4th Annual

# GENOTOXIC IMPURITIES SUMMIT in Pharmaceuticals

DATES: October 7-9, 2024
LOCATION: Prague, Czech Republic
FORMAT: In-Person + Virtual

PDF | WEB | REGISTER | LINKEDIN

## SPEAKERS BOARD

**Dr. Andrew Teasdale**
Senior Principal Scientist / Head of Impurity Management & CMC Strategy
AstraZeneca, UK

**Dr. Lutz Mueller**
Chair Translational Safety Committee Pharma Research and Early Development
F. Hoffmann-La Roche Innovation Center Basel, CH

**Raphael Nudelman**, Ph.D., ERT
Senior Director Impurity Expert, R&D Operations
Teva Pharmaceutical Industries Ltd., IL

**Lance Smallshaw**, BSc(Hons) PhD EurChem CSci CChem FRSC
Regulatory Intelligence and External Advocacy (Quality Analytical and Pharmacopoeia)
UCB Pharma S.A., BE

**Dr. Joerg Schlingemann**
Director, Principal Expert Quality Control Systems
Merck Healthcare KGaA, DE

**Dr. George Johnson**
Associate Professor in the Institute of Life Science
Swansea University, UK

**Dr. Michael Burns**
Principal Research Scientist – Mirabilis Lead
Lhasa Limited, UK

## ATTENDEES - 3rd Genotoxic Impurities in Pharmaceuticals Virtual Summit 2023

https://qepler.com/events/gti23.html
https://qepler.com/pdf/gti23.pdf

**249** ATTENDEES **23** PRESENTATIONS

AbbVie • ACS DOBFAR S.p.A. • ADAMED • Alcaliber • Amgen • Angelini Pharma • Aptar CSP Technologies • Astellas Pharma Europe B.V • AstraZeneca • Bausch Health • Bayer AG • Bibra toxicology advice & consulting Ltd • Boehringer Ingelheim Pharma GmbH & Co. KG • Bristol-Myers Squibb • Broughton Labs • Charles River Laboratories • Chromicent • Chugai Pharmaceutical Co., Ltd. • CONTINUUS Pharma • DDS • Debiopharm Research & Manufacturing SA • DEVA Holding • Dipharma Francis S.r.l • DIPHARMA SA • Discngine • DKMA • DuPont Nemours • Egis Pharmaceuticals PLC • Eli Lilly & Company • Ellutia Ltd • Esteve • Esteve Química • EUROFINS • F.I.S. • Fabbrica Italiana Sintetici S.p.A. • FARMHISPANIA GROUP • Fidia Farmaceutici S.p.a. • FLAMMA S.P.A. • Galenicum Health SLU • Genentech • Gilead Sciences • GM Pharma • GSK • Industriale Chimica s.r.l. • Innovatune srl • Instem • Intertek • JSC Farmak • KernPharma • L. MEDICAMENTOS INTERNACIONALES, S.A. • LABORATORIOS NORMON S,A. • Lhasa Limited • Luye Pharma AG • Maven E&L Ltd • Medochemie Ltd • Merck • Merck & Co. • Merck Healthcare KGaA • Mérieux NutriSciences Italy • Nanjing Milestone Pharma Co. Ltd • Neogen • Neurocrine Biosciences • Newgen Pharm • Novartis • Novartis Institutes for Biomedical Research • OLON • Orion Corporation • Pfizer • Pharmaron • PhRMA • PolPharma • PROCOS S.P.A • ProtoQSAR • PTM consulting s.r.l. • QDOT Associates • Recordati • Rentschler Biopharma SE • Roche • Sandoz • Sanofi • Sanofi Aventis Deutschland GmbH • SERVIER • Solvias • STADA Pharma AG • Swansea University • Synergy • Synthon BV • Takeda • Teva Pharmaceutical Industries Ltd. • Towa Pharmaceutical Europe • ToxMinds BVBA • UCB Biopharma sprl. • Universidade de São Paulo • Valpharma International Spa • Vertex Pharmaceuticals • Viatris • Waters Corporation • Xellia • Yuria-Pharm LLC • and others.

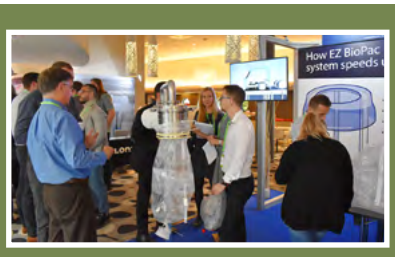
## ATTENDEES - 2nd Genotoxic Impurities in Pharmaceuticals Virtual Summit 2021

https://qepler.com/events/gti21.html
https://qepler.com/pdf/gti21.pdf

**104** ATTENDEES **14** PRESENTATIONS

Abbott • Amgen • Angelini Pharma Spa • Apotex Research Pvt Ltd • AstraZeneca • Bayer AG • Bibra toxicology advice & consulting Ltd • Boehringer Ingelheim Pharmaceuticals • Bristol-Myers Squibb • Charles River Laboratories Montreal ULC • Charles River Laboratories • Corteva • CP Pharmaceuticals Ltd • Egis Pharmaceuticals Plc. • European Environmental Mutagenesis and Genomics Society • Exponent International Ltd • Freyr Global Regulatory Solutions and Services • FUJIFILM Corporation • Gilead Sciences • GlaxoSmithKline • Hemogfarm AD • Innovature Srl • Intertek (Schweiz) AG • King & Spalding • Kirkland Consulting • Lek d.d. • LEO Pharma • Lhasa Limited • Litron Laboratories • Medichem Manufacturing • Merck & Co. • Novartis GDD/CHAD • Novartis • Pall Corporation • Pfizer Global Research and Development • Pfizer • Polpharma • ProtoQSAR SL • QACS, LTD. • Rentschler Biopharma SE • Risk Science Consortium, LLC • SafeBridge Regulatory & Life Sciences • SafeBridge Regulatory and Life Sciences Group • SE Tylose GmbH & Co. KG • St. George's University • Surface Measurement Systems Ltd. • Teva Pharmaceutical Industries Ltd. • Tofwerk • ToxHub Srl • ToxMinds BVBA • UCB Biopharma SRL • UCB Biopharma • VERFORA • Vertex Pharm • Vertex • VYNE • Waters Corporation • World Health Organization (WHO) • Yuria-Pharm LLC • and others.






## October 7, 2024 | 1st DAY

*Central European Summer Time (CEST, Prague, UTC/GMT +2 hours)*

| | |
|---|---|
| **08:00** | ✓ Registration and Welcome Coffee |
| **08:30** | Opening Address |
| **08:40** | **Case Study 1** |
| **09:20** | Speed Networking |
| **10:00** | **To Be Announced** |

Dr. Andrew Teasdale | Senior Principal Scientist /
Head of Impurity Management & CMC Strategy | AstraZeneca, UK

| | |
|---|---|
| **10:40** | Morning coffee and Networking break |
| **11:10** | **Case Study 3** |
| **11:50** | **Case Study 4** |
| **12:30** | Business lunch |
| **13:30** | **Application of the New Guidelines for NDSRIs and the Challenges that Still Need to be Solved** |

Raphael Nudelman, Ph.D., ERT | Senior Director Impurity Expert |
Teva Pharmaceutical Industries Ltd., IL

| | |
|---|---|
| **14:30** | **Nitrosamines and the cohort of concern - how to place under ICH M7? An industry perspective** |

Dr. Lutz Mueller | Chair Translational Safety Committee Pharma Research
and Early Development | F. Hoffmann-La Roche Innovation Center Basel, CH

| | |
|---|---|
| **15:10** | Afternoon coffee and networking break |
| **15:40** | **[RESERVED]** |

Dr. Michael Burns | Principal Research Scientist – Mirabilis Lead |
Lhasa Limited, UK

| | |
|---|---|
| **16:20** | **To Be Announced** |

Lance Smallshaw, BSc(Hons) PhD EurChem CSci CChem FRSC | Regulatory Intelligence and
External Advocacy (Quality Analytical and Pharmacopoeia) | UCB Pharma S.A., BE

| | |
|---|---|
| **17:00** | **Panel Discussion** |
| **17:40** | Closing remarks and end of day one |
| **19:00** | Business dinner |

## October 8, 2024 | 2nd DAY

*Central European Summer Time (CEST, Prague, UTC/GMT +2 hours)*

| | |
|---|---|
| **08:00** | ✓ Registration and Welcome Coffee |
| **08:30** | Opening Address |
| **08:40** | **Case Study 1** |
| **09:20** | **Case Study 2** |
| **10:00** | Morning coffee and Networking break |
| **10:30** | **To Be Announced** |

Dr. Joerg Schlingemann | Director, Principal Expert Quality Control Systems | Merck Healthcare KGaA, DE

| | |
|---|---|
| **11:10** | **Case Study 4** |
| **12:00** | Business lunch |
| **13:00** | **Case Study 5** |
| **13:40** | **Case Study 6** |
| **14:20** | **Case Study 7** |
| **15:00** | Afternoon coffee and networking break |
| **15:30** | **Case Study 8** |
| **16:10** | **Case Study 9** |
| **16:50** | Closing remarks and end of day two |
| **19:00** | Business dinner |

## October 9, 2024 | 3rd DAY

*Central European Summer Time (CEST, Prague, UTC/GMT +2 hours)*

| | |
|---|---|
| **08:00** | ✓ Registration and Welcome Coffee |
| **08:30** | Opening Address |
| **08:40** | **Case Study 1** |
| **09:20** | **Case Study 2** |
| **10:00** | Morning coffee and Networking break |
| **10:30** | **Case Study 3** |
| **11:10** | **Case Study 4** |
| **12:00** | Business lunch |
| **13:00** | **Case Study 5** |
| **13:40** | **Case Study 6** |
| **14:20** | **Case Study 7** |
| **15:00** | Closing remarks and end of summit |
| **15:10** | Afternoon coffee and networking break |

**Dr. Andrew Teasdale | Senior Principal Scientist /**
**Head of Impurity Management & CMC Strategy | AstraZeneca, UK**

*Andrew Teasdale PhD has 30 years' experience in the pharmaceutical industry as an analytical chemist and within quality assurance and regulatory roles. In his current role he chairs AstraZeneca's Impurity Advisory Group. Dr Teasdale has published a number of papers relating to mutagenic impurities, extractables and leachables, mutagenic impurities and other impurity related matters. Andrew has also represented EFPIA in ICH Q3C, Q3D and Q3E Expert working groups. He has also advanced a number of key scientific advancements in the control of impurities as the inventor of the purge factor concept and the instigator of the development of Elemental Impurities database for excipients. With over 50 scientific papers, he has also written 3 books:*

- *Genotoxic Impurities – Strategies for Identification and control. Editor A Teasdale. Publisher Wiley. ISBN 978-0-470-49919-1*
- *ICH Quality Guidelines – An Implementation Guide. Editors A Teasdale, D Elder, R W Nims. Publisher Wiley. ISBN 978-1-118-97111-6.*

**Mutagenic Impurities – Strategies for Identification and Control Second Edition. Editor A Teasdale. Publisher Wiley. ISBN 978-1-119-55121-8**

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**Lance Smallshaw BSc(Hons) PhD EurChem CSci CChem FRSC | Regulatory Intelligence and External Advocacy (Quality Analytical and Pharmacopoeia) | UCB Pharma S.A., BE**

*Dr. Lance Smallshaw has 42 years of experience in Pharma and Biopharma (30 years at Eli Lilly and Company) and is currently Head of Compendial Affairs and a Global Analytical/QA Expert within the UCB Regulatory Intelligence Network based in the Global Sites Quality Operations Team - located at UCB Pharma S.A. Belgium. He is also a contributor developing the company's worldwide policy for new regulatory requirements. Lance led development of the company worldwide strategy and oversaw the worldwide implementation of ICH Q3D guideline for elemental impurities . Lance was nominated to the Advisory Board and Co-Chairman of the European Compliance Academy (ECA), since 2013 and a European Qualified Person (QP) trainer for 14 years and he also chairs the Medicinal Cannabis Working Group for ECA. He currently a member of the Efpia working group for N-Nitrosamines.*

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**Raphael Nudelman, Ph.D., ERT | Senior Director Impurity Expert |**
**Teva Pharmaceutical Industries Ltd., IL**

*Raphael has over 20 years of pharmaceutical industry experience. He has a Ph.D. in organic chemistry from the Weizmann Institute of Science in Israel, a post-doctorate at the US Air Force Research Lab in Aberdeen Proving Ground, Maryland, and another post-doctorate at Duke University Medical Center, North Carolina. In 2003 Raphael joined the Medicinal Chemistry department at Teva Pharmaceuticals.*
*In 2010 he established the Chemical & Computational Toxicology group in Teva, and now he is Senior Director Impurity Expert in R&D Operations. Raphael's main topics of expertise are impurity and excipient qualification in drug substances and drug products. Over the past few years he has specialized in risk assessment of nitrosamine impurities in pharmaceuticals.*

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**Dr. Lutz Mueller | Chair Translational Safety Committee Pharma Research and Early Development | F. Hoffmann-La Roche Innovation Center Basel, CH**

*I am a biologist with a Ph.D. in genetics as of 1986 and supplemental qualifications in EUDIPHARM and PharmaTrain in the EU. I started my professional career in the German Federal Health Office in 1986 as a reviewer in the Department of Pharmacology and Toxicology at the Institute for Drugs in Berlin, Germany. In 1989, I was appointed Head of the Section on Mutagenicity and Carcinogenicity in the German Federal Institute for Drugs and Medical Devices. In leading this section, I translated the results of experimental research activities of the section on mechanisms of action in these areas into the risk/benefit assessment and approval process of new pharmaceuticals on the national and EU level. The section included an active experimental safety research group that was supported by various German and EU research grants. On the international level, I was appointed to serve as an expert toxicologist to the Safety Working Party of the EU CHMP and became ICH Rapporteur for the ICH guidelines on genotoxicity in 1992. These guidelines were successfully finalized and came into operation in 1995 and 1997.*

*In June 2000, I joined the global Preclinical Safety Organization of Novartis Pharma AG in Basel, Switzerland. At Novartis I supported the research and development process within Preclinical Safety (PCS) towards an optimized screening and selection strategy as global expert in Experimental and Molecular Toxicology and subsequently as Head of Investigational and in silico Safety & Metabolism. In addition, in my role as an international project team representative, I contributed to safety testing, evaluation and regulatory documentation for several projects in oncology. As globally responsible advisor for drug quality, I supported the Novartis technical organization for drug quality processes.*

*In November 2004, I joined the Pharmaceutical Sciences organization of F. Hoffmann-La Roche in Basel as Toxicology Project Leader. Since then, I have led the toxicology program for various projects in immunology, inflammation, virology, cardiovascular & metabolic, CNS and rare diseases involving small molecules and biologics. Currently, I have responsibility for oversight on non-clinical safety for projects in early and advanced stages of pre-clinical, clinical development and selected marketed drugs. Projects with my contribution have passed successfully reviews by Health Authorities in all ICH regions (US, Europe and Japan) as well as in other countries such as China in all stages of preclinical, clinical development, approval for marketing and post-approval reviews. Since 2006, I represent the European Pharmaceutical industry in the ICH process for ICH safety guidelines, including the revision of ICH S2 (genotoxicity testing) and ICH M7 (Mutagenic and Carcinogenic Impurities). Within F. Hoffmann-La Roche, I serve on the Non-Clinical Drug Safety Governance body and chair the Carcinogenicity Strategy Advisory Board. I am the liaison for the neuroscience, ophthalmology and rare diseases therapeutic areas in Roche Pharma Research and Early Development (pRED) and for the non-clinical/clinical translation into clinical development.*

*My contributions to research on and guidance for toxicity testing and assessment thereof for pharmaceuticals have resulted so far in more than 100 original publications, monographs and book chapters. I have frequently organized and lectured on international conferences in toxicology and R&D in drug development.*

# SPEAKER'S BIOGRAPHIES

**Dr. George Johnson | Associate Professor in the Institute of Life Science | Swansea University, UK**

*Dr. George Johnson is an Associate Professor in the Institute of Life Science at Swansea University, UK. George is co-chair of the Quantitative Workgroup within the Health and Environmental Science Institute (HESI) Genetic Toxicology Technical Committee (GTTC).*
*Dr. Johnson carries out research and consultancy in the area of quantitative analysis of genetic toxicity and cancer bioassay data, for application in human health risk assessment.*

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**Dr. Joerg Schlingemann | Director, Principal Expert Quality Control Systems | Merck Healthcare KGaA, DE**

*Joerg Schlingemann is a director and principal expert for quality control systems within Merck KGaA's/EMD Serono's healthcare quality unit. He studied molecular biology in Uppsala and Heidelberg, where he completed a doctorate degree at the German Cancer Research Center in 2005. He has 14 years of experience in the pharmaceutical industry from various roles within quality control and quality assurance. Since late 2019, Joerg has been leading EMD Serono's analytical activities for N-nitrosamines. Joerg is married and has three children.*

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# REGISTRATION FORM

## 4th Annual Genotoxic Impurities in Pharmaceuticals Summit

October 7-9, 2024, Prague, Czech Republic

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

## PROMO CODE: _____

| IN-PERSON PARTICIPATION: | Register by 8.03.2024 | Register by 10.05.2024 | Register by 12.07.2024 | Standard Price |
|---|---|---|---|---|
| In-Person Ticket - 3 Days | € 995 (save € 900) ☐ | € 1,295 (save € 600) ☐ | € 1,595 (save € 300) ☐ | € 1,895 ☐ |
| In-Person Group - 3 Days (*2-3 delegates, per person) | € 795 (save € 900) ☐ | € 1,095 (save € 600) ☐ | € 1,395 (save € 300) ☐ | € 1,695 ☐ |
| In-Person Group - 3 Days (*4+ delegates, per person) | € 695 (save € 900) ☐ | € 995 (save € 600) ☐ | € 1,295 (save € 300) ☐ | € 1,595 ☐ |
| **RECORDING:** | | | | |
| Recording Only - Without attending the summit (*Each Participation Package already includes this option). | | | | € 495 ☐ |
| **PARTNERSHIP PACKAGES** | | | | |
| SPEAKER - € 2,495 ☐ | POP UP STAND - € 3,495 ☐ | BOOTH - € 5,495 ☐ | BRONZE - € 4,995 ☐ | SILVER - € 6,995 ☐ | GOLD - € 8,995 ☐ |

| ATTENDEE DETAILS | 1ST ATTENDEE | 2ND ATTENDEE | 3RD ATTENDEE | 4TH ATTENDEE | 5TH ATTENDEE | 6TH ATTENDEE |
|---|---|---|---|---|---|---|
| Title: | | | | | | |
| Name: | | | | | | |
| Surname: | | | | | | |
| Company: | | | | | | |
| Country: | | | | | | |
| Job Title: | | | | | | |
| Direct phone: | | | | | | |
| Email: | | | | | | |
| Special Requirenments: (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: _____

Job Title: _____

Direct Phone: _____ Mobile: _____ Email: _____

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

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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 (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.

**DATA PROTECTION:**
The personal information provided by you will be held in the Qepler database. It may be used to infrom you about other Qepler products and services. Unless you click here ☐, your details may be made available to third parties for marketing purposes. For data update please write to databasemanager@qepler.com.

**DATE & SIGNATURE:**
**«I agree to be bound by Terms and Conditions of registration»**

SEND

# PARTNERSHIP PACKAGES

| BENEFITS | SPEAKER € 2,495 | POP UP STAND € 3,495 | BOOTH € 5,495 | BRONZE € 4,995 | SILVER € 6,995 | GOLD € 8,995 |
|---|---|---|---|---|---|---|
| Included passes | 1 | 1 | 2 | 2 | 3 | 4 |
| Additional company representatives registration fees | € 1,095 | € 1,095 | € 995 | € 895 | € 795 | € 695 |
| Pop up stand in the break area: 3m wide x 3m height with 1 table, chairs, 1 electrical socket | | • | | • | | |
| Exhibition booth with LCD monitor for video presentations in the break area: 3m wide x 3m height x 3m deep with 1 table, chairs, 1 electrical socket | | | • | | • | • |
| Pull-up banner at the Presenter area, close to the screen (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 (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 (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.

Denis Polikarpov
Executive Director
QEPLER

Cell / Whatsapp / Telegram: +420 608 030 490
Email: denis.polikarpov@qepler.com
LinkedIn: https://www.linkedin.com/in/denis-polikarpov-conferences/


# EVENTS **CALENDAR** 2023-2024

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

https://qepler.com/events/4hpapi24.html
https://qepler.com/calendar/4hpapi24.pdf

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

https://qepler.com/events/4el24.html
https://qepler.com/calendar/4el24.pdf

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

https://qepler.com/events/5hpapi24.html
https://qepler.com/calendar/5hpapi24.pdf

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4th Annual Genotoxic Impurities in Pharmaceuticals Summit | October 7-9, 2024 | Prague, Czech Republic

https://qepler.com/events/4gti24.html
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