

4th Annual

# HIGHLY POTENT APIs SUMMIT 2024

DATES: February 21-23, 2024

FORMAT: VIRTUAL edition

LINKEDIN

## SPEAKERS BOARD



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



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



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



**Jack Brown**  
Consultant  
Scale up Solutions, LLC, USA



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



**Thomas R. Evans**  
Director EHS &  
Facilities Management  
Halozyme, USA



**Solenn Brajeul Janvier**  
Quality Control Responsible  
Laboratoires Pierre Fabre, FR



**Richard Hall Hall**  
Mechanical Engineer  
Rattiinox, SA, ES



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



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



**Prasanth Kondragunta**  
Associate Director  
International Safety  
Systems Inc., IE



**Eric White**  
Senior EHS Manager -  
EHS Tech Center  
AbbVie, USA



**Fred Ohsiek**  
Principal Cleaning  
Process Consultant  
VTI Life Sciences, USA



**Dean Calhoun**  
President/CEO  
Affyglity Solutions, USA



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



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



**Douglas E. Kiehl**  
Senior Director, Disruptive &  
Transformative Technologies &  
Digital Twin CoE  
Eli Lilly and  
Company, USA



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



**Mariann Neverovitch**  
Senior Manager  
Bristol-Myers Squibb, USA



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



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



# WHO YOU WILL MEET

## ATTENDEES - 3rd Annual Highly Potent APIs Virtual Summit 2023

<https://qepler.com/events/hpapi23.html>

<https://qepler.com/pdf/hpapi23.pdf>

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ATTENDEES

25

PRESENTATIONS

3P Innovation • AbbVie • Alcami Corporation • Alexion • AstraZeneca • Bayer • Biopharma Group • Boehringer Ingelheim • Bristol-Myers Squibb • BSP Pharmaceuticals • Chiesi • Clovis Oncology • CONTINUUS Pharmaceuticals • Corden Pharma • CSL Behring • Debiopharm Research & Manufacturing SA • Dechra Pharmaceuticals PLC • Deva Holding • DPS Group • DuPont • Eli Lilly and Company • Esteve Healthcare, S.L. • Esteve Química, S.A. • Euroapi • Eurofins Biolab Srl • Evonik • Farmhispania Group • Ferring International Center SA • GEA • Greg Erexson Toxicology Consulting, LLC • GSK • Guido Maik Consulting • Hikma Pharmaceutical • Hovione FarmaCiencia SA • HPAPI Project Services Limited • Icom SpA • ILC Dover • IMA • Janssen Pharmaceutica • Lipomed AG • Lonza • Lugaia Deutschland GmbH • Merck • Merck & Co., Inc. • Merck Life Science KGaA • Mersana Therapeutics, Inc. • MSD • Newgen Pharm • Novartis • Olon • Oncomed manufacturing a.s. • Pharmaceutical Cleaning Innovation • Pharmascience • Piramal • Polpharma • Praevena AG, CH • Rattiinox, SA • RCPE GmbH • Roche • SafeBridge Europe • Schedio SA • SGS Tecnos • Siegfried • Sintenovo, S.A. • Skan AG, CH • Sterling Pharma • SUN PHARMA • Symeres Netherlands BV • Takeda • Teva Pharmaceuticals • Vanessa Research Magyarország Kft. • Vertex Pharmaceuticals (Europe) Ltd • Vetter Pharma Fertigung GmbH & Co. KG • others.

## ATTENDEES - 2nd Annual Highly Potent APIs Summit 2020, Prague

<https://qepler.com/events/hpapi20.html>

<https://qepler.com/pdf/hpapi20.pdf>

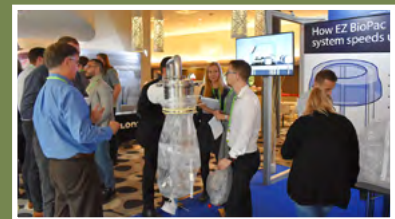
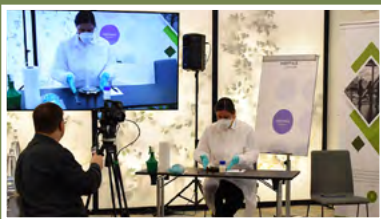
71

ATTENDEES

18

PRESENTATIONS

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. • Hebel 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.



12:00  Opening Address

12:10 **HPAPI Process Design and Project Implementation**



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

HPAPI Project Services

12:50 **To Be Announced**



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



13:30  Coffee break

13:50 **EHS by Design – EHS Integrations in Capital Project and Technology Transfer**



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

CSL Behring  
Biotherapies for Life®

14:30 **To Be Announced**



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



15:10  Coffee break

15:30 **Case Study 5**

16:10 **To Be Announced**



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



16:50  Coffee break

17:10 **AI advancements in HPAPI CDMO industry**

Artificial intelligence (AI) is revolutionizing the HPAPI CDMO industry by enhancing drug discovery and development processes, improving manufacturing efficiency and quality control, optimizing supply chain management, and enabling improvements in the categorizations of HPAPIs. AI algorithms and machine learning techniques are now being employed to analyze vast amounts of compound data and make data-driven decisions regarding the classification of compounds and the setting of robust OELs and ADEs. The impact of AI on the HPAPI CDMO industry is expected to grow in the coming years, as AI continues to evolve and become more sophisticated. This will lead to even more innovation, efficiency, and quality in the development and manufacturing of HPAPI drugs. In this presentation, we will discuss the following:

- The basics of AI
- AI tools currently being used in the pharmaceutical industry
- A novel database of OELs/ADEs and how AI will be used to improve decisions regarding HPAPI compound categorization



Dean Calhoun | President/CEO | Affygitly Solutions, USA



17:50 **To Be Announced**



Thomas R. Evans | Director EHS & Facilities Management | Halozyme, USA



18:50  Closing remarks

12:00  Opening Address

12:10 **To Be Announced**



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



12:50 **New Exposure Monitoring Results During Handling Highly Potent Liquids in a Filling Isolator**



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



13:30  Coffee break

13:50 **Case Study 3**

14:30 **To Be Announced**



Prasanth Kondragunta | Associate Director | International Safety Systems Inc., IE



15:10  Coffee break

15:30 **To Be Announced**



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



16:10 **To Be Announced**



Douglas E. Kiehl | Senior Director, Disruptive & Transformative Technologies & Digital Twin CoE | Eli Lilly and Company, USA



16:50  Coffee break

17:10 **To Be Announced**



Jack Brown | Consultant | Scale up Solutions, LLC, USA

17:50 **Achieving Industrial Hygiene Principles of Good Practice in Pharmaceutical R&D and Manufacturing**

- Definition of the AIHA/ACGIH Principles of Good Industrial Hygiene Practice
- Application to the Pharmaceutical R&D and Manufacturing Environment
- Case Studies for Success



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



Eric White | Senior EHS Manager - EHS Tech Center | AbbVie, USA



18:30  Closing remarks

12:00  Opening Address

12:10 **Case Study 1**

12:50 **Case Study 2**

13:30  Coffee break

13:50 **Clean by Design (CbD)**



Richard Hall Hall | Mechanical Engineer | Rattiinox, SA, ES



14:30 **Analytical development for cleaning validation: HPAPI case study**



Solenn Brajeul Janvier | Quality Control Responsible | Laboratoires Pierre Fabre, FR



15:10  Coffee break

15:30 **Quantitative Measurement of Risk in Cleaning**



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



16:10 **To Be Announced**



Fred Ohsiek | Principal Cleaning Process Consultant | VTI Life Sciences, USA



16:50  Coffee break

17:10 **Lifecycle Management of Analytical Methods for Cleaning Verification Support**



Mariann Neverovitch | Senior Manager | Bristol-Myers Squibb, USA

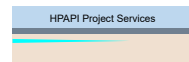


17:50  Panel Discussion

18:30  Closing remarks



**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.



**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. 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.



**Jack Brown | Consultant | Scale up Solutions, LLC, USA**

Started professional studies under the direction of Professor Albert I. Meyers at Colorado State University Fort Collins, Colorado. Followed by a career at Syntex Chemicals, as a Principal Scientist; worked for Hoffmann La Roche, until 2002 and rose to the rank of Distinguished Scientist while working on multiple projects, such as Naproxen®, Saquinavir®, Tamiflu®. In 2002 moved to Boehringer Ingelheim Chemicals in Petersburg, Virginia as the Manager of Process Chemistry and stayed there until 2014. Between 2014 to 2019 worked at Boehringer Ingelheim Pharmaceuticals in Ridgefield Connecticut as a Principal Research Scientist and retired in September 2019 as a Senior Research Fellow.



**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.



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



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 received 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 achievements in the field of physical and theoretical chemistry.



**Thomas R. Evans | Director EHS & Facilities Management | Halozyme, USA**



Tom Evans is the Director of EHS and Facilities for Halozyme in San Diego, CA. Tom has many years of experience managing EHS within the HPAPI manufacturing space and recently help to commission a new high potent aseptic vial filling line.

Tom has 20+ years of EHS experience within the life sciences – biopharma industry, has a Master of Science in Environmental Management from National University, and is a Certified Hazardous Materials Manager (CHMM).





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



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 Diplomat 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.



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

Nancy McClellan practiced industrial hygiene management on a global scale for both AbbVie, a major producer of highly potent biopharmaceuticals and LafargeHolcim, the world's largest building materials corporation. She has invested over 25 years in practicing occupational hygiene in a wide variety of high hazard industries and I provide expert witnessing, management, training, and select field services to sectors such as the pharmaceutical, automotive, military, hospital, electronic, food, chemical, and commercial facility industries. As a result of combined experience, education, and certifications, she was interviewed in October 2020 on the ABC Network's Good Morning America program regarding Covid pandemic controls, as well as a number of ABC News and professional journal articles regarding the association between HVAC systems, Indoor Air Quality and the Covid pandemic to advance public and worker health protections. Ms. McClellan currently serves as the Chair of the University of Michigan Graduate School of Public Health COEHS External Advisory Board and serves on the American Industrial Hygiene Association Executive Board of Directors as the Treasurer. She recently was the Co-chair and leader for the globally recognized Occupational Hygiene Training Association (OHTA) for 13 years she facilitated the growth of the organization and profession to train over 13,000 IH students worldwide.



**Richard Hall Hall | Mechanical Engineer | Rattiinox, SA, ES**



Richard Hall Hall is a Mechanical Engineer and is responsible for business development at Rattiinox, SA – an Italian manufacturer of CIPfriendly aseptic valves, connectors and PUPSIT filters. He is a member of: four ASME BPE task groups (CIP, valve certification, Appendix K/valve testing and vessel certification), the ISPE Europe Biotech SIG, PDA, A3P and is the technical lead for the ASTM E55.03 group: Clean by Design, which is writing a new standard for the specification, design, manufacture & test of easy-to-CIP-clean manufacturing systems for the (bio)pharmaceutical industry. Richard describes himself as an SME - Subject Matter Enthusiast (not Expert) and is passionate about helping change-resistant, stainless-steel (multi-use) equipment manufacturers to improve the cleanability of their equipment to improve production efficiencies and use less water, energy and chemicals in CIP cleaning processes. Richard hopes that this will allow a re-appraisal of the multi/single-use conundrum for users.



**Solenn Brajeul Janvier | Quality Control Responsible | Laboratoires Pierre Fabre, FR**



Solenn Janvier is a pharmacist and holds a PhD in organic synthesis. She has worked for the Pharmaceutical Industry for more than 15 years in chemical development, analytical development and Quality Control. Solenn has also worked on Cleaning Validation Analysis for more than 7 years. She has taken part in the A3P group "Cleaning Validation" for 6 years. She has worked for Pierre Fabre Group in Gien (France) since January 2020, where she is heading the Quality Control Laboratory (85 people).



**Prasanth Kondragunta | Associate Director International Safety Systems Inc., IE**



Prasanth Kondragunta was a Certified Industrial Hygienist from Board for Global EHS Credentialing (from 2015 to 2022) and is in the process of obtaining Diploma in Occupational Hygiene Certification from British Occupational Hygiene Society (BOHS), with 12+ years of experience in conducting Industrial Hygiene and safety assessments at over 150 client sites in 20 plus countries and managing the Europe team of 10 dynamic EHS professionals with International Safety Systems based in Ireland, Dublin. Prasanth had conducted cross contamination studies and provided potent compound safe handling support at 25+ pharmaceutical client sites.



**Dean Calhoun | President/CEO | Affygitly Solutions, USA**



Dean Calhoun is an American Board of Industrial Hygiene Certified Industrial Hygienist (CIH). He has been an environmental health and safety professional for over 33 years. Prior to starting Affygitly Solutions, Dean was the Associate Director of Environmental Health and Safety for Gilead Sciences, Inc., a biopharmaceutical company focused on developing pharmaceuticals for infectious, viral, and oncology applications. His experiences including development and implementation of global EHS guidelines, implementation and coordination of an executive management EHS Steering Committee, establishment of occupational exposure limits for pharmaceutical active ingredients, industrial hygiene program management, and EH&S auditing of research, manufacturing and contract manufacturing facilities. Dean is an international speaker on the topic of potent compound safety and has presented at conferences throughout the United States, Europe, and Asia. Dean graduated with a B.Sc. degree in Engineering from the University of Wyoming and has dual master degrees in Environmental Policy and Management, and Technology Management from the University of Denver. He is a member of AIHA, ISPE, and NAEM.



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



Currently Manager, Industrial Hygiene & Toxicology at Pharmascience Inc., Rich leads a team tasked with determining HBELs 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.



**Silke Buechl | Deputy Managing Director, Occupational Hygienist | Praevana 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.

Before she started as Occupational Hygienist and deputy of the managing director at Praevana 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.

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



**Mariann Neverovitch | Senior Manager | Bristol-Myers Squibb, USA**



Mariann Neverovitch is Senior Manager at Bristol-Myers Squibb. She is a cleaning validation subject matter expert with over 20 years of experience in cleaning verification method development and support. She has been leading cleaning verification programs in Support of Clinical Supply Operations for ten years, and has presented a number of papers on Cleaning Validation lifecycle management and co-authored a number of papers along with the international team of industry experts on Cleaning Validation in the 21st Century. She is co-author of ASTM Standard Guide for Science-Based and Risk-Based Cleaning Process Development and Validation (E3106-17), Standard Guide for Derivation of Health-Based Exposure Limits (HBELs) (E3219-20), and Standard Practice of Visual Inspection of Pharmaceutical Manufacturing Equipment and Medical Devices for Residues (E3263-20). She is an active member of the task force team for PDA TR 29, the Eastern Analytical Symposium Governing Board, and USP Expert Committee.

She 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.



**Douglas E. Kiehl | Senior Director, Disruptive & Transformative Technologies & Digital Twin CoE | Eli Lilly and 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.



**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 was involved in many technical (transfer)-projects so as the planning.



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



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 (SIF) 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.





# REGISTRATION FORM

## 4th Annual Highly Potent APIs Summit

February 21-23, 2024, Virtual Edition

This registration form is editable. Once you have completed the form, please save and email it to [register@qepler.com](mailto:register@qepler.com)

PROMO CODE: \_\_\_\_\_

ONLINE PARTICIPATION:	Register by 22.12.2023	Register by 26.01.2024	Register by 02.02.2024	Standard Price		
Online Ticket - 3 Days	€ 245 (save € 150)	€ 295 (save € 100)	€ 345 (save € 50)	€ 395		
Online Group - 3 Days (*2-3 delegates, per person)	€ 175 (save € 150)	€ 225 (save € 100)	€ 275 (save € 50)	€ 325		
Online Group - 3 Days (*4+ delegates, per person)	€ 145 (save € 150)	€ 195 (save € 100)	€ 245 (save € 50)	€ 295		
ONLINE PARTICIPATION:	Register by 26.01.2024	Register by 02.02.2024	Standard Price			
Online Ticket - 3 Days (*NPO/Academic, per person)	€ 145 (save € 100)	€ 195 (save € 50)	€ 245			
Online Ticket - 3 Days (*Past Attendees, per person)	€ 95 (save € 100)	€ 145 (save € 50)	€ 195			
RECORDING:						
Recording Only - Without attending the summit (*Each Participation Package already includes this option).				€ 495		
PARTNERSHIP PACKAGES						
PROMO - € 995	PRESENTER - € 1.595		PARTNER - € 2.595			
ATTENDEE DETAILS	1 <sup>ST</sup> ATTENDEE	2 <sup>ND</sup> ATTENDEE	3 <sup>RD</sup> ATTENDEE	4 <sup>TH</sup> ATTENDEE	5 <sup>TH</sup> ATTENDEE	6 <sup>TH</sup> ATTENDEE
Title:						
Name:						
Surname:						
Company:						
Country:						
Job Title:						
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Email:						
Special Requirements: (If you have any special dietary requirements or other needs that would enhance your enjoyment of this summit, please let us know.)						

## INVOICE DETAILS:

Title: \_\_\_\_\_ Name: \_\_\_\_\_ Surname: \_\_\_\_\_  
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Direct Phone: \_\_\_\_\_ Mobile: \_\_\_\_\_ Email: \_\_\_\_\_  
Company: \_\_\_\_\_ Country: \_\_\_\_\_ City: \_\_\_\_\_ EU VAT #: \_\_\_\_\_  
Address: \_\_\_\_\_ Postcode: \_\_\_\_\_  
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## TERMS & CONDITIONS:

### 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 (2) working days 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 30 days or more before the event start date will be refunded with no charges. Cancellations made less than 29-7 days before the event start date will be refunded 50% of the registration fees. Cancellations made less than 6 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.

### EVENT CHANGES & CANCELLATIONS:

While all efforts will be made to adhere to the advertised package, Qepler s.r.o. reserves the right to change event dates, sites, or locations, omit event features or merge the event with another event as it deems necessary without penalty. In such situations, refunds, part refunds or alternative offers will be made upon request. In the case that Qepler s.r.o. permanently cancels the event for any reason, and provided that the event is not postponed to a later date nor is merged with another event, you will receive a credit note with a refund for 100% of the conference fee paid.

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### DATE & SIGNATURE:

I agree to be bound by Terms and Conditions of registration

BENEFITS	PROMO € 995	PRESENTER € 1.595	PARTNER € 2.595
Included passes to the event	1	2	3
Registration fees for additional company representatives	€ 245	€ 195	€ 145
FREE tickets for your customers (from any companies)	10	20	40
Case Study		20 min	40 min
Workshop (optional, replaces Case Study)		30 min	60 min
Opening & closing speech (optional)			•
Exhibition virtual profile with company video and promos through the event translation page			•
Color advertisement placement on the agenda	1/4 Page	1/2 Page	1 Page
Logo and URL on summit website, agenda and pre/post-summit communication activities	•	•	•
Links to landing pages, white papers, and webinars through the event webpage and agenda	•	•	•
Recognition in the chairman's opening address	•	•	•
Recognition on Qepler social media channels	•	•	•
Online distribution of your company's promotional materials to all attendees (to be provided by sponsor)	•	•	•

## MARKETING CAMPAIGN:

► Website ► Email Marketing ► Digital Advertising ► Social Marketing ► Press ► Direct Sales

## PARTICIPATION FEES:

**VIRTUAL** - Fees are inclusive of the complete summit materials, online post-event documentation/presentation package, list of participants, video recordings, and certificate of participation.

**In-Person** - Fees are inclusive of the 3-day summit, materials, online post-event documentation/presentation package, list of participants, video recordings, certificate of participation, lunches, snacks, refreshments, and business dinner.

## TRAVEL AND ACCOMMODATION:

Hotel accommodation and travel expenses are not included in the fee. Special rates for the event venue accommodation will be sent upon availability.

## STREAMING:

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

## POST-EVENT DOCUMENTATION:

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:

Early booking discounts are not valid in conjunction with any other offers.



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**QEPLER**

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# EVENTS CALENDAR 2023-2024



4th Annual Highly Potent APIs Summit | February 21-23, 2024 | 🌐 VIRTUAL

**Registration is Open Now!**

🌐 <https://qepler.com/events/4hpapi24.html>

📄 <https://qepler.com/calendar/4hpapi24.pdf>

4th Annual Genotoxic Impurities in Pharmaceuticals Summit | March 13-15, 2024 | 🌐 VIRTUAL

**Registration is Open Now!**

🌐 <https://qepler.com/events/4gti24.html>

📄 <https://qepler.com/calendar/4gti24.pdf>

4th Annual Extractables & Leachables Summit | June 12-14, 2024 | 🌐 Prague, Czech Republic

**Call for Speakers is Open Now!**

🌐 <https://qepler.com/events/4el24.html>

📄 <https://qepler.com/calendar/4el24.pdf>

5th Annual Highly Potent APIs Summit | September 18-20, 2024 | 🌐 Prague, Czech Republic

**Call for Speakers is Open Now!**

🌐 <https://qepler.com/events/5hpapi24.html>

📄 <https://qepler.com/calendar/5hpapi24.pdf>

5th Annual Genotoxic Impurities in Pharmaceuticals Summit | October 9-11, 2024 | 🌐 Prague, Czech Republic

**Call for Speakers is Open Now!**

🌐 <https://qepler.com/events/5gti24.html>

📄 <https://qepler.com/calendar/5gti24.pdf>