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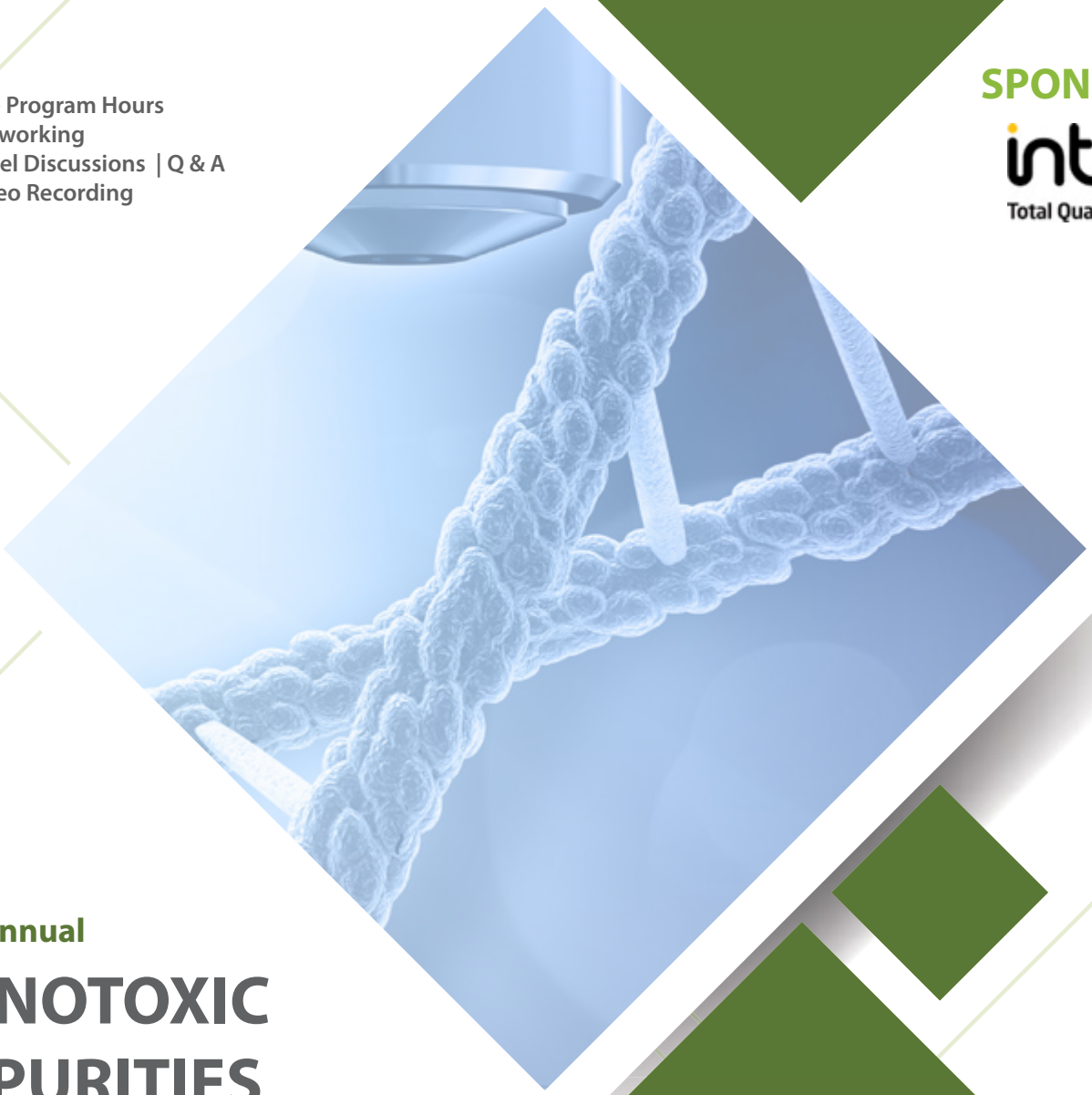

2nd Annual

GENOTOXIC IMPURITIES in PHARMACEUTICALS SUMMIT

15-16 July 2021

- **VIRTUAL CONFERENCE**

hopin

12:00 - 19:00 CEST (Prague - UTC/GMT +2 hours)

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Associate research fellow in Drug Safety
Pfizer Global Research and Development, USA

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Director, Chemical & Computational Toxicology
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Margaret Maziarz
Principal Scientist, Scientific Operations
Waters Corporation, USA

Tom van Wijk, PhD
Principal Scientist, Analytical Science and Technology Team lead Pharmaceutical analysis
Abbott Healthcare Products BV, NL

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Associate Professor in the Institute of Life Science
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European Registered Toxicologist (ERT)
CEO - Toxicology Risk Assessor
ToxHub Srl, IT

Ron Brown
Owner and Principal Toxicologist
Risk Science Consortium LLC, USA

Daniel Roberts
Genetic Toxicologist and Flow Cytometrist
Charles River Laboratories, USA

Dr. Michael Burns
Principal Research Scientist
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Rachael Tennant
Senior Research Scientist
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- **White Paper | Analytical Approaches For Control of Genotoxic Impurities**
  https://www.intertek.com/pharmaceutical/whitepaper-control-genotoxic-impurities-reinach/
- **Case Study | Identification and Quantification of Potential Epoxide Genotoxic Impurities**
  https://www.intertek.com/pharmaceutical/case-study-identification-quantification-epoxide-impurities-reinach/

SNAPSHOT OF ATTENDEES - VIRTUAL 2nd Annual Extractables & Leachables Conference 2020:

3P Biopharmaceuticals, ES - Abbott Healthcare Products B.V., NL - Abbvie Deutschland GmbH & Co. KG, DE - Accord-UK Ltd, UK - Advent Consulting Canada, CA - ALK, DK - Alkermes Pharma Ireland Limited, IE - Alphamed Formulations PVT LTD, IN - Apotex Research Pvt Ltd., IN - Aspen Holdings, ZA - Aspen Pharmacare, ZA - B.Braun medical SA, CH - Bavarian Nordic, DK - Becton Dickinson, CN - Becton Dickinson, FR - Biogen, USA - Boston Analytical, USA - Claudia Cusa, d.i., IT - CSL Behring AG, CH - Datwyler Pharma Packaging International NV, BE - DuPont, USA - DuPont-Asahi Flash Spun Products, JP - EirGen Pharma, IE - Eli Lilly and Company, USA - EMS SA, CH - Eurofins Analytical Science Laboratories, Inc., JP - Fujifilm Diosynth Biotechnologies, UK - GSK, US - GSK Vaccines, BE - Hall Analytical, UK - Hemofarm AD, RS - HTL-Strefa S.A., PL - Intertek (Schweiz) AG, CH - Janssen, USA - Kora Healthcare, IE - LEO Pharma, IE - Maven E&L Ltd, UK - Medline Industries, USA - Merck KGaA, DE - MilliporeSigma a business of Merck KGaA, USA - Novartis, CH - Novartis Pharma Stein AG, CH - NOVAVAX CZ a.s., CZ - Orexo AB, SE - Orion Corporation - FI, Philips, NL - Polifarma İlaç San. ve Tic. A.Ş., TR - PPD, IE - Rentschler Biopharma SE, DE - Safetree Consulting e.U., AT - Sandoz Manufacturing Inc., CA - Sanofi, FR - Sanofi, DE - Sanofi Pasteur, CA - Sartorius Stedim Biotech GmbH, DE - SCHOTT AG, DE - SCIEX, UK - Selvita S.A., PL - Septodont, FR - SGS, CN-TW - SGS Institut Fresenius GmbH, DE - Solvias AG, CH - Sthree, BE - Swedish Biomimetics 3000 Ltd, UK - Takeda Pharmaceuticals, USA - Vet-Agro Sp. z o.o., PL - West Pharmaceutical Services, USA - Wockhardt Ltd, IN - and others.

Agenda: https://qepler.com/agendas/agenda-2nd-extractables-and-leachables-20.pdf

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- Principals, Fellows & Scientists
- Toxicologists & Chemists
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- Other Professionals, Experts & Specialists

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- Pharmacovigilance
- Process Chemistry
- Process Development
- QbD
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GENOTOXIC IMPURITIES in PHARMACEUTICALS VIRTUAL SUMMIT 2021

July 15 | 1st DAY

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

12:00 - 12:20 Registration

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

12:30 - 13:00

Regulatory Updates on Nitrosamine Impurities.

It has become mandatory to understand current regulations and recommendations by FDA, EMA, WHO and other authorities to implement adequate quality risk management principles to make science-based decisions to mitigate potential risks. Competent staff, sound knowledge and in-depth understanding of products and processes are critical when assessing potential risks to manufacturing processes to ensure that patient safety is adequately protected.

Vimal Sachdeva | Technical Officer (Expert Inspector)
Inspection Services, Prequalification Unit Regulation and Prequalification Department
Access to Medicines and Health Products Division
World Health Organization (WHO), CH

13:00 - 13:10 Q & A

13:10 - 13:40

Meeting the challenge of trace analysis of N-nitrosamines -The impact for the pharmaceutical industry.

- The history of the N-nitrosamine challenge.
- How has Industry met this challenge?
- What are the practical measures needed to provide ultra-trace N-nitrosamine data?

Mark Harrison | Principal Analyst
AstraZeneca, UK

13:40 - 13:50 Q & A

13:50 - 14:00 Break

14:00 - 14:30

Risk Assessment of Nitrosamines in Pharmaceuticals: Not All Nitrosamines are Highly Potent.

- Commercial product nitrosamine risk assessment using nitrosamine structural groupings
- Read-across approach developed to minimize compound-specific risk assessments and analytical testing
- Case example compound-specific risk assessment

Michelle Kenyon | Associate research fellow in Drug Safety
Pfizer Global Research and Development, USA

14:30 - 14:40 Q & A

14:40 - 15:20

Development of a Drug Product workflow for Nitrosamine Risk Assessments.

- Development of a cross industry aligned approach to the nitrosamine risk assessment of drug products
- GSK experiences of using this workflow to perform drug product risk assessments
- Shared experiences relating to regulatory submissions

Mike Urquhart | Scientific Director
GlaxoSmithKline, UK

15:20 - 15:30 Q & A

July 15 | 1st DAY

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

15:30 - 16:00

Quantitative Analysis of In Vivo Mutagenicity Dose-Response Data for Risk Assessment and Regulatory Decision-making: A Case Study of Alkylnitrosamines.

- Use of genetic toxicity data for assessing alkylnitrosamines.
- Mechanism of action, and dose response characterisation for noteworthy alkylnitrosamines.
- Risk assessment opportunities for specific alkylnitrosamines using these approaches.

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

16:00 - 16:10 Q & A

16:10 - 16:20 Break

16:20 - 16:50

Setting limits for nitrosamines that lack carcinogenicity data.

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

16:50 - 17:00 Q & A

17:00 - 17:30

Analytical Solutions for the Detection and Quantification of Nitrosamines Using Separations and Mass Spectrometry

The analytical methodology applied for genotoxic impurity analysis needs to provide an appropriate level of sensitivity to meet the required detection limits and demonstrate good accuracy, precision, and reproducibility. In this work, we present robust analytical approaches for the detection and quantification of nitrosamine impurities using UV, MS and HRMS techniques. The performance and sensitivity of these methodologies are demonstrated by analyzing several nitrosamine impurities in drug substances and drug product formulations.

Margaret Maziarz | Principal Scientist, Scientific Operations
Waters Corporation, USA

17:30 - 17:40 Q & A

17:40 - 18:40

PANEL DISCUSSION: 3 general suggestions for assessing positive response.

- Pairwise comparison to concurrent control
- Dose-related trend assessment.
- Biological relevance (within the historical bounds).

Panel Lead:
Daniel Roberts | Genetic Toxicologist and Flow Cytometrist
Charles River Laboratories, USA

Panelists:
David Lovell | Redader in Medical Statistics | St. George's University, UK
Stephen Dertinger | Director of Research | Litron Laboratories, Rochester, USA
Carol Beevers | Managing Scientist | Exponent International Ltd, UK
David Kirkland | Genetox Consultant | Kirkland Consulting, UK
George Johnson | Associate Professor | Swansea University, UK
Abby Myhrw | Technical Lead | Corteva, USA

18:40 - 19:40 Networking Hour

19:50 - 20:00 End of Day 1

July 16 | 2nd DAY

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

12:00 - 12:20 Registration

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

12:30 - 13:00

Continuing development of applied chemical knowledge for an in silico purge tool; Incorporating lessons from nitrosamines.

The impact of nitrosamines within drug substances has been felt widely across the regulatory landscape in the last few years. The application of chemistry knowledge within the risk assessment process for nitrosamines has been one of the subjects that has drawn interest from both industry and regulators. The in silico purge tool, Mirabilis, has therefore been adapting to reflect the lessons which have been learnt from the nitrosamine crisis, incorporating an understanding of both the risk of carry-over, and the risk of formation.

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

13:00 - 13:10 Q & A

13:10 - 13:40

Assessment of potential mutagenic degradation products.

- Expectations on degradation products.
- Approaches for assessing degradation products.
- Analytical strategies.

Tom van Wijk | Principal Scientist, Analytical Science and Technology Team lead
Pharmaceutical analysis | Abbott Healthcare Products B.V., NL

13:40 - 13:50 Q & A

13:50 - 14:00 Break

14:00 - 14:30

From in silico to in vivo assessment for mutagenicity of impurities.

- From the literature to in silico analyses.
- How to address positive AMES results.
- In vivo genotoxicity testing strategies.

Carla Landolfi | European Registered Toxicologist (ERT)
CEO - Toxicology Risk Assessor | ToxHub Srl, IT

14:30 - 14:40 Q & A

14:40 - 15:10

A Journey for Risk Mitigation of Genotoxic Impurities in Pharmaceutical Products.

SPONSOR

- Risk Assessment of Raw Materials, Intermediates, Process Contact Materials and Container Closure Systems.
- Analytical Screening for Nitrosamines and other Genotoxic Impurities.
- Monitoring of critical Targets in Pharmaceuticals over their Shelf Life.

Jörg Freudenberger | Manager Strategy & Global Business Development
Intertek (Schweiz) AG, CH

15:10 - 15:20 Q & A

July 16 | 2nd DAY

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

15:20 - 15:30 Break

15:30 - 16:00

Handling mutagenic extractable and leachable compounds released from devices.

Genotoxic compounds can be released from some medical devices during their clinical use. The ISO 10993-17:2002 standard outlines steps to assess the risk posed by patient exposure to genotoxic compounds released from device materials. It is important to note; however, that the ISO 10993-17 standard is currently undergoing revision and the procedures for conducting a toxicological risk assessment of genotoxic compounds are likely to change following revision of the standard. This talk will outline the proposed changes to the ISO 10993-17 standard regarding methods to assess the risk posed by patient exposure to genotoxic compounds released from medical devices and will describe steps to mitigate the risk using risk management strategies. The talk will also briefly address how Carcinogenic, Mutagenic, and Reproductive (CMR) compounds will be handled in Europe under the new Medical Devices Regulation 2017/745/EU.

Ron Brown | Owner and Principal Toxicologist
Risk Science Consortium, LLC, USA

16:00 - 16:10 Q & A

16:10 - 16:40

Can the Ames test adequately predict the carcinogenic potential of nitrosamines?

Mutagenicity data is a core component of the safety assessment data required by regulatory agencies for acceptance of new drug compounds, with the OECD-471 bacterial reverse mutation (Ames) assay most widely used as a primary screen to assess drug impurities for potential mutagenic risk. Previous literature reports indicated that the Ames test might not be sensitive enough to detect the mutagenic potential of N-nitrosamines in order to accurately predict a risk of carcinogenicity. To explore this hypothesis, public Ames and rodent carcinogenicity data pertaining to the N-nitrosamine class of compounds was collated for analysis. Here we present how variations to the OECD 471-compliant Ames test, including type of metabolic activation, solvent type and pre-incubation/plate incorporation methods, may impact the predictive performance for carcinogenicity. An understanding of optimal conditions for testing of N-nitrosamines may improve both the accuracy and confidence in the ability of the Ames test to identify potential carcinogens.

Rachael Tennant | Senior Research Scientist
Lhasa Limited, UK

16:40 - 16:50 Q & A

16:50 - 17:50 Networking Hour

17:50 - 18:00 Closing remarks and end of conference

SPEAKER'S BIOGRAPHIES

Vimal Sachdeva,
Technical Officer (Expert Inspector)
Inspection Services,
Prequalification Unit Regulation and Prequalification Department
Access to Medicines and Health Products Division
World Health Organization (WHO), CH

Mr Sachdeva holds a Master Degree in Chemistry as well as a Specialized Diplomas in Pharmaceutical and Biopharmaceutical manufacturing. He also holds a Postgraduate Diploma in Business Administration.
He has more than 30 years of experience including 15 years as a regulator of health products. He started his career as a chemist and moved on to lead Quality Control, Quality Assurance, Regulatory Affairs and Compliance departments within generic and innovator pharmaceutical companies. Before joining WHO, he worked with the Singapore Health Sciences Authority (HSA) as a Senior GMP Auditor and Senior Regulatory Specialist.
To date, he has performed more than 300 on-site GMP inspections (active pharmaceutical ingredients, finished pharmaceutical ingredients, vaccines and in-vitro diagnostic manufacturers) as a Lead Inspector in Asia, Africa, Latin America and North America.

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 GlaxoSmithKline (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 co-chair of the Impurities Oversight Panel, where he is a GSK mutagenic impurity risk assessment subject matter expert and Scientific Director as well as the GSK Drug Substance nitrosamine risk assessment lead for small molecules

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).

Tom van Wijk
Principal Scientist,
Analytical Science and Technology Team lead
Pharmaceutical analysis
Abbott Healthcare Products BV, NL

Tom van Wijk is a principal Scientist with over 20 years of experience in pharmaceutical analysis. Supporting established marketed products at Abbott Healthcare Products in the Analytical Science and Technology Department in Weesp (the Netherlands). Specialized in small molecule impurity profiling, mass spectrometry and method development for the active materials as well as the formulated products. One of his key interests is developing applications and strategies to control trace levels of potential mutagenic impurities, elemental impurities and leachables.

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.

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. 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.

Margaret Maziarz
Principal Scientist,
Scientific Operations
Waters Corporation, USA

Margaret is responsible for development, validation, and transfer of analytical methods within the pharmaceutical applications development team, based in Milford, MA. She specializes in development of new applications on Waters instrumentation and related control software, creating technical seminar materials, marketing collateral and demo projects to support the sales and marketing organizations globally. Margaret also supports testing and development activities of instruments and software solutions. Before joining waters, Margaret worked at Boston Scientific and Purdue Pharma.

Michelle Kenyon
Associate research fellow in Drug Safety
Pfizer Global Research and Development, USA

Michelle Kenyon is an associate research fellow in Drug Safety at Pfizer Research and Development in Groton, CT where she has worked since 1993. She received her undergraduate degree in Biology from Quinnipiac University in New Haven, CT and her graduate degree in Biology (MA) from Brown University in Providence, RI.
Michelle has more than 25 years of experience in the application of genetic toxicology testing in support of pharmaceutical development, with expertise in screening and regulatory bacterial mutagenicity assays and the use of in silico tools to assess the mutagenic potential of pharmaceutical intermediates and impurities. She represents Drug Safety on a multidisciplinary council that provides advice to teams regarding impurity qualification matters and contributes to the development of risk assessments to address potential safety issues that arise across Pfizer's global marketed product supplies. She is involved in IQ DruSafe and EFPIA workgroups addressing qualification of pharmaceutical impurities, as well as industry nitrosamine collaborations. Michelle is a long-time member of the Genetic Toxicology Association and is a past chair of the board of directors.

Daniel Roberts
Genetic Toxicologist
and Flow Cytometrist
Charles River Laboratories, USA

Dan Roberts is a Principal Research Scientist in the Genetic and In Vitro Toxicology Department at Charles River Labs with over 15 years of experience in applied genetic toxicity testing. He received his MS in biotechnology from Johns Hopkins University and obtained PhD Candidacy in the toxicology program at Rutgers University while working as a Research Scientist at Bristol-Myers Squibb Company. Mr. Roberts specializes in flow cytometric techniques and participated in the interlaboratory validation of the pig-a gene mutation assay. He is former Chairman of the Genetic Toxicology Association and presently co-chairs the Applied Genetic Toxicology Special Interest Group (EMGS) and a subgroup within HESI's Genetic Toxicology Committee. Mr. Roberts' research aim is to integrate new methods into regulatory genetic toxicity testing paradigms that will enrich our understanding of how chemicals interact with cellular material to induce adverse apical responses.

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Chairman of Day 1			•
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Logo and URL on summit website, agenda and pre/post-summit communication activities	•	•	•
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- VIRTUAL CONFERENCE

GTI strategies & new methodologies: analysis, in silico & regulations. Challenges & opportunities.
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3rd Annual Pharmaceutical Lyophilization Summit ..... **July 29-30, 2021**
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Discuss best practices in tech & regulatory updates, process, formulation, testing, monitoring, new products development.
https://qepler.com/pdf/v3lyo21.pdf
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Please send your session title and summit name to:

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