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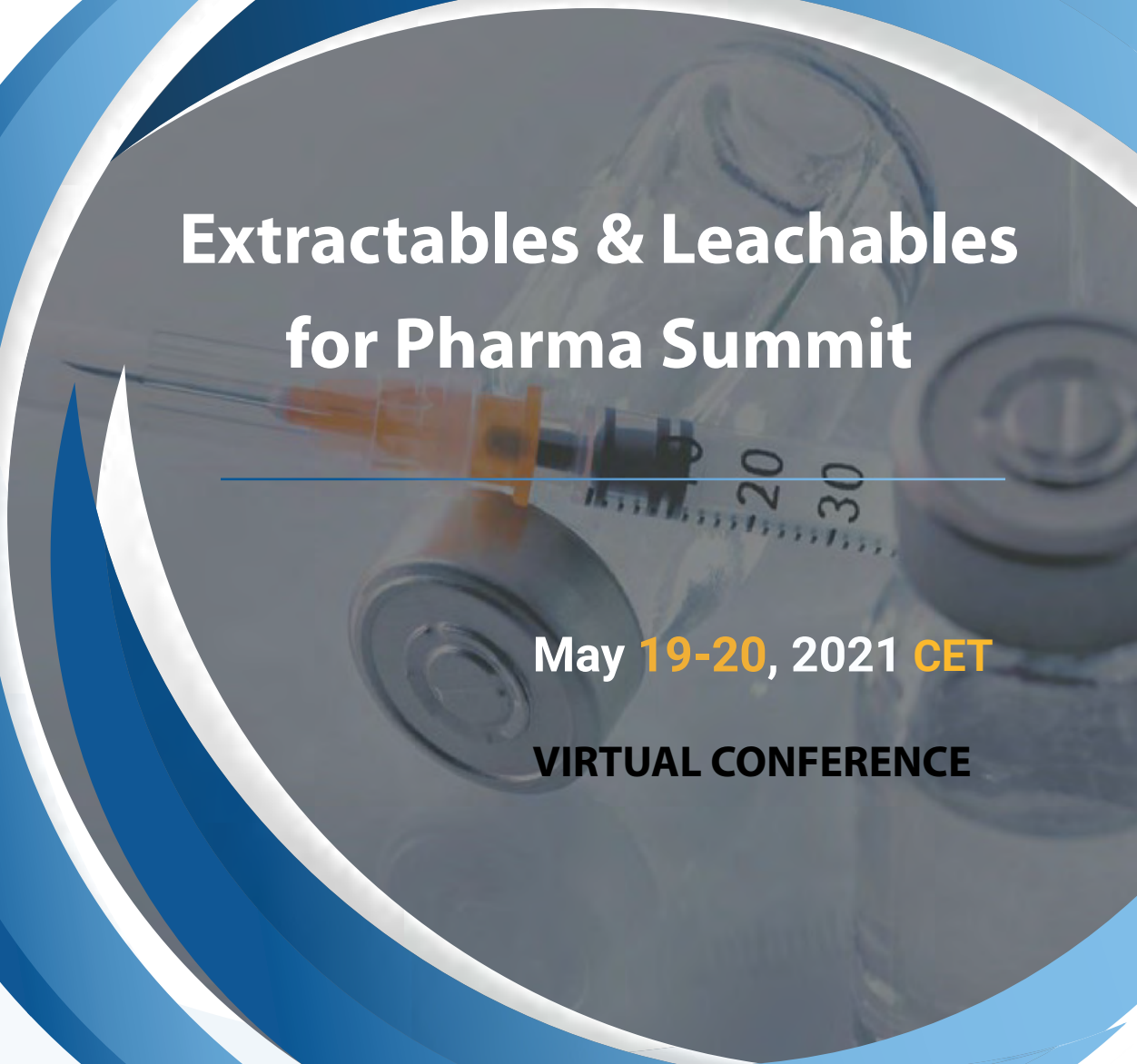
Extractables & Leachables for Pharma Summit



May 19-20, 2021 CET

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EXTRACTABLES & LEACHABLES FOR PHARMA SUMMIT

UVENTIA

May 19-20, 2021 | ONLINE

KEY SPEAKERS:

Dr. Andrew Feilden
European E&L Strategic Director
Hall Analytical, UK

Atish Sen
Staff Scientist
AstraZeneca, USA

Dr. Clemens Günther
Director, Senior Expert Nonclinical Safety
Bayer AG, DE

Wenjing Zhao
Scientist
Medtronic LTD., CN

Alicja Sobańtka
Material Qualification and E&L Expert
Octapharma, AT

Dr. Thomas Broschard
Director, Chemical Toxicology
Merck Healthcare KGaA, DE

Dr. Lukas Mogler
Associate Principal Scientist
Forensic Chemistry
Lonza DPS, CH

Thomas Egert
Research Scientist Pharmaceutical Contact Materials
Boehringer Ingelheim, DE

Greg Erexson
Senior Principal Research Toxicologist
AbbVie, Inc., USA

Noemí Dorival-García
Research Fellow
National Institute for Bioprocessing Research and Training (NIBRT), IE

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

Bill Scott
Scientist II, Materials Science
Biogen, USA

Jack Steed
Technical Specialist
SCIEX, UK

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EXTRACTABLES & LEACHABLES FOR PHARMA SUMMIT

UVENTIA

May 19-20, 2021 | ONLINE

WHO IS IT FOR?

CxO, VPs, Directors, Heads, Managers of

- Extractables and Leachables/ E&L
- Analytical Chemistry/ Analytical Development/ Analytical Science
- Product Characterisation/ Risk Assessment
- Drug Development/ Drug Substance
- Drug Safety/ Compound Safety/ Toxicology
- Device Development/ Device Engineering/ Container Development
- Good Laboratory Practice (GLP)/ Good Manufacturing Practice (GMP)
- Manufacturing Science & Technology/ Single Use Systems
- Bioprocessing/ Bioproduction
- Regulatory Affairs & Compliance
- Materials Science/ Materials Selection/ Biocompatibility
- Packaging & Labelling
- LC-MS/ Mass Spectrometry

CONFERENCE OVERVIEW

Extractables and leachables (E&L) studies has now become a key component of product launch. Regulatory agencies are very concerned about the interaction between the final drug product and container closure systems, drug delivery devices, as well manufacturing components. Hence, the migration of mobile chemicals from components and ingredients used in drug production and storage demands careful evaluation.

Our dedicated online meeting brings together managers, scientists and toxicologists in the E&L field to share the latest in analytical methods for E&L, regulatory updates and compliance, risk based E&L programs, chemical characterization, toxicological risk assessment, E&L studies validation, E&L assessment in biomanufacturing and processing equipment, E&L data for selection and qualification of single use systems, material selection/screening/qualification, custom approaches for the specific type of product.

Be present at our virtual meeting to equip yourself with new tools and vital knowledge to analyse and test for extractables and leachables in biopharmaceutical development to effectively minimize E&L associated risks and assure patients' safety and product quality.

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EXTRACTABLES & LEACHABLES FOR PHARMA SUMMIT

Day One
May 19th CET

1 2

10:00 - 10:15 Registration

10:15 - 10:30 Opening Address from the Chairman

CREATING AND VALIDATING E&L STUDIES

10:30 - 11:00

Dr. LUKAS MOGLER
Associate Principal Scientist
Forensic Chemistry
Lonza DPS, CH

Lonza

E&L PROGRAMS TO BALANCE COSTS AND TURNAROUND TIME

- EL studies for single use systems used for biologics
- EL studies for biologics manufacturing processes
- Risk-based EL assessments.

11:00 - 11:10 Short Break

11:10 - 11:40

Dr. ANDREW FEILDEN
European E&L Strategic Director
Hall Analytical, UK

hallanalytical
expert analytical testing

EFFECTIVE E&L STUDY DESIGNS

- Key factors in designing extraction studies
- Factors to consider when designing and implementing leachable studies

11:40 - 11:50 Short Break

11:50 - 12:20

Dr. CLEMENS GÜNTHER
Director, Senior Expert
Nonclinical Safety
Bayer AG, DE

BAYER

TOXICOLOGICAL ASSESSMENT FOR E&L

- Assessing toxicological risk and toxicity data
- PQRI recommendations on analytical and safety thresholds
- Qualification thresholds and use of QSAR
- Considerations on quality and safety

12:20 - 12:30 Short Break

12:30 - 13:00

Dr. THOMAS BROSCHARD
Director, Chemical Toxicology
Merck Healthcare KGaA, DE

MERCK

FROM KNOWNS AND KNOWN UNKNOWNS: MANAGING UNCERTAINTIES IN THE RISK ASSESSMENT OF LEACHABLES & EXTRACTABLES

- Toxicological risk assessment of L&E
- Data-rich vs. data-poor compounds
- Degradation products
- Case studies

13:00 - 14:00 Lunch Break

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EXTRACTABLES & LEACHABLES FOR PHARMA SUMMIT

Day One
May 19th CET

1 2

SPEAKER SPONSOR

14:00 - 14:30

Dr. TINO OTTE
Head of Sales and Consulting
Intertek (Schweiz) AG, CH

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FROM EXTRACTABLES TO LEACHABLES – HOW TO DEAL WITH COMPLICATED FORMULATIONS

Extractables and Leachables are a serious problem, which is getting worse with increasing complexity of packaging systems and drug matrices. In this presentation I will discuss the following topics in detail:
- Best study design which covers the whole product cycle from production-process to the final container closure system
- Practical solutions for E&L-evaluations of complex material combinations
- Potential difficulties with formulation interference during Leachables Studies including possible solutions
- Unknown Extractables and Leachables and how to deal with them

14:30 - 14:40 Short Break

14:40 - 15:10

ATISH SEN
Staff Scientist
AstraZeneca, USA

AstraZeneca

ANALYTICAL CHALLENGES IN E&L ASSESSMENT

- Test standards for E&L analytical assessments
- Materials information – CCS and manufacturing
- Choosing the right analytical methods
- Data interpretaion – ID and structure, quantitation, relative response factors
- Managing life cycle

15:10 - 15:20 Short Break

15:20 - 15:50

GREG EREXSON
Senior Principal Research Toxicologist
AbbVie, Inc., USA

abbvie

HOW TO WRITE A TOXICOLOGICAL RISK ASSESSMENT TO SUPPORT EXTRACTABLES AND/OR LEACHABLES PROFILES: A STEP-BY-STEP PROCESS

- Conversion of ppm (mcg/L or mcg/g) to maximum daily exposure (MDE) values
- Selection of the point of departure for permitted daily exposure (PDE) values
- Undesirable compounds (heavy metals, mutagens, carcinogens, unknowns) identified in analytical E&L profiles

15:50 - 16:00 Short Break

16:00 - 16:30

BILL SCOTT
Scientist II, Materials Science
Biogen, USA

Biogen

HOW TO CREATE AND DEPLOY AN EXTRACTABLES/LEACHABLES TESTING PROGRAM FOR A MULTI-MODAL COMPANY/FACILITY

- Know your processes; understand the full range of conditions from all modalities (monoclonal antibodies, Small molecule, gene therapy, etc.) that SUT can be exposed to
- Can you apply a standard risk assessment across all modalities?
- Emerging guidance on new modalities like gene therapy

16:30 - 16:40 Chairman's closing remarks and end of day one

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EXTRACTABLES & LEACHABLES FOR PHARMA SUMMIT

Day Two
May 20th CET

1 2

10:00 - 10:15 Registration

10:15 - 10:30 Opening Address from the Chairman

E&L ASSESSMENT FOR COMPLEX MATERIALS, PRODUCTS AND PROCESSES

10:30 - 11:00

WENJING ZHAO
Scientist
Medtronic LTD., CN

Medtronic

CHEMICAL CHARACTERIZATION IN BIOCOMPATIBILITY TESTING OF MEDICAL DEVICES

- The importance of chemical characterization for medecal device
- The general considerations of chemical characterization
- Toxicological risk assessment of medical device based on chemical characterization results (tentative)

11:00 - 11:10 Short Break

11:10 - 11:40

ALICJA SOBAŃTKA
Material Qualification and E&L Expert
Octapharma, AT

octapharma

EXTRACTABLES AND LEACHABLES IN BIOLOGICS – LESSONS LEARNED AND HANDS-ON SOLUTIONS

11:40 - 11:50 Short Break

11:50 - 12:20

THOMAS EGERT
Research Scientist Pharmaceutical Contact Materials
Boehringer Ingelheim, DE

Boehringer Ingelheim

PREDICTIVE MODELING IN SUPPORT OF CHEMICAL SAFETY RISK ASSESSMENTS

- Understanding Physicochemical Factors as Impacting Material Suitability
- Role of Mass Transport Modeling in a Modernized Safety Risk Assessment Concept – ICH Q3E

12:20 - 12:30 Short Break

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12:30 - 13:00

JACK STEED
Technical Specialist
SCIEX, UK

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EXTRACTABLES AND LEACHABLES ANALYSIS USING A QUADRUPOLE TIME-OF-FLIGHT (QTOF) MASS SPECTROMETER AND SWATH ACQUISITION

- The utilization of the SCIEX X500 QTOF system to provide qualitative and quantitative E&L data
- SWATH acquisition to ensure that all compounds can be both detected, identified and quantified in complex E&L matrices
- SCIEX OS software provides an easy to use and accessible platform for processing, whether utilizing libraries or looking to identify and quantify true unknown compounds

13:00 - 13:10 Short Break

13:10 - 13:40

NOEMÍ DORIVAL-GARCÍA
Research Fellow
National Institute for Bioprocessing Research and Training (NIBRT), IE

SINGLE-USE BIOREACTOR MATERIAL CHARACTERISATION AS CRITICAL ISSUE FOR CHO CELLS PERFORMANCE: NEW APPROACHES

- Single-use technologies, in particular disposable bioreactor bags (SUBs) have become integral within the biopharmaceutical community. However, safety concerns arose upon the identification of toxic leachable compounds derived from the plastic materials.
- Material characterisation becomes critical to determine if substances potentially detrimental to cells are present in the films.
- This study includes a comprehensive evaluation of the material composition, which is supported and correlated with different types of biological tests, which demonstrates that current awareness on leachables effects has produced an improvement in the materials composition used in modern generations of SUBs for safe application in the bioprocess.

13:40 - 13:50 Chairman's closing remarks and end of day two

Speakers Biographies

Dr. Andrew Feilden

European E&L Strategic Director

Hall Analytical, UK

Dr Andrew Feilden joined Hall Analytical in November 2019 as the European E&L Strategic Director. He is a technical expert in the field of E&L testing, having been involved in the field of E&L for over 20 years. At Hall he undertakes Commercial, Operational and technical thought leadership activities.
Andrew has presented on the field of extractables and leachables in over 16 countries worldwide. He has written a number of papers and publications and is the inventor of 2 patents.
He has a degree and D Phil from the university of York, is a Fellow of the Royal Society of Chemistry and was a Scientific Advisor to IPAC-RS and ex-co-chair of ELSIE.

Dr. Lukas Mogler

Associate Principal Scientist Forensic Chemistry

Lonza DPS, DE

After finishing my study of pharmacy in Freiburg (Germany), I did my diploma thesis in breast cancer metabolomics at the Center for Biological Systems Analysis (ZBSA) in Freiburg. During my Ph.D. at the Institute of Legal Medicine in the department of Forensic Toxicology (Freiburg) I further focused on analytical chemistry and metabolism of new synthetic drugs of abuse. Since February 2020 I am working at Lonza DPS, Basel (Switzerland), leading the group extractables and leachables.

Wenjing Zhao

Scientist

Medtronic LTD., CN

Wenjing Zhao is the chemistry scientist of Medtronic Technology Center (MTC) in Greater China. She is responsible for the Chemical Characterization and material of concern work for the whole MTC medical devices.
In 2019 and 2020, She participated in the drafting of NMPA's Guidelines for Technical Review of Establishment of Evaluation Method and Characterization of Unknow Leachables of Medical Device (Exposure Draft) as the main drafter.
She graduated from Soochow University and had been engaged in the research and development of Pharmaceutical Chemistry and medical device for 10 years. She is good at chemical synthesis, chemical analysis and chemical characterization, and she is also familiar with Macromolecular chemistry.

Dr. Clemens Günther

Director, Senior Expert Nonclinical Safety

Bayer AG, DE

Dr. Clemens Günther received his diploma in biology and doctorate for natural sciences from the Free University, Berlin-Germany. He started his professional career in 1990 at Schering AG, Berlin-Germany. From 2007 to 2013, he was Head of Global Preclinical Development at Intendis GmbH. In this position, he was responsible for Nonclinical Safety for the marketed product portfolio of Bayer Dermatology as well as the global preclinical development strategy for development and life cycle management projects. After integration of Intendis GmbH into Bayer AG in 2013, he became Director Nonclinical Safety Consumer Care and later-on Senior Expert Nonclinical Safety within the Division of Bayer Pharmaceuticals.
Meanwhile he has gained 30 year experience in drug development. He has been involved in nonclinical development and regulatory toxicology of small molecules, biologics, medical devices and drug device combination products in various medical indications.

Atish Sen

Staff Scientist

AstraZeneca, USA

Currently a Staff Scientist with AstraZeneca in the Research Triangle Park (RTP) working on trace analysis, extractables and leachables (E&L). I have been in the field since 2001. I began my E&L career extracting and analyzing flavor compounds from soy protein. In 2005 I began to work with pMDI container closure systems. Currently I manage the E&L activities at RTP and support other R&D groups within AstraZeneca. Testing for nitrosamines in drug product and packaging is at present an area of focus.
A member of the Materials Working Group within ELSIE and Knowledge Base sub-team I have been supporting the development of an extractables knowledge base.
A member of the IPAC-RS Materials working group and involved with defining medical grade plastics and nitrosamine testing on container closure systems. I have a Ph.D. in Physics from the University of Wyoming.

Thomas Egert

Research Scientist Pharmaceutical Contact Materials

Boehringer Ingelheim, DE

Thomas is a research scientist at Boehringer Ingelheim, Germany. Dedicated to analytical chemistry for 25+ years, his current role includes responsibility for materials selection and E&L qualification as well as analytical troubleshooting in packaging development.
Thomas is an active member of the Extractables and Leachables Safety Information Exchange Consortium (ELSIE) and the PQRI Parenteral and Ophthalmic Drug Product (PODP) – E&L Working Group. While contributing to several industry seminars in the field of pharmaceutical packaging, his special interest is devoted to predictive physicochemical models describing mass transport between polymers and contacting pharmaceuticals.
Prior to joining Boehringer Ingelheim, he held various positions in the field of organic trace analysis at an analytical service provider. Thomas holds a diploma in chemical engineering and a master's degree in bio- and pharmaceutical analysis.

Alicja Sobańtka

Material Qualification and E&L Expert

Octapharma, AT

Alicja is currently employed at the Octapharma where she is responsible for material qualification at corporate level. Her tasks include the testing of materials such as filters, tubing and single-use equipment for suitability in production and chemical safety. Alicja performs extractables and leachables assessments including the planning and supervision of extractables and leachables studies.
Alicja's background is chemical engineering with a focus on polymer technology and materials science.

Noemí Dorival-García

Research Fellow

National Institute for Bioprocessing Research and Training (NIBRT), IE

Noemí holds a Ph.D. in Analytical Chemistry from the University of Granada, Spain, which was focused on the development of analytical methods for the determination of pharmaceuticals, endocrine disruptors and emerging contaminants in environmental and biological matrices. She joined the Characterisation and Comparability Lab at NIBRT in 2015 on a project entitled "Facility of the future: the plastic factory, enabling single use technologies", focusing on the characterisation of E&L compounds from single-use technology solutions, using different mass spectrometry-based analytical techniques, and modern sample preparation approaches. In the same line of investigation, she is currently working on 2 Projects: one about "Determining the Reduction Capacity of Ultrafiltration/Diafiltration for Removing Leachables from Process Streams", leading the technical part, funded by Enterprise Ireland in collaboration with Janssen Sciences Ireland; and also she was awarded with a Research Grant to lead another Project about "Assessing Effects of Leachables and the Quality of Single-Use Systems in Cell and Gene Therapy Manufacturing".

Speakers Biographies

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

Dr. Tino Otte, is the Head of Sales and Consulting at Intertek in Switzerland.
He joined the company in 2016. Tino is specialized in Extractables & Leachables Studies, Impurity Characterization and Method Development.
Tino has more than 13 years of experience in Analytical Chemistry, Pharmaceuticals and Polymer Characterization.
He holds a degree in Polymer-Chemistry from the University of Halle/Saale and a Ph.D. from the Darmstadt Technical University, where he graduated in 2010.
Prior to joining Intertek, he worked at different CROs and Laboratory Instrument Manufacturers in Switzerland and Germany.

Bill Scott
Scientist II, Materials Science
Biogen, USA

Bill Scott is a scientist in the Materials Science department at the Biogen, Research Triangle Park, NC facility. He has 27 years of experience working in the biotechnology industry in multiple roles and companies. Since 2005, Bill has been working within the global Biogen Manufacturing Sciences division that is responsible for raw materials characterization and has become a subject matter expert regarding extractables and leachables. Bill is one of the co-authors of the current BPOG Extractables protocol: Testing of Polymeric Single-use Components used in Biopharmaceutical Manufacturing. Additionally, he has been a content contributor for PDA, USP and other organizations regarding extractables and leachables.

Jack Steed
Technical Specialist
SCIEX, UK

Technical specialist with substantial experience of the pharma sector. Within the last 5 years my main emphasis has been on small molecule analysis, specializing in high performance liquid chromatography (HPLC) and high performance liquid chromatography coupled with mass spectrometry (HPLC-MS).

Greg Erexson
Senior Principal Research Toxicologist
AbbVie, Inc., USA

Forty years of experience in science (E.G.: immunology, microbiology, genetic toxicology, risk assessment, medical devices and combination products, extraneous matter, occupational toxicology, impurities, excipients, residual solvents, etc.)
With Abbott/AbbVie since May 2012
Education/Experience: I have a B.S. in Biology from UNC-Chapel Hill, NC; a Masters in Toxicology and Ph.D. in Comparative Biomedical Sciences from N.C. State University, Raleigh, NC. Prior to joining AbbVie, I was a Regulatory Toxicologist at Baxter, Round Lake, IL, a Manager in Study Direction at Covance, Vienna, VA and a Toxicologist at NIEHS-NTP, RTP, NC working primarily in genetic and general toxicology as well as risk assessment".
DABT 1999 to present; ATS 2015 to present; FRSB 2015 to present; ERT 2015-present

Dr. Thomas Broschard
Director, Chemical Toxicology
Merck Healthcare KGaA, DE

Thomas Broschard is a toxicologist at Merck Healthcare KGaA in Darmstadt, Germany. He studied food chemistry at the University of Kaiserslautern and received his PhD in 1995 from the German Cancer Research Center (DKFZ), where he investigated mechanisms of chemical carcinogenesis. After a postdoctoral position at the Ecole Supérieure de Biotechnologie in Strasbourg, France, he started his career as an industrial toxicologist in 1998. Since 2000, he held several positions at Merck's Toxicology/Chemical and Preclinical Safety Department. In his current position he is heading the Chemical Toxicology Group that is responsible for the risk assessment of impurities in drug products including leachables and extractables.

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