedemeier is a pharmaceutical professional with over a decade of experience in micronization and handling of high potent compounds. He has an established background in the industry, having worked in both mid and large CDMOs. Throughout his career, he has played a key role in expanding the reach of these organizations worldwide. As the current head of the sales and marketing division at Schedio, Mattia is responsible for driving growth and success for the company. He is also a respected voice in the industry, regularly contributing articles and white papers on the subject of micronization and high potent compounds. Mattia looks forward to sharing his insights and expertise with attendees.

Milko Leone | CEO and Technical Director | Schedio SA, CH

Milko Leone is the CEO and Technical Director of Schedio, an equipment manufacturing company that specializes in jet mills and isolators for the pharmaceutical industry. With a strong background in engineering and a track record of success, Milko has made significant contributions to the field of particle engineering and high containment during his experience in the pharma industry. He holds several patents and previously served as the Director of Engineering at Lonza Monteggio. Milko's leadership has played a key role in the success of Schedio, which has been recognized for its innovative solutions and high-quality equipment for pharmaceutical companies.

PARTNER

SCHEDIO
The Power of Together

Presented by:

Mattia Wiedemeier
Commercial Director
Schedio SA, CH

Milko Leone
CEO and Technical Director
Schedio SA, CH

Schedio Aftersales Program

Schedio Company Brochure

White paper "What are some hidden risks associated with isolators?"

White paper "Reducin gas consumption by 20% during the micronization process with the coaxial jet mill"

Schedio was born from a group of passionate and experienced specialists from the pharmaceutical industry who launched the company and created something new and unique established on specific core values and commitments including equality and diversity, work-life balance, entrepreneurship and continuous learning, among others.

REGISTRATION FORM

This registration form is editable.
When you have completed the form - please save and email it to register@qepler.com

SUMMIT NAME:

3rd Annual Highly Potent APIs Virtual Summit | February 22-24, 2023

PARTICIPATION PACKAGES				Standard price
VIRTUAL Ticket - 2 Days				€ 445 ☐
VIRTUAL Group - 2 Days (*2-3 delegates, per person)				€ 395 ☐
VIRTUAL Group - 2 Days (*4+ delegates, per person)				€ 355 ☐
VIRTUAL Ticket - 2 Days (*NPO/Academic, per person)				€ 295 ☐
VIRTUAL Ticket - 2 Days (*Past Attendees, per person)				€ 295 ☐
RECORDING				
RECORDING only - Without live summit attendance (*Each ticket already contains this option)				€ 345 ☐
SPONSORSHIP PACKAGES				
PROMO - € 995 ☐		PRESENTER - € 1.595 ☐		PARTNER - € 2.595 ☐

CONFERENCE MATERIALS:
All participation packages, already contain complete post-event materials distribution. Including - slide decks, a list of participants, and video recordings. You don't need to order additional «Documentation Packages».
All materials will be sent to the attendees within 72 hours after the event. The presentation content is subject to the speaker's company's approval for distribution.

ATTENDEE DETAILS	1ST ATTENDEE	2ND ATTENDEE	3RD ATTENDEE	4TH ATTENDEE	5TH ATTENDEE	6TH ATTENDEE
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Name:						
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Special Requirenments: (If you have any special dietary requirements or other needs that would enhance your enjoyment of this summit, please specify)						

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REGISTRATION & PAYMENT:
Upon receiving the signed registration form, we will process your application. The registration confirmation and the invoice will be sent to you within one (1) working day with the relevant payment instructions and terms. The registration fee includes access to all sessions and conference materials. Payment is due 14 working days from the invoice date. Payment should be made by Credit Card, Pay Pall or by Bank Transfer. The delegate is responsible for any bank charges/fees associated with the payment.

CANCELLATION & SUBSTITUTION POLICY:
You may substitute a delegate at any time and at no extra cost. Cancellations must be in a written notice. Cancellations made 14 days or more before the event start date will be refunded with no charges. Cancellations made less than 13-3 days before the event start date will be refunded 50% of the registration fees. Cancellations made less than 2 days before the event start date will receive no refund. If you cannot attend an event due to illness or other unforeseen circumstances, you may transfer your delegate pass to another upcoming event within one year from original event start date.

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DOCUMENTATION (*if you have no plans to join the live conference) Post-event presentations with video records, list of participants and other materials. The presentation content is subject to speaker's companies approval for distribution.	€ 345

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Included passes	1	2	3
Additional company representatives registration fees	€ 295	€ 245	€ 195
Link to Landing Page/White Papers/Webinars trough the live event translation.	•	•	•
Link to Virtual Exhibition Page trough the live event translation			•
Opening keynote presentation (optional)			20 min
Case Study		30 min	30 min
Workshop (optional, replacing Case Study)		40 min	60 min
Recognition in chairman's opening address	•	•	•
Opening & closing speech (optional)		•	•
Chairman of Day 1 (optional)			•
Chairman of Day 2 (optional)		•	
Logo and URL on summit website, agenda and pre/post-summit communication activities	•	•	•
Recognition on Qepler social media channels	•	•	•
Color advert placement on agenda	1/4 Page	1/2 Page	1 Page
Company flyer/brochure included in conference folder (to be provided by sponsor)	•	•	•
Online distribution of your company's promotional materials to all attendees	•	•	•

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PARTICIPATION FEES:
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The online streaming link will be announced and sent to the delegates within a reasonable period, not less than 1 week before the summit start date.

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Presentations and other materials will be sent to the attendees within 72 hours after the event. The presentation content is subject to the Speaker's companies approval for distribution.

DISCOUNTS:
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EVENTS **CALENDAR** 2023-2024

3rd Annual Highly Potent APIs Summit | February 22-24, 2023 | VIRTUAL
Get Recordings!

https://qepler.com/events/hpapi23.html
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3rd Annual Genotoxic Impurities in Pharmaceuticals Summit | March 9-10, 2023 | VIRTUAL
Get Recordings!

https://qepler.com/events/gti23.html
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3rd Annual Extractables & Leachables Summit | October 11-13, 2023 | VIRTUAL
Registration is Open Now!

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4th Annual Highly Potent APIs Summit | February 21-23, 2024 | VIRTUAL
The Call for Speakers is Open Now!

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https://qepler.com/calendar/hpapi24.pdf

4th Annual Genotoxic Impurities in Pharmaceuticals Summit | March 13-15, 2024 | VIRTUAL
The Call for Speakers is Open Now!

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