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3rd Annual

GENOTOXIC IMPURITIES in PHARMACEUTICALS SUMMIT 2022

REGISTER

WEB

November 14-15, 2022

● **VIRTUAL CONFERENCE**

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

www.qepler.com +420 608 030 490 register@qepler.com

SPEAKERS BOARD

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

Robert Foster
Senior Scientist
Lhasa Limited, UK

Leon F. Stankowski, Jr., PhD
Senior Scientific Director, Genetic and In Vitro Toxicology
Charles River Laboratories, USA

Mark Harrison
Principal Analyst
AstraZeneca, UK

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

Dr. Tino Otte
Head of Sales and Consulting
Intertek (Schweiz) AG, CH

Jared Fennell
Senior Scientist
Eli Lilly and Company, USA

BM Rao, Ph.D.
VP&Head – Emerging Markets, Analytical Science & Technology & Corporate Quality control
Dr. Reddy's Laboratories, IN

Mike Urquhart
Scientific Director & GSK Senior Fellow
Drug Substance Development
Medicine Development & Supply
Pharma R&D
GSK, UK

Dr. Michael Burns
Principal Research Scientist
Lhasa Limited, UK

WHO YOU WILL MEET

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SNAPSHOT OF ATTENDEES - 2nd Genotoxic Impurities in Pharmaceuticals Virtual Summit 2021:

Abbott ▸ Amgen ▸ Angelini Pharma Spa ▸ Apotex Research Pvt Ltd ▸ AstraZeneca ▸ Bayer AG ▸ Bibra toxicology advice & consulting Ltd ▸ Boehringer Ingelheim Pharmaceuticals, Inc. ▸ Bristol-Myers Squibb ▸ 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, UK ▸ Litron Laboratories ▸ Medichem Manufacturing (MALTA) Ltd. ▸ Merck & Co., Inc. ▸ Novartis ▸ Pall Corporation ▸ Pfizer Global Research and Development ▸ Polpharma ▸ ProtoQSAR SL ▸ QACS, LTD. ▸ Rentschler Biopharma SE ▸ Risk Science Consortium, LLC ▸ SafeBridge Regulatory & Life Sciences ▸ 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 ▸ ▸ VERFORA ▸ Vertex Pharm ▸ VYNE ▸ Waters Corporation ▸ World Health Organization (WHO) ▸ Yuria-Pharm LLC ▸ others.

Agenda: https://qepler.com/agendas/2nd-annual-genotoxic-impurities-in-pharmaceuticals-summit-agenda-2021.pdf

RECORDINGS

SNAPSHOT OF ATTENDEES - Genotoxic Impurities in Pharmaceuticals Summit 2019:

Abbott Healthcare Products B.V. ▸ Alkaloid AD ▸ Angelini ▸ Astellas Pharma Europe BV ▸ AstraZeneca ▸ Bayer AG ▸ Bristol-Myers Squibb ▸ Charles River Laboratories ▸ Cipla Limited ▸ Elanco Animal Health ▸ Elpen Pharmaceutical Co.Inc. ▸ Eurofarma labs ▸ F. Hoffmann-La Roche Ltd ▸ Fresenius Kabi Deutschland GmbH ▸ GlaxoSmithKline ▸ Intertek (Schweiz) AG ▸ Lhasa Limited ▸ Merck & Co., Inc. ▸ Nelson Labs Europe ▸ S-IN Soluzioni Informatiche Srl ▸ SCIEX ▸ Smithers Rapra Ltd. ▸ Teva ▸ Teva Pharmaceutical Industries Ltd. ▸ ToxMinds BVBA ▸ UCB Biopharma sprl. ▸ others.

Agenda: https://qepler.com/agendas/genotoxic-impurities-in-pharmaceuticals-summit-agenda-2019.pdf

WEB





DIVISIONS

- ADME
- Analytical Chemistry
- Analytical Development
- Analytical R&D
- Analytical Science
- Analytical Science & Technology
- Analytical Sciences
- API
- Biocompatibility
- Chemical Toxicology
- CMC
- Compound Safety
- Computational Toxicology
- Data Sciences & Artificial Intelligence
- Drug Development
- Drug Safety
- Drug Safety Research & Evaluation
- Genetic Toxicology
- Genetics & Mutagenesis
- Genotoxicity
- GMP
- GTIs
- Impurities
- In Silico Toxicology
- Metabolism
- Mutagenicity
- Pharmaceutical Sciences
- Pharmacokinetics
- Pharmacology
- Pharmacovigilance
- Process Chemistry
- Process Development
- QbD
- Quality Assurance & Operations
- Quality Control
- Regulatory Affairs & Compliance
- Research & Development
- Risks Assessment
- Small Molecules
- Toxicology
- Toxicology Discovery
- Validation
- Other

POSITIONS

- C-Level, Presidents, Chairs, Members of the Board & VPs
- Vice presidents, Directors, & Heads
- Leaders & Managers
- Principals, Fellows & Scientists
- Toxicologists & Chemists
- Advisors, Coordinators, Auditors & Consultants
- Other Professionals, Experts & Specialists

INDUSTRIES

- Pharmaceutical
- Biotechnology
- Chemical
- Medical Devices
- CDMOs
- CMOs
- CROs
- NOPs
- Regulatory Agencies
- Plastics
- Training providers
- Other

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GENOTOXIC IMPURITIES
in PHARMACEUTICALS
VIRTUAL SUMMIT
2022

SCHEDULE AT GLANCE

November 14, 2022 | 1st DAY

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

12:00 - 12:10	Opening Addres
12:10 - 12:50	Case Study #1
12:50 - 13:30	Case Study #2
13:30 - 13:50	Coffee break
13:50 - 14:30	Case Study #3
14:30 - 15:10	Case Study #4
15:10 - 15:50	Case Study #5
15:50 - 16:10	Coffee break
16:10 - 16:50	Development of in silico systems for expert review under ICH M7 guideline: increasing efficiency through automated arguments
16:50 - 17:30	Case Study #7
17:30 - 18:10	Case Study #8
18:10 - 18:20	Closing remarks and end of day

November 15, 2022 | 2nd DAY

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

12:00 - 12:10	Opening Addres
12:10 - 12:50	Case Study #1
12:50 - 13:30	Case Study #2
13:30 - 13:50	Coffee break
13:50 - 14:30	Case Study #3
14:30 - 15:10	Case Study #4
15:10 - 15:50	Case Study #5
15:50 - 16:10	Coffee break
16:10 - 16:50	Case Study #6
16:50 - 17:30	Case Study #7
17:30 - 18:10	Case Study #8
18:10 - 18:20	Closing remarks and end of conference

SPEAKER'S BIOGRAPHIES

Raphael Nudelman,
Ph.D. ERT
Director, Chemical & Computational Toxicology
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.

Leon F. Stankowski,
Jr., PhD,
Senior Scientific Director, Genetic and In Vitro Toxicology
Charles River Laboratories, USA

Leon F. Stankowski, Jr., PhD, is currently Senior Scientific Director for Genetic and In Vitro Toxicology at Charles River Laboratories in Skokie, IL.
He obtained BS degrees in premedicine and biophysics from The Pennsylvania State University, and received his PhD in biomedical sciences (genetics) from the University of Tennessee – Oak Ridge Graduate School of Biomedical Science.
Leon has previously worked at multiple other contract research organizations, and also spent three years managing the genetic toxicology group at Johnson & Johnson PRD.
Leon has authored or coauthored dozens of peer-reviewed and invited papers/presentations, and over 100 posters/talks. He served/serves on numerous industrial and regulatory workgroups including ASTM, ILSI-HESI GTTC, IWGT and US EPA, and was/is a member of most of the expert workgroups that revised and/or drafted OECD genotoxicity test guidelines.
Leon has been a member of the Genetic Toxicology Association (GTA) and the Environmental Mutagenesis and Genomics Society for more years than he cares to admit.
He has been an editorial board member for Environmental and Molecular Mutagenesis, and a reviewer for that and multiple other journals.
In GTA, he has served as director, assistant treasurer, meeting coordinator, session and workshop chair, and is presently its treasurer.

Mark Harrison
Principal Analyst
AstraZeneca, UK

Mark worked for AstraZeneca for 18 years within Operations, Global Medicines Development. In my role as a Mass Spectrometry specialist leading pmi analysis and with a focus on extractable and leachable analysis. His first degree is in Chemistry from Queen Mary University of London, and he is achieved his PhD in Pharmaceutical Chemistry from the The School of Pharmacy and Medicine, University of Bradford.
He has a wide range of international publications covering the areas of trace analysis, separation science, extractables and leachables, genotoxins analysis and mass spectrometry.

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.

Dr. Tino Otte
Head of Sales and Consulting
Intertek (Schweiz) AG, CH

Tino Otte received his PhD at Darmstadt Technical University (Germany). The focus of his research was on the chromatographic characterization of synthetic and natural macromolecules.
After graduating he worked for different companies in the instrumental analysis and pharmaceutical services industry.
Before joining Intertek he was applied as a product manager for laboratory equipment at Hamilton Bonaduz AG followed by his positions as divisional manager for pharmaceutical services at UFAG Laboratorien AG in Sursee/Switzerland where he was responsible for development and validation of analytical methods used for characterization and quality control of pharmaceutical formulations.
Tino Otte is now Senior Consultant at Intertek in Switzerland responsible for contract analysis projects in GMP and medical environment. He is an expert for impurity characterization in pharmaceutical products and extractables-leachables studies.

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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 Genotoxic Impurities in Pharmaceuticals Virtual Summit | November 14-15, 2022

PROMO CODE:

PARTICIPATION PACKAGES	Register by 1.08.2022	Register by 1.09.2022	Register by 1.10.2022	Standard price
VIRTUAL ticket - 2 Days	€ 445 (save € 150) ☐	€ 495 (save € 100) ☐	€ 545 (save € 50) ☐	€ 595 ☐
VIRTUAL Group - 2 Days (*2-3 delegates, per person)	€ 345 (save € 200) ☐	€ 395 (save € 150) ☐	€ 445 (save € 100) ☐	€ 545 ☐
VIRTUAL Group - 2 Days (*4+ delegates, per person)	€ 295 (save € 200) ☐	€ 345 (save € 150) ☐	€ 395 (save € 100) ☐	€ 495 ☐
VIRTUAL ticket - 2 Days (*NPO/Academic, per person)	€ 145 (save € 150) ☐	€ 195 (save € 100) ☐	€ 245 (save € 50) ☐	€ 295 ☐
VIRTUAL ticket - 2 Days (*Past Attendees, per person)				€ 195 ☐

SPONSORSHIP PACKAGES		
PROMO - € 895 ☐	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
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 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.

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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.

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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.
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«I agree to be bound by Terms and Conditions of registration»

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PARTICIPATION PACKAGES

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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

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BENEFITS	PROMO € 995	PRESENTER € 1.595	PARTNER € 2.595
Included passes	1	2	3
Additional company representatives registration fees	€ 445	€ 345	€ 295
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	•	•	•

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.

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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