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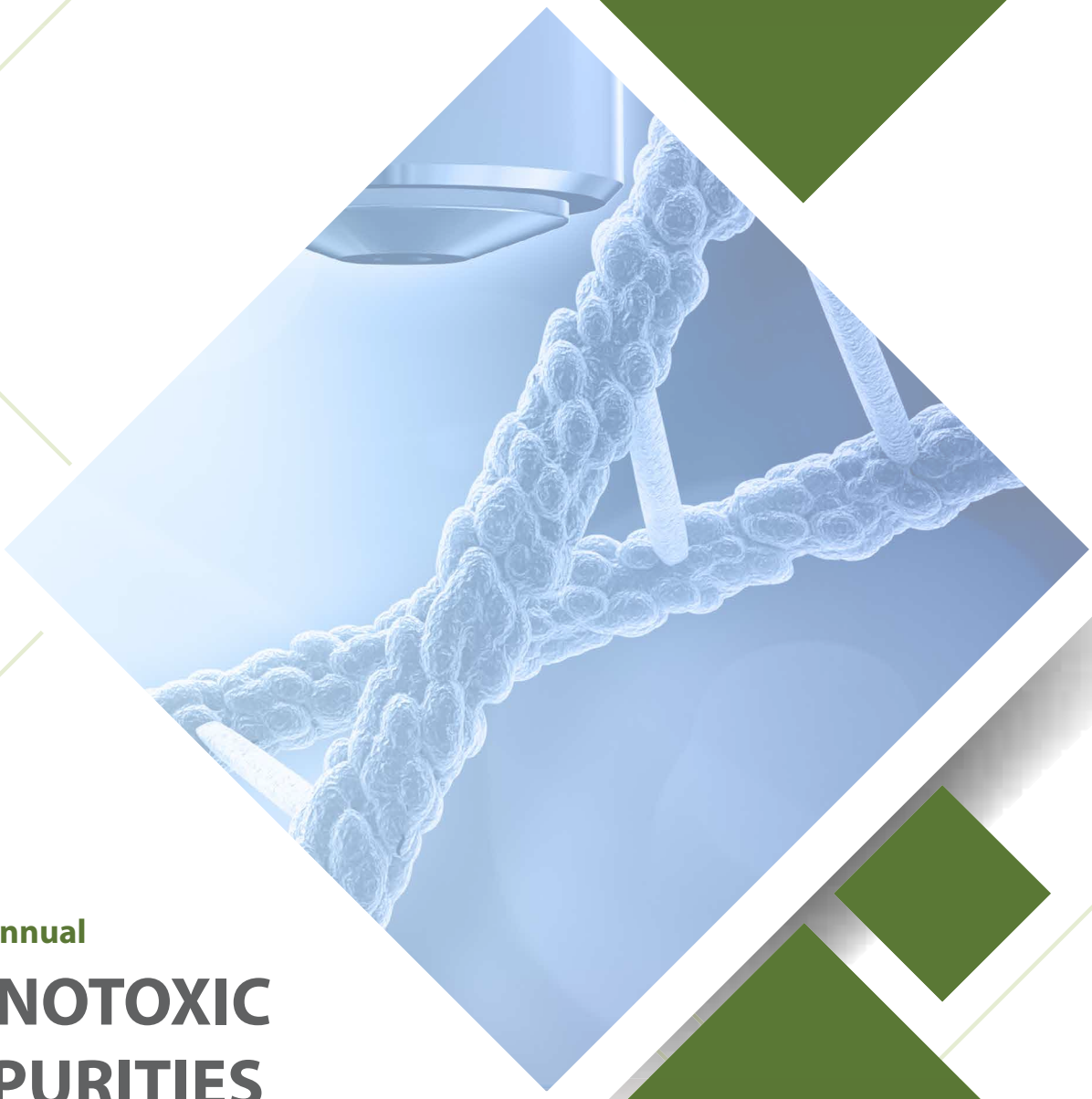

2nd Annual

GENOTOXIC IMPURITIES

in PHARMACEUTICALS

SUMMIT 2020

19-20 November

• VIRTUAL CONFERENCE

(Central European Time)

SPEAKERS BOARD

Lance Smallshaw BSc(Hons) PhD EurChem CSci CChem FRSC
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Dr. Lutz Müller
Toxicology Project Leader – Distinguished Scientist
F. Hoffmann-La Roche Ltd., CH

Raphael Nudelman, Ph.D., ERT
Director, Chemical & Computational Toxicology
Teva Pharmaceutical Industries Ltd., IL

Dr. Jacques Van Gompel PhD
EU Head Genetic Toxicology
Janssen Pharmaceutica NV, BE

Mark Harrison
Principal Analyst
AstraZeneca, UK

Carla Landolfi, ERT
European Registered Toxicologist (ERT)
R&D, Head of WEP Toxicology - Preclinical Development
Angelini, IT

Mike Urquhart
Scientific Director
GlaxoSmithKline, UK

WHO YOU WILL MEET

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SNAPSHOT OF ATTENDEES - Highly Potent APIs Summit 2019:

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

Agenda: https://qepler.com/pdf/hpapi.pdf

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/pdf/genetoxic.pdf

SNAPSHOT OF ATTENDEES - Drug/Device Combination Products Summit 2018:

AbbVie - Ablynx - anteris medical - AOP Orphan Pharmaceuticals - Astellas Pharma - AstraZeneca - BIOCORP - Biogen - Boehringer Ingelheim microParts - Bristol-Myers Squibb - BSI Group - Corvus Device - Cytel - Design Science - Eli Lilly - Freelancer - GSK - H&B Electronic - H&T Presspart - Hanway Associates - Janssen - LEO Pharma - Maetrics - Medac - Medtronic - Nelson Labs - Nelson Labs Europe - Novartis - Orion Corporation - Orion Pharma - Pall Life Sciences - Pharmathen - Progress - PME - Regeneron Pharmaceuticals - Sanofi R&D - Sanofi-Aventis - sfm medical devices - Sharp Clinical Services - Spiegelberg - TERUMO EUROPE - tesa Labtec - Teva - UPM Raflatac - Others

Agenda: https://qepler.com/pdf/ddc.pdf

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- Vice presidents, Directors, & Heads
- Leaders & Managers
- Principals, Fellows & Scientists
- Toxicologists & Chemists
- Advisors, Coordinators, Auditors & Consultants
- Other Professionals, Experts & Specialists

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
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- Research & Development
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- Toxicology Discovery
- Validation
- Other

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GENOTOXIC IMPURITIES
in PHARMACEUTICALS
VIRTUAL SUMMIT
2020

November 19-20

PROPOSED TOPICS

Regulatory guidelines on genotoxic impurities and strategies.
Regulatory updates for the control and analysis of GTIs.
Practical implementation of ICH M7 and ICH Q3D. Regulatory submission guidance.
ICH M7(R1) and (R2) additions and compliance.
ICH guidelines and extractables & leachables.
Genotoxic risk evaluation - preclinical perspective:
Genotoxic risk evaluation. In Vitro genotoxicity testing for alerting GTIs qualification.
Genotoxic risk evaluation. In Vivo genotoxicity testing for alerting GTIs qualification.
DNA binding assays for alerting GTIs qualification.
Evaluating GTIs potential through structure activity relationship.
Compound risks assessment for GTIs.
Genotoxic metabolites identification and risk management.
Genotoxic thresholds identification.
Perspective GTIs risks identifications.
GTIs risks evaluation.
Strategies for GTIs analysis.
Identifying API degradants potential for genotoxicity.
Genotoxicity and carcinogenicity alerts.
Acceptable exposure limits for impurities and compounds from carcinogenic perspective.
Evaluation of genotoxic impurities through In silico assessment.
In silico prediction systems.
In silico assessment. Risks reduction through use of predictive tools.
Preclinical assessment of GTIs. Regulatory updates, assays, data interpretation.
Compounds purification for early toxicology profiling.
GTIs analysis through gas chromatography.
GTIs quantification in APIs.
Analytical testing and control approaches for GTIs in drug substance.
Genotoxic degradation products identification and control.
Compound specific risk assessment - acceptable levels identification.
Calculating compound specific exposure limits.
Potential impurities identification - safety assessment from EL.
GTIs risk assessment through genotoxicity screening assay.
GTI testing at all stages of drug development.
Genotoxic risk assessments and the purge factor methodology.
Big Data use to improve GTIs predictions: computational methods for a better mutagenicity.
Analytical methods and techniques to monitor potential GTIs.
Analytical control for genotoxic impurities.
Implementing QbD approach into genotoxic impurities control.
Purge tools application to improve mutagen control strategies.

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GENOTOXIC IMPURITIES in PHARMACEUTICALS VIRTUAL SUMMIT 2020

November 19 | 1st DAY

12:00 -12:20 — Registration

12:20 - 12:30 — Opening Address from the Chairman

12:30 - 13:10 — Case Study 1 - TBA

Dr. Lutz Müller | Toxicology Project Leader – Distinguished Scientist | F. Hoffmann-La Roche Ltd., CH

13:10 - 13:50 — ICH M7 : Case studies and reflections

Dr. Jacques Van Gompel PhD | EU Head Genetic Toxicology | Janssen Pharmaceutica NV, BE

janssen | Pharmaceutical Companies of Johnson & Johnson

13:50 - 14:00 — Break

14:00 - 14:40 — Case Study 2 - TBA

14:40 - 15:20 — Case Study 3 - TBA

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

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15:20 - 15:30 — Break

15:30 - 16:10 — Slot Reserved for a Gold or Silver Sponsor

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GENOTOXIC IMPURITIES in PHARMACEUTICALS VIRTUAL SUMMIT 2020

November 19 | 1st DAY

16:10 - 16:50 Case Study 4 - TBA

Carla Landolfi, ERT | European Registered Toxicologist (ERT) R&D, Head of WEP Toxicology - Preclinical Development | Angelini, IT

ANGELINI

16:50 - 17:00 Break

17:00 -17:40 Case Study 5 - TBA

Mark Harrison | Principal Analyst | AstraZeneca, UK

AstraZeneca

17:40 - 17:50 Chairman's closing remarks and end of day one

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GENOTOXIC IMPURITIES in PHARMACEUTICALS VIRTUAL SUMMIT 2020

November 20 | | 2nd DAY

12:00 - 12:20 — Registration

12:20 - 12:30 — Opening Address from the Chairman

12:30 - 13:10 — Case Study 1 - TBA

Raphael Nudelman, Ph.D., ERT | Director, Chemical & Computational Toxicology | Teva Pharmaceutical Industries Ltd., IL

13:10 - 13:50 — Case Study 2 - TBA

Mike Urquhart | Scientific Director | GlaxoSmithKline, UK

13:50 - 14:00 — Break

14:00 - 14:40 — Case Study 3 - TBA

14:40 - 15:20 — Case Study 4 - TBA

15:20 - 15:30 — Break

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GENOTOXIC IMPURITIES in PHARMACEUTICALS VIRTUAL SUMMIT 2020

November 20 | 2nd DAY

15:30 -16:10 Case Study 5 - TBA

16:10 - 16:50 Case Study 6 - TBA

16:50 - 17:00 Break

17:00 - 17:40 Case Study 4

17:40 -17:50 Chairman's closing remarks and end of day two

November 19-20 | **Prague, Czech Republic**

BIOGRAPHIES

Raphael Nudelman, Ph.D., ERT
Director, Chemical & Computational Toxicology
Teva Pharmaceutical Industries Ltd., IL

Raphael completed his Ph.D. in organic chemistry from the Weizmann Institute of Science in Israel, followed by postdoctoral positions in the US Air Force Research Lab in Aberdeen Proving Ground, Maryland USA and in Duke University Medical Center, North Carolina USA. He joined Teva Pharmaceutical Industries' Medicinal Chemistry department in 2003 and in 2010 he established the Chemical & Computational Toxicology group which he currently heads. Raphael is a member of the American Chemical Society (ACS), the American Association of Pharmaceutical Scientists (AAPS), and of the Israel Chemical Society (ICS). From 2011 to 2016, Raphael was the President of the Medicinal Chemistry Section of the Israel Chemical Society, and was as a Council member of the European Federation of Medicinal Chemistry (EFMC). He is a member of the Advisory Council of High School Chemistry Education in the Israel Ministry of Education and a member of the Advisory Editorial Boards of Elsevier's journal Drug Discovery Today: Technologies, and of Trends in Medicine and Health (TMH).

Dr. Lutz Müller
Toxicology Project Leader – Distinguished Scientist
F. Hoffmann-La Roche Ltd., 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.

November 19-20 | **Prague, Czech Republic**

BIOGRAPHIES

Lance Smallshaw
BSc(Hons) PhD EurChem CSci CChem FRSC
Regulatory Intelligence and External Advocacy (Quality Analytical and Pharmacopoeia)
UCB Biopharma sprl., BE

After completing nearly a total of 38 years at Eli Lilly and Company and UCB Biopharma sprl based in various international locations he has specialised in both biopharmaceutical / chemical analytical development and GMP QC. Lance has been associated with numerous UK government new analytical technologies projects from routine testing to PAT and was a trainer in Statistical Process Control (SPC) for more than 15 years. He was one of the original conception members of the European CMC Committee for CaSSS in Biopharmaceuticals. He has more than a decades experience as trainer in Good Quality Control Laboratory Practice and in the associated Chapters / Annexes of the European GMP Guide for the European Qualified Person Association (EQPA) and in 2013 Lance was appointed to the Foundation Board of the European Compliance Acacdemy (ECA) and is currently their Co-Chairman. In the past six years Lance has led the UCB Global team to define the strategy and to revise the compendial heavy metals test following ICH's announcement to update the test using a risk based approach with the introduction of its Guideline on Elemental Impurities (ICH Q3D). Lance is currently based in Belgium working in the UCB Corporate Analytical Sciences (CAS) team as Regulatory Intelligence and External Advocacy (Quality Analytical and Pharmacopoeia).

Dr. Jacques Van Gompel PhD
EU Head Genetic Toxicology
Janssen Pharmaceutica NV, BE

After studies in Cell Biology & Genetics at the Free University of Brussels (1987), Jacques Van Gompel was appointed a position as research assistant within the dept. of Experimental Pathology at the University Hospital (AZ-VUB). There, he performed research on the morphology, genetics and immunology of Diabetes mellitus type I. There after he joined the Janssen Research Foundation in 1992. Until February 2000 he was Study Director for the bacterial and mammalian gene mutation assays within the dept. of Genetic and in vitro Toxicology. Meanwhile he also obtained his PhD at the Free University of Brussels on the topic of "Development, Evaluation and Implementation of Acute and Chronic in vitro Exposure Methods in Applied Genetic Toxicology". Between 1995 and 2000 he successfully completed two European Community funded projects in the area of hepatotoxicity and perfusion culture. From February 2000 until April 2001 he became responsible for the genetic toxicology profiling within the newly formed dept. of Exploratory Development. Since May 2001 he became group leader within the ADME/TOX dept. of Johnson&Johnson Pharmaceutical Research & Development. Next to the functional responsibility for the genotoxicity screening activities, he is ADME/TOX representative for discovery projects in the areas of CNS, Oncology and HIV from Hit-to-Lead until delivery into the Preclinical Development Organization. In June 2005 he became Head of the dept of Genetic and in vitro Toxicology within the Global PreClinical Development organization. Furthermore the dept. has end-to-end responsibilities within Janssen Pharmaceutica from Hit-to-Lead until brand support and for high throughput genotoxicity screening and genotoxic impurities. Jacques is member of the Janssen Global Impurity Steering Team and the Johnson&Johnson Genotox Review Committee.

Mark Harrison
Principal Analyst
AstraZeneca, UK

I have 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. My first degree is in Chemistry from Queen Mary University of London, and my I achieved my PhD in Pharmaceutical Chemistry from the The School of Pharmacy and Medicine, University of Bradford. I have a wide range of international publications covering the areas of trace analysis, separation science, extractables and leachables, genotoxins analysis and mass spectrometry.

Carla Landolfi, ERT
European Registered Toxicologist (ERT) R&D, Head of WEP Toxicology - Preclinical Development
Angelini, IT

About 20 years of experience in toxicology field in the pharmaceutical industry. Currently Head of Well Established Products Toxicology at Angelini, an Italian mid-size Pharmaceutical Company. Experience in safety programs for pharmaceuticals, cosmetics, medical devices, biocides and other consumer products. Experience in REACH, Toxicological Risk Assessment, Environmental Risk Assessment; occupational toxicology. Main or co-author of several papers and posters, published in peer-reviewed journals or presented at International Congresses.

BIOGRAPHIES

Mike Urquhart
Scientific Director
GlaxoSmithKline, UK

Mike Urquhart (Ph.D.) has over 20 years' experience within the Pharmaceutical industry, working mainly in process development as a synthetic organic chemist. Since starting at GSK, Mike has had positions of increasing responsibility ranging from lab chemist and team manager through to Chemistry Manufacturing and Control (CMC) project manager. During his GSK career, Mike has led the primary development / delivery of 10 products, spanning early through to late phase development. Mike's current roles are GSK CMC Due Diligence lead for small molecules and co-chair of the Genotoxic Risk Assessment (GRA) review team, where he is GSK subject matter expert. Mike also represents GSK on the Lhasa Mirabilis Pharmaceutical Consortium.

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SUMMIT NAME: VIRTUAL - 2ND ANNUAL GENOTOXIC IMPURITIES IN PHARMACEUTICALS SUMMIT 2020

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PACKAGE NAME	Standard price	
Individual ticket - 1st Day (17th September 2020)	€195	☐
Individual ticket - 2nd Day (18th September 2020)	€195	☐
Individual ticket - 2 Days	€345	☐
Group ticket - 2 Days (2-3 delegates)	€265	☐
Group ticket - 2 Days (4+ delegates)	€195	☐
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Promotional materials distribution	€445	☐
SPEAKER SPONSOR	☐	
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Speaking slot	20 min	30 min	30 min
Workshop slot			60 min
Recognition in chairman's opening address		•	•
Opening & closing speech			•
Chairman of Day 1			•
Chairman of Day 2		•	
Logo and URL on summit website, agenda and pre/post-summit communication activities	•	•	•
Recognition on Qepler social media channels (LinkedIn/Facebook/Twitter/Instagram)	•	•	•
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Online distribution of your company's promotional materials to all attendees		•	•

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