



- ▶ 18+ Program Hours ▶ 8+ Networking Hours
- ▶ 16+ Speakers ▶ 60+ Attendees
- ▶ Case Studies ▶ Workshops
- ▶ Panel Discussion ▶ Q&A
- ▶ Networking ▶ Refreshments ▶ Coffee Breaks
- ▶ Business Lunches ▶ Dinner
- ▶ Online Streaming ▶ On-demand Recordings

A photograph of a person in a white lab coat and gloves using a microscope in a laboratory setting. The image is framed by a green border and overlaid with the text "HIGHLY POTENT APIs".

HIGHLY POTENT APIs

3rd Annual

HIGHLY POTENT APIs

SUMMIT 2022

REGISTER

WEB

October 24-25, 2022 | Prague, Czech Republic

HYBRID: In-Person+VIRTUAL

Venue: Novotel

Praha Wenceslas Square Hotel





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



Martin Axon, CFFOH, CMIOSH
Principal Occupational Hygienist
SafeBridge Europe, Ltd., UK



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



Thomas Weingartner
Managing Director
Lugaia Deutschland GmbH, DE



Greg Erexson
Greg Erexson Toxicology Consulting, LLC
Senior Principal Research Scientist
ABBVIE, Inc., USA



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



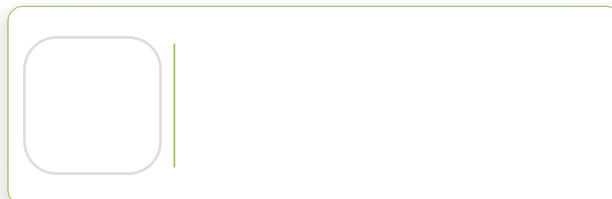
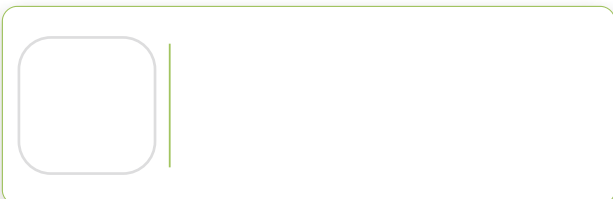
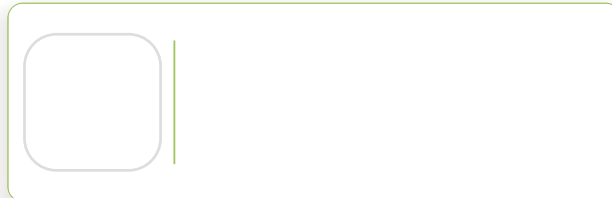
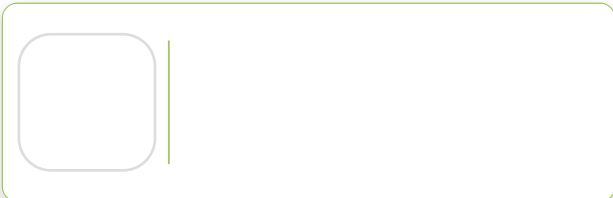
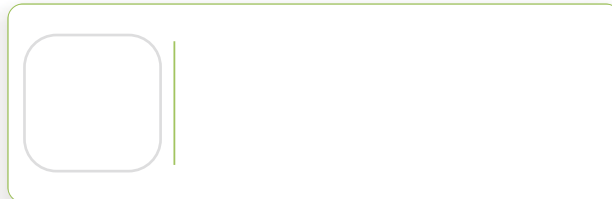
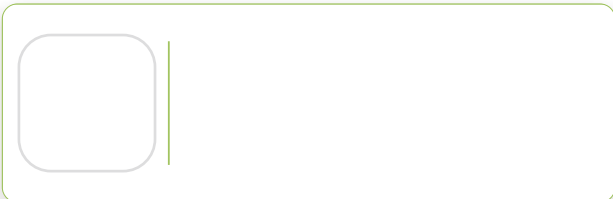
Olindo Lazzaro
Head, Global EHS by Design
CSL Behring, CH



Dr. Andreas Flueckiger
Consultant Occupational Toxicology
and Containment, Head of Occupational
Health @ Roche (retired)
Andreas Flueckiger Consulting, CH



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



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

AbbVie ▶ Acino Pharma AG ▶ Affyglity 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 ▶ Pharmarec 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.

Agenda: <https://qepler.com/agendas/2nd-Annual-Highly-Potent-APIs-Summit-2020.pdf>

SNAPSHOT OF ATTENDEES - Highly Potent APIs Summit 2019:

▶ Affyglity 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 ▶ Hebel 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 ▶ Lusochemica 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.

Agenda: <https://qepler.com/agendas/Highly-Potent-APIs-Summit-2019.pdf>



DIVISIONS

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







POSITIONS

- ▶ C-Level, Presidents, Chairs, Members of the Board & VPs
- ▶ Vice presidents, Directors, & Heads
- ▶ Leaders & Managers
- ▶ Principals, Engineers, Analysts & Scientists
- ▶ Instructors & Trainers & Teachers
- ▶ Advisors, Coordinators, Auditors & Consultants
- ▶ Toxicologists, Chemists, Hygienists, Physicians, & Engineers
- ▶ Coaches, Consultants, Supervisors, & Advisers
- ▶ Other Professionals, Experts & Specialists

INDUSTRIES

- ▶ Pharmaceutical
- ▶ Biotechnology
- ▶ Chemical
- ▶ CMOs / CDMOs / CROs / NOPS
- ▶ API & HPAPI manufacturers & suppliers
- ▶ Bioprocessing services and equipment
- ▶ EHS consultancies
- ▶ Engineering contractors
- ▶ Equipment suppliers
- ▶ Exposure and containment solution providers
- ▶ Occupational and industrial health & safety advisors

SCHEDULE AT GLANCE

8:30 - 9:00	 Registration
9:00 - 9:10	 Opening Address from the Chairman
9:10 - 9:50	Case Study #1
9:50 - 10:30	 Speed Networking
10:30 - 11:10	Case Study #2 - SPONSOR
11:10 - 11:40	 Morning coffee and Networking break
11:40 - 12:20	Case Study #3
12:20 - 13:00	HPAPI Process Design and Project Implementation
13:00 - 14:00	 Business lunch
14:00 - 14:40	EHS Integration in Capital Projects and Tech Transfer
14:40 - 15:20	Case Study #6 - SPONSOR
15:20 - 15:50	 Afternoon coffee and Networking break
15:50 - 16:30	Handling and cleaning of HPAPI within chemical development
16:30 - 17:10	Case Study #8
17:10 - 17:50	 Panel Discussion
17:50 - 18:00	 Chairman's closing remarks and end of day
19:00 - 21:00	 Business dinner

9:00 - 9:10	 Opening Address from the Chairman
9:10 - 9:50	Case Study #1
9:50 - 10:30	Case Study #2 - SPONSOR
10:30 - 11:00	 Morning coffee and Networking break
11:00 - 12:00	Workshop: Flexible Isolator- Occupational Hygiene Experience
12:00 - 12:40	Case Study #4
12:40 - 13:20	Case Study #5 - SPONSOR
13:20 - 14:20	 Business lunch
14:20 - 15:00	Antibody-Drug Conjugates – antibodies meeting HPAPIs for specific and efficient bio-pharmaceutical drugs
15:00 - 15:40	Case Study #7
15:40 - 16:20	Case Study #8
16:20 - 16:30	 Chairman's closing remarks and end of summit
16:30 - 17:30	 Afternoon coffee and Networking break

HIGHLY POTENT APIs

SPEAKER'S BIOGRAPHIES



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



Martin Axon, CFFOH,
CMIOSH
Principal Occupational
Hygienist
SafeBridge Europe,
Ltd., UK



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



Dr. Ulrich Rümenapp
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Greg Erexson Toxicology
Consulting LLC, USA
Senior Principal Research
Scientist
ABBVIE, Inc., USA



Dr. Andreas Flueckiger
Consultant Occupational
Toxicology and Containment,
Head of Occupational Health
@ Roche (retired)
Andreas Flueckiger
Consulting, CH



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

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

Justin Mason-Home is an organic chemist with extensive health, safety, environmental and chemical engineering experience in senior technical, legal and commercial aspects of the 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.

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.

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 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.

Dr. Rümenapp is based in Wuppertal, Germany and works within the Biological Development Organisation of Bayer AG, where he is responsible for the transfer of Bayer's pipeline candidates (antibodies and antibody drug conjugates) to external manufacturing partners and regulatory submission and launch preparations. Prior to working in development, Dr. Rümenapp was head of biotech projects in Product Supply Biotech at Bayer, where he was responsible for contract manufacturing partnerships in the field of biotechnological drug substances, drug products, and interdisciplinary project management with the goal to ensure market supply. Before it was acquired by Bayer, Dr. Rümenapp held a similar position at Schering AG, and before that, he worked in the production & logistics department of Schering, where he was responsible for production aspects of in-and-out-licensing deals, due diligences, and product acquisitions of small molecule products and biologics.

Dr. Rümenapp studied chemistry and holds a Ph.D. in biosciences. He has several years of experience in academic research in the field of signal transduction and as an assistant teacher in the field of general pharmacology.

Currently, Dr. Rümenapp's area of expertise is the set-up and management of external relationships for the development and supply of bio-pharmaceutical products. He has more than 15 years of experience in the bio-pharmaceutical industry.

Greg Erexson, PhD, DABT, ATS, FRSB, ERT recently retired as a Senior Principal Research Scientist at AbbVie, Inc. in North Chicago, IL (January 2013-May 2022) in Occupational and Environmental Toxicology, Preclinical Safety.

He was at Abbott Laboratories, North Chicago, IL in 2012 prior to the split of Abbott into two separate companies, Abbott and AbbVie on January 2, 2013. Greg was at Baxter Healthcare in Round Lake, IL from 2006 to 2012 as a Regulatory Toxicologist primarily working in the areas of risk assessment of E&L and extraneous matter. He received both his PhD and Master's degrees from North Carolina State University, Raleigh, NC in Toxicology and Comparative Biomedical Sciences, respectively. Greg received his Bachelor's degree in Biology from the University of North Carolina, Chapel Hill, NC. From 2000 to 2006, Greg was a Manager-Study Direction at Covance Laboratories, Inc. in Vienna, VA. He was board-certified in general toxicology by the American Board of Toxicology (DABT) in 1999 and recertified in 2004, 2009, 2014 and 2019.

Greg was a Global Regulatory Toxicologist at Baxter International from 2006 to 2012. He was inducted as a Fellow into the Academy of Toxicological Sciences (ATS) in 2014 and as a Fellow in the Royal Society of Biology (FRSB)-UK in 2015. Greg became a European Registered Toxicologist (ERT) in 2015. He was on the board of directors of the Extractables and Leachables Information Safety Exchange (ELSIE) consortium since its inception in 2007 through April 2022 and served as Vice-Chair and Chair of ELSIE from 2014-2016.

Greg was also a member of the USP Toxicology Expert Committee from 2010 to 2015, former president of the Midwest Regional Society of Toxicology and the Medical Device and Combination Product Specialty Section. As of May 2022, Greg is an independent toxicology consultant (Greg Erexson Toxicology Consulting, LLC) specializing in numerous areas of toxicology. In particular, toxicology risk assessments of extraneous matter, extractables and leachables, derivation of permissible daily exposure values, combination and medical device products, occupational toxicology and genetic toxicology.

Greg has authored over 90 peer-reviewed scientific publications and has over 44 years of experience in the field.

Andreas Flückiger, MD, holds Swiss Governmental certifications in General Internal and Occupational Medicine. Before his retirement from the company in 2018, he was Chief Occupational Health Officer for the Roche Group for over 32 years. In this corporate function, he managed Roche's occupational health and its hazard assessment programs. This activity included standard-setting, auditing and teaching activities in the broader field of SHE, but in particular in occupational health. Between 1986 and 2018, he and his team have set health-based exposure limits for over 2000 molecules.

He has participated in numerous training courses on the GMP context in which these limits are used, in particular quality risk management in multi-product facilities. Andreas Flückiger is a member or honorary member in several professional organizations.

He now continues to work as a consultant mainly in the areas of occupational toxicology, exposure control and general EHS matters.

Thomas Adam studied Chemistry at the University in Saarbruecken and Mainz, Germany. After post-doc at Novartis, Switzerland, he joined Bayer AG. He worked in different Q-functions. Since 2011 he is Head of GQA-Chemical APIs within Chemical Development Department at Bayer AG and responsible for the release of APIs for clinical trials, Qualification, Validation and Supplier Qualification.

SUMMIT NAME: 3rd Annual HIGHLY POTENT APIs Summit 2022 | 24-25 October, 2022

PROMO CODE: _____

PACKAGE NAME	Register by 1.07.2022	Register by 1.08.2022	Register by 1.09.2022	Standard price
Individual ticket - 2 Days	€ 1.195 (save € 500)	€ 1.395 (save € 300)	€ 1.495 (save € 200)	€ 1.695
Group ticket - 2 Days (*2-3 delegates, per person)	€ 995 (save € 600)	€ 1.195 (save € 400)	€ 1.295 (save € 300)	€ 1.595
Group ticket - 2 Days (*4+ delegates, per person)	€ 895 (save € 600)	€ 1.095 (save € 400)	€ 1.195 (save € 300)	€ 1.495
VIRTUAL ticket - 2 Days	€ 345 (save € 150)	€ 395 (save € 100)	€ 445 (save € 50)	€ 495
VIRTUAL Group - 2 Days (*2-3 delegates, per person)	€ 245 (save € 200)	€ 295 (save € 150)	€ 345 (save € 100)	€ 445
VIRTUAL Group - 2 Days (*4+ delegates, per person)	€ 195 (save € 200)	€ 245 (save € 150)	€ 295 (save € 100)	€ 395
VIRTUAL ticket - 2 Days (*NPO/Academic, per person)	€ 145 (save € 150)	€ 195 (save € 100)	€ 245 (save € 50)	€ 295

Promotional materials distribution

SPEAKER - € 2.495	POP UP STAND - € 3.495	BOOTH - € 4.495	BRONZE - € 4.995	SILVER - € 6.495	GOLD - € 7.995
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CONFERENCE MATERIALS: All participation tickets, already contains complete conference materials distribution package, with - slide deck, list of participants and session recordings. You don't need to order an additional «Documentation Packages».

ATTENDEE DETAILS	1 ST ATTENDEE	2 ND ATTENDEE	3 RD ATTENDEE	4 TH ATTENDEE	5 TH ATTENDEE	6 TH ATTENDEE
Title:						
Name:						
Surname:						
Company:						
Country:						
Job Title:						
Direct phone:						
Email:						
Special Requirements: (If you have any special dietary requirements or other needs that would enhance your enjoyment of this summit, please specify)						

INVOICE DETAILS:

Title: _____ Name: _____ Surname: _____

Job Title: _____

Direct Phone: _____ Mobile: _____ Email: _____

Company: _____ Country: _____ City: _____ EU VAT #: _____

Address: _____ Postcode: _____

Payment Method: Bank Transfer Credit Card Pay Pall

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 (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 30 days or more before the event start date will be refunded less than 50% of the registration fee. Cancellations made less than 30 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 effort will be made to adhere to the advertised package, Qepler s.r.o. reserves the right to change event dates, sites, or location, omit event features or merge the event with another event as it deems necessary without penalty. In such situations, no refunds, part refunds or alternative offers will be made. In the event 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 or refund for 100% of the conference fee paid. Please note, Qepler s.r.o. will not be held liable for any accommodation or associated travel costs should the event be canceled or rescheduled.

DATA PROTECTION:
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Date & Signature: _____
«I agree to be bound by Terms and Conditions of registration»



ONLINE PACKAGES:

If you are unable to attend, you may purchase these packages

PACKAGE NAME	PRICE
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.	€ 695
PROMOTIONAL MATERIALS DISTRIBUTION Distribution of your company's promotional materials to all attendees	€ 595

SPONSORSHIP PACKAGES:

BENEFITS	SPEAKER	POP UP STAND	BOOTH	BRONZE	SILVER	GOLD
	€ 2.495	€ 3.495	€ 4.495	€ 4.995	€ 6.495	€ 7.995
Included passes	1	1	2	2	3	4
Additional company representatives registration fees	€ 1095	€ 1095	€ 895	€ 895	€ 795	€ 795
Pop up stand in the break area (3m wide x 3m height; includes 1 table, chairs, 1 electrical socket)		•		•		
Exhibition booth with LCD monitor for video presentations in the break area (3m wide x 3m deep; includes 1 table, chairs, 1 electrical socket)			•		•	•
Pull-up banner at the Presenter area, close to the screen (to be provided by sponsor)						•
Case Study	20 min			30 min	30 min	30 min
Workshop (optional, replacing Case Study)					40 min	60 min
Opening keynote presentation (optional)						15 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	•	•	•	•	•	•
Colour advert in placed in agenda			1/2 Page	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			•	•	•	•
Lanyards for summit badges, notepads, pens and other promotional materials given to all participants and speakers (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 2-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 week 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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 INHALATION - ASEPTIC PROCESSING - MDR - CMC - QRM - PFS - DDC - EM

4th Annual Pharmaceutical Lyophilization Summit May 12-13, 2022

• HYBRID CONFERENCE: In-Person+VIRTUAL

Prague, Czech Republic

REGISTRATION IS OPEN

[AGENDA](#)

[WEB](#)

3rd Annual Extractables & Leachables Summit September 15-16, 2022

• HYBRID CONFERENCE: In-Person+VIRTUAL

Prague, Czech Republic

REGISTRATION IS OPEN

[AGENDA](#)

[WEB](#)

3rd Annual Highly Potent APIs Summit October 24-25, 2022

• HYBRID CONFERENCE: In-Person+VIRTUAL

Prague, Czech Republic

REGISTRATION IS OPEN

[AGENDA](#)

[WEB](#)

3rd Annual Genotoxic Impurities in Pharmaceuticals Summit November 14-15, 2022

• HYBRID CONFERENCE: In-Person+VIRTUAL

Prague, Czech Republic

REGISTRATION IS OPEN

[AGENDA](#)

[WEB](#)



CONTACTS

Please send your session title and summit name to:



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