OCTOBER 11-13, 2023

EXTRACTABLES & LEACHABLES SUMMIT

VIRTUAL / ZOOM

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

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PARTNERS: intertek Total Quality. Assured. Mérieux NutriSciences

PARTNER

Mérieux NutriSciences

Nitrosamines Analysis

Pharma Service Catalogue

Mérieux NutriSciences is a valued partner to the global healthcare industry, offering R&D and quality control testing of pharmaceutical products and medical devices.
Our fully equipped, state-of-the-art laboratories offer comprehensive testing services in compliance with euGMP/cGMP. Investigation studies and contract research services are provided according to customer specifications. Dedicated GMP/GLP area of about 2800 sqm.
3 independent laboratories and huge storage capacity in the same facility:

- R&D Lab
- Chemical Lab
- Microbiological Lab (equipped with 2 Cleanrooms)

Presented by:

Dr. Margherita Monico
E&L Senior Project Manager
Mérieux NutriSciences
Italy, IT

PARTNER

intertek Total Quality. Assured.

Analytical Approaches For Control of Genotoxic Impurities

Intertek_Schweiz_ Polymer Analysis

Intertek_ Schweiz_Particle Characterization

Intertek_Schweiz_E&L

Intertek_Schweiz_ Service_Portfolio

General Presentation

Helping our clients achieve Total Quality Assurance through custom, flexible, contract services, we provide regulatory-driven, phase-appropriate laboratory services in support of CMC programs for both small molecules and biologics from our GLP / GCP / GMP laboratory network. Services include method development and validation, analysis, stability studies, extractables and leachables, cGMP quality control testing, cGMP batch release testing and formulation development. Our teams have specialist drug development experience for complex medicines such as biologic therapeutics or vaccines and drug delivery systems such as inhaled or nasal drug products. Over the last 30 years, we have helped some of the World's largest and most innovative pharmaceutical companies navigate the challenges of drug development. Now, our scientists at our newly expanded European Centres of Excellence are ready to work with you to enable and accelerate your product development.
Intertek's Switzerland testing laboratory, located in Reinach / Basel-Area, is an advanced analytical testing facility, providing comprehensive pharmaceutical testing, materials analysis and chemical testing to clients in the pharmaceutical, medical device, drug delivery, chemical, packaging, polymers and consumer healthcare sectors across Europe and the world. Our laboratory is equipped with state-of-the-art instrumentation, capable of performing chemical trace analysis, reverse engineering, complex analyses, substance identification and a wide range of other applications. With a significant corporate research heritage, the Intertek Reinach testing laboratory is staffed by highly trained and experienced scientists with many years of industry knowledge. Our flexible approach includes project and study-oriented work to support customers at various stages of their product life cycle – from research and development, registration, to ongoing production or post-market failure or complaints. We also provide a range of routine testing services to meet our client's current needs.
The laboratory provides analytical testing to Good Laboratory Practice (GLP) compliant requirements and is on the WHO list of Prequalified Quality Control Laboratories (since 2014). The laboratory has ISO 17025 and ISO 9001 certification and holds Good Manufacturing Practice Compliant (GMP) certification and is FDA inspected

Presented by:

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

SPEAKERS BOARD

Dr. Greg Erexson, PhD, DABT, FATS, FRSB, ERT
AbbVie Retiree
Greg Erexson Toxicology Consulting, LLC USA

Dr. Christina Reufsteck
Biocompatibility Expert
TUV SUD
Product Service GmbH, DE

Atish Sen, PhD
Staff Scientist Analytical Sciences Inhalation Product Development
AstraZeneca, USA

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

Jason Creasey
Managing Director
Maven E&L Ltd, UK

Dr. Andreas Nixdorf
Life Sciences - Business Development Manager Extractables & Leachables Testing
SGS Institut Fresenius GmbH, DE

Bram Jongen
Vice President Materials & Surface Technologie
Datwyler Pharma Packaging International NV, BE

Markus Obkircher
Director R&D, Head of Reference Materials and Proficiency Testing
Merck, DE

Diego Zurbriggen
Sr. Manager Strategic Studies & Analytical Lifecycle
West Pharmaceutical Services USA

Dr. Roberto Menzel
Laboratory Supervisor and Manager Extractables
Sartorius Stedim Biotech, DE

Delphine Brissaud
R&D Staff Scientist
BD, FR

Melisa Masuda-Herrera
Senior Associate Scientist
Gilead Sciences, USA

Dr. Martyn Chilton
Principal Scientist
Lhasa Limited, UK

Dr. Candice Johnson
Senior Research Scientist
Instem, USA

Dr. Margherita Monico
E&L Senior Project Manager
Mérieux NutriSciences Italy, IT

Lukas Mogler
Principal Scientist / Sr Group Leader
Lonza, CH

Dr. Andrew Feilden
Director Analytical Sciences
Bicycle Therapeutics, UK

Wenjing Zhao
Biocom Technical Manager, Global Lab Operation Value Stream Sterile Fluids
Fresenius Medical Care R&D (Shanghai), CN

Chris Waine
Senior Toxicologist
bibra toxicology advice and consulting, UK

Isabelle Sbille
Associate director- Material Safety Expert (E&L)
UCB Biopharma SRL, BE

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

Ron Brown
Toxicologist
Risk Science Consortium, LLC, USA

Pierre Van Durm
Material of Contact global quality SME
UCB Biopharma SRL, BE

Samuel N Kikandi, PhD
Deputy Director-Principal Engineer/ Material Science & E&L SME
Sanofi, USA.

Steve Zdravkovic
Research Scientist II
Baxter International Inc., USA

Etienne Michel
Global Quality Expert
GSK Vaccines, BE

Marine Lepoutre
Global Subject Matter Expert
GSK Vaccines, BE

Weifeng Lin
Staff Scientist
Thermo Fisher Scientific, USA

WHO YOU WILL MEET

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*

GEOs

- *Central and Eastern Europe*
- *North America*
- *Middle East and Africa*
- *Asia-Pacific*
- *Other*

DIVISIONS

- Analytical Chemistry
- Bioprocessing
- Bioproduction
- CCIT
- CMC
- Container Development
- Device Engineering
- E & L
- Formulation
- Glass
- Manufacturing Science & Technology
- Materials Science & Selection
- Medical Devices
- Packaging & Labelling
- Parenterals
- PFS
- Polymers
- Product & Process Development
- QA/QC
- Quality Testing
- R & D
- Regulatory Affairs
- Risk Management & Assessment
- Rubber
- Safety Assessments
- Scientific Affairs
- Single Use Systems
- Standardisation
- Toxicology
- Validation
- Other

SNAPSHOT OF ATTENDEES - 2nd Annual Extractables & Leachables Summit 2020

https://qepler.com/events/el20.html
https://qepler.com/pdf/el20.pdf

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 • 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 • others

12:00 **Opening Address**

12:10 **Extractables and leachables study design in context of a biopharma production process**

The goal will be to present a lifecycle approach of our existing park of single-use, based on leachable risk, to ensure a compliance for the effectivity date of the USP in 2026.

- *What sources of extractables and leachables need to be considered?*
- *How can a study be designed to cover all steps from DS production to final DP shelf storage?*
- *How can supplier data or general studies on extractables be used?*
- *After the discovery of targets above the threshold - how are they identified and quantified for further tox evaluation?*
- *Recommendations for target selection, validation, and routine monitoring are provided.*
- *Case studies and examples of all steps of the study are shown*

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

intertek Total Quality. Assured.

13:10 **Extractable and leachables challenges and issues with Biologicals**

- *Why are large molecules of more concern*
- *Challenges of highly hazardous APIs*
- *Interaction of biologicals with leachables*

Dr. Andrew Feilden | Director Analytical Sciences | Bicycle Therapeutics, UK

Bicycle

13:50 **Break**

14:10 **Extractables and leachables assessments in biologics manufacturing processes**

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

Lukas Mogler | Principal Scientist / Sr Group Leader | Lonza, CH

Lonza

14:50 **Assessment of Extractables and Leachables from Single-Use Systems in Cell and Gene Therapy and ATMP Processes**

The differences between cell and gene therapies (CGT) and traditional biopharmaceutical products create new challenges for extractables and leachables (E&L) assessments. These issues are particularly important considering the increasing reliance on single-use systems (SUS). While SUS extractables data can serve as a basis for assessing CGT applications, there are significant opportunities to improve assessment tools for exposure estimation and toxicological evaluation. In CGT applications cells are the therapeutic product and a patient exposure estimation for leachables must consider both the liquid phase and the therapeutic cells.
We tested forty-five commonly found E&Ls and processing aids in a high-throughput cell-painting assay using a U2OS human cell line. Results showed that most compounds did not create a response in the > 550 cell features analyzed. Only three candidates were found to show an effect in this assay, including the antioxidant degradant bDtBPP, known to be detrimental to cell growth. Further, a concept is developed that allows to model process equipment-related leachables (PERLs) in a CGT production environment.
In summary, cell-based products' exposure to PERLs is expected to fall far below critical concentrations. Nonetheless, avoiding construction materials containing extractables with a known detrimental effect to cells is advisable. These results indicate that SU devices are suited for CGT applications.

- *Assessing extractables and leachables (E&L) in cell and gene therapies (CGT) presents unique challenges compared to single-use systems (SUS) in biopharmaceutical manufacturing.*
- *A cell-painting assay (CPA) of common and critical E&Ls on a U2OS cell line revealed minimal impact on cell properties for most compounds.*
- *Single-use systems are generally suitable for CGT, and the CPA aids in material selection to avoid critical extractables harmful to cells*

Dr. Roberto Menzel | Laboratory Supervisor and Manager Extractables | Sartorius Stedim Biotech, DE

SARTORIUS

15:30 **Break**

15:50 **Taking a step further in your Extractables & Leachables testing**

- *Optimizing information gathering to improve study management*
- *Implementing target compounds databases*
- *Addressing the unknown (with case studies)*
- *Simulation study v. leachables assessment (with case studies)*

Dr. Margherita Monico | E&L Senior Project Manager | Mérieux NutriSciences Italy, IT

Mérieux NutriSciences

16:30 **Using expert knowledge and machine learning to assess the mutagenicity and sensitisation potential of extractables and leachables**

Dr. Martyn Chilton | Principal Scientist | Lhasa Limited, UK

17:10 **Break**

17:30 **Applications of computational methods in the assessment of extractables and leachables**

[REC] [SLIDES]

- *Use of in silico approaches supporting the assessment of Extractables and Leachables (E&L)*
- *Prevalence of predicted mutagens and potent sensitizers in large representative databases of E&L*
- *Use of in silico models to assess leachable reactivity with biomolecules*
- *Biomolecule reactivity in silico workflow*

Dr. Candice Johnson | Senior Research Scientist | Instem, USA

18:10 **TBA**

Diego Zurbriggen | Sr. Manager Strategic Studies & Analytical Lifecycle | West Pharmaceutical Services USA

18:50 **Closssing remark**

12:00 **Opening Address**

12:10 **Challenge for Industry with new USP665/1665** [REC] [SLIDES]

- *Risk Assessment Methodology (Upstream, Downstream process)*
- *Analysis of regulation and Requirements*
- *Key Challenge and experience from USP 1665*

Isabelle Sbille | Associate director- Material Safety Expert (E&L) | UCB Biopharma SRL, BE
Pierre Van Durm | Material of Contact global quality SME | UCB Biopharma SRL, BE

12:50 **How to Improve the Accuracy of your E&L Testing** [REC] [SLIDES]

- *ISO/IEC 17025 requirements, traceability and uncertainty*
- *Certification of relevant reference standards*
- *Intended use of CRMs, applications, and use cases*
- *Proficiency testing to improve your laboratory performance*
- *Compound databases for screening*

Markus Obkircher | Director R&D, Head of Reference Materials and Proficiency Testing | Merck, DE

13:30 **Break**

13:50 **Ruggedness and Robustness in Nitrosamine Analysis from Pharmaceutical Elastomers, factors to consider.**

This presentation outlines areas to consider when approaching the analysis of nitrosamines in elastomeric materials used in the pharmaceutical industry. Nitrosamines represent a class of substances which are potentially mutagenic and as such need to be closely monitored to avoid patient exposure at levels which might represent a risk. The nature of the potential risk has led to requirements to monitor quantitatively down to the parts per billon (ppb) in elastomeric components used in pharmaceuticals. At these levels, (ng per gram of elastomers) it is very likely that the analytical method will suffer a lack of robustness and/or ruggedness unless, extreme care is taken in the development of the analytical methodology.

- *Choice of Sample preparation*
- *Choice of chromatography system*
- *Choice of detector*
- *Methods of assessing recovery*
- *Methods of maximising sensitivity, precision, and accuracy of measurement*

Jason Creasey | Managing Director | Maven E&L Ltd, UK

14:30 **Toxicological Risk Assessment on Extractables and Leachables** ~~[REC]~~ [SLIDES]

- *Introduction: why do we need to care about E&L?*
- *In silico assessment using computer expert systems*
- *Concept of Threshold of Toxicological Concern*
- *Concept of Permitted Daily Exposure*
- *Compounds of specific concern: nitrosamines*

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

15:10 **Break**

15:30 **Improving the Accuracy of your E&L Testing**

- *Uncertainties that adversely affect accuracy of E&L testing*
- *Improving sample preparation for better assessment*
- *Improving analytical testing procedures for more accurate E&L assessment*
- *Future advancements in E&L testing*

Atish Sen, PhD | Staff Scientist Analytical Sciences
Inhalation Product Development | AstraZeneca, USA

16:10 **How to Write a Toxicological Risk Assessment to Support Extractables and/or Leachables: A Step-by-Step Process [REC] [SLIDES]**

- *Analytical identification of E&L compounds (tentative, definitive and unknowns)*
- *No toxicity data exists for your E&L compound: What to do?*
- *The E&L toxicology risk assessment process*
- *Derivation of maximum daily exposure (MDE) values*
- *Regulatory guidance as references for PDE values*
- *Toxicology databases to obtain toxicity data*
- *Selection of the point of departure to derive the PDE value*

Dr. Greg Erexson, PhD, DABT, FATS, FRSB, ERT | AbbVie Retiree | Greg Erexson Toxicology Consulting, LLC, USA

GREG EREXSON Toxicology Consulting, LLC

16:50 **Break**

17:10 **Duration-Based Non-Mutagenic Thresholds of Toxicological Concern (TTC) for Parenteral Extractables and Leachable [REC] [SLIDES]**

- *The ELSIE consortium derived duration-based, non-mutagenic thresholds of toxicological concern (TTCs) for parenteral extractables and leachables substances.*
- *The first part of the presentation will provide a brief background on the ELSIE consortium and the ELSIE Risk Management Framework for extractables and leachable assessments.*
- *This will be followed by a general overview of the TTC concept and its application to mutagenic and non-mutagenic impurities.*
- *A majority of the presentation will then focus on the process for deriving the duration-based TTCs for parenteral E&Ls, including an overview of the ELSIE database, evaluation of the toxicological data used to determine the parenteral point of departuand application of adjustment factors.*

Melisa Masuda-Herrera | Senior Associate Scientist | Gilead Sciences, USA

GILEAD

17:50 **Closssing remark**

12:00 **Opening Address**

12:10 **How to implement USP 665 requirements before 2026 [REC] [SLIDES]**

The goal will be to present a lifecycle approach of our existing park of single-use, based on leachable risk, to ensure a compliance for the effectivity date of the USP in 2026.

- Management of existing items, lifecycle and retrospective approach
- Management of new items created between 2021 and 2026
- Ensure full compliance for items after 2026
- Quid of Chinese pharmacopea?

Marine Lepoutre | Global Subject Matter Expert | GSK Vaccines, BE

12:50 **Health risk assessment of Extractables and Leachables – things are not always what they seem [REC] [SLIDES]**

- Extractables and leachables (chemical characterisation) studies are a requirement for both medicines and medical devices.
- E&Ls can arise from containers and closure systems used for pharmaceuticals, from medical devices, and from packaging of both.
- Uncertainties exist in the characterisation of the source, identity and quantity of E&Ls, which can impact the toxicological risk assessment.
- This presentation will include several case studies of the toxicity assessment of E&Ls where these uncertainties were addressed.

Chris Waine | Senior Toxicologist | bibra toxicology advice and consulting, UK

13:30 **Break**

13:50 **Case sharing of chemical characterization applications during the whole life cycle of Medical Devices [REC] [SLIDES]**

- *Brief introduction to the application of chemical characterization*
- *Chemical characterization application for material selection*
- *Chemical characterization application for PCRB*
- *Chemical characterization application for NMPA registration*

Wenjing Zhao | Biocom Technical Manager, Global Lab Operation
Value Stream Sterile Fluids | Fresenius Medical Care R&D (Shanghai), CN

14:30 **Leveraging Analytical Chemistry Data of Medical Devices to Derisk Drug Combination Product Submission**

- *Normative landscape around drug delivery systems development*
- *Challenges for defining the appropriate study design for upcoming of complex, highly sophisticated wearable systems*
- *Strategy proposal around potential standardization of test protocols in the context of Drug Combination Products*

Delphine Brissaud | R&D Staff Scientist | BD, FR

15:10 **Break**

15:30 **E&L studies from a Notified Body Perspective ~~[REC]~~ [SLIDES]**

- *Importance of Chemical Characterization in the biological evaluation of medical devices*
- *E&L testing as part of the chemical characterization*
- *Importance of reporting thresholds*
- *Use of E&L data in addressing biological endpoints*
- *Life-time aspects in biological evaluation*

Dr. Christina Reufsteck | Biocompatibility Expert | TÜV SÜD Product Service GmbH, DE

16:10 **Topics on potential complaints in connection with the chemical characterization of medical devices. ISO 10093-18 Practical aspects in study designs.**

The most widely used standard to assess the potential biological risks of medical devices in accordance with the requirements is the ISO 10993 series and cited references therein. An essential part of the standard series is the chemical test according to ISO 10993 part 18. The chemical characterization provides information about the specific substances in the device construction, including which of them are released during the intended application.
The chemical profiles generated according to the standard are evaluated according to toxicological aspects and therefore represent an integral part of the risk assessment of the medical device.
However, when creating a study design, one must be aware that ISO 10993 part 18 makes many recommendations for creating a test design tailored to the medical device application, but often does not provide detailed methodological solutions for the overarching study requirements.
The ISO series is a European standard, and it is not recognized by all authorities in all aspects. The requirements for the range of chemical analytical methods are high. Modern analysis techniques can achieve a lot, but they also have limitations. Some of these limitations will be highlighted and discussed in the lecture.
These so-called "gray areas" in the study concept often lead to official questions or can even lead to a complaint if no conclusive and satisfactory answer is provided to official concerns.

Dr. Andreas Nixdorf | Life Sciences - Business Development Manager
Extractables & Leachables Testing | SGS Institut Fresenius GmbH, DE

16:50 **Break**

17:10 **Composition and shelf life considerations for the extractables profile of rubber [REC] [SLIDES]**

- *Effect of elastomer base on the extractables profile of rubbers*
- *Simulation study showing the effect of the elastomer base and coating*
- *Avoiding nitrosamine risk by choosing the right rubber composition*
- *Effect of shelf life on rubber extractables*

Bram Jongen | Vice President Materials & Surface Technologie |
Datwyler Pharma Packaging International NV, BE

17:50 **ISO 10993-17 update**

Ron Brown | Toxicologist | Risk Science Consortium, LLC, USA

18:30 **Closssing remark**

SPEAKER'S BIOGRAPHIES

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

Tino Otte, Senior Scientific Consultant at Intertek, is an expert for analysis of impurities and contaminations in pharmaceutical products.

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.

He joined Intertek (Schweiz AG) in 2016. Prior to joining Intertek, he worked with different research, development and manufacturing companies where he served in several functions in product management and development of analytical services.

He has more than 7 years of experience in GMP regulated environment within multiple areas of product analysis including method development, validation and QC.

Dr. Greg Erexson, PhD, DABT, FATS, FRSB, ERT | AbbVie Retiree | Greg Erexson Toxicology Consulting, LLC, USA

Globally boarded (DABT, ATS, ERT) toxicology consultant with over 43 years of fulltime work experience. I have an extensive background in all four general employment areas of the toxicology discipline: academia, government, contract and pharmaceutical industry environments. Consulting services are provided in multiple areas of toxicology including, but not limited to general toxicology, occupational toxicology, assessments of extraneous matter, extractables and leachables, solvents, impurities, degradants, excipients, trace elements, metals, biocompatibility, genetic toxicology, finished product medical devices and combination products as well as their individual components in addition to manufacturing components that are used in the process stream (e.g., filters, tubing, bioreactor liners, containers, films, coatings, inks/pigments, etc.). Experience as an expert toxicologist in litigation events.

Jason Creasey | Managing Director | Maven E&L Ltd, UK

Jason Creasey is a graduate analytical chemist. In 2019, he established Maven E&L Ltd, as its Manging Director and Principal Consultant. Maven E&L was setup to provide advice to clients working in the pharmaceutical industry on all aspects relating to the topic of extractables and leachables (E&L) and the risks that leachables pose to the quality and safety of drug products. Prior to this, he worked for GSK where he was the director of their R&D E&L Team.
He has worked in the topic area of E&L since the mid 1990's on a wide range of modalities and dose forms seeing this area expand and grow in significance for the pharmaceutical and medical device industries. In addition to running his consultancy, he is a scientific advisor to the ELSIE consortium. Since setting up Maven E&L; he continues to present, discuss, and write about E&L. He now publishes a regular E&L blog through LinkedIn and his Website (www.MavenEandL.com), for the exchange of ideas and discussion.
As well as supporting client projects, among recent E&L activity, he is presenting and commenting on risk- based approaches to E&L requirements within the pharmaceutical industry that he hopes will form part of an ICH guidance in the not-too-distant future and has helped ELSIE publish and discuss their whitepapers linked to Concepts in Leachable Risk Management and develop their database further.

Atish Sen, PhD | Staff Scientist Analytical Sciences
Inhalation Product Development | AstraZeneca, USA

Currently a Staff Scientist with AstraZeneca in the Research Triangle Park (RTP) working on 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 manage the E&L activities at RTP and support other R&D groups within AstraZeneca. 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 bio-compatibility. I have a Ph.D. in Physics from the University of Wyoming.

Wenjing Zhao | Biocom Technical Manager, Global Lab Operation Value Stream Sterile Fluids |
Fresenius Medical Care R&D (Shanghai), CN

Wenjing Zhao is a biocompatibility technical manager in Fresenius Medical Care and has the responsibility for biocompatibility and chemical characterization of medical device, as well as the compatibility of drug-packaging materials.
Prior to this position, she was a senior scientist in Medtronic, in charge of medical devices of Chemical Characterization and Materials of Concern for 7 years.
Wenjing was invited as the main drafter to draft several Chinese guidance and standards for medical device E&L during the past years. She holds a Bachelor of Science degree in Pharmaceutical Chemistry from Soochow University and had been engaged in the research and development of Pharmaceutical Chemistry and Medical Device for over 12 years.

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.

SPEAKER'S BIOGRAPHIES

Dr. Andreas Nixdorf | Life Sciences - Business Development Manager
Extractables & Leachables Testing | SGS Institut Fresenius GmbH, DE

Andreas studied organic chemistry at the University of Bielefeld in Germany with the main focus on mass spectrometry and computational chemistry.
Since the date of his PhD/doctorate in 1997, he worked in different scientific and managerial positions ranges from head of laboratory to GMP QA site manager in Life Science industry prior he proceeds with his carrier at SGS in 2007.
From 2007 to 2010 he was responsible for project management and regulatory consultancy at the customer service Pharma at SGS Institute Fresenius GmbH. Andreas introduced Extractables & Leachables testing services at SGS in 2008 and got his current position of an business development manager in 2010.
Andreas applies technical and regulatory knowledge, scientific experience and expert judgment to address solutions for a broad range of difficult problems. He troubleshoots and directs the resolution of QC method issues by fostering effective interdepartmental and cross-functional partnerships with clients from pharmaceutical and medical industry.
With over 20 years' experience in Life Science segment he is a frequent speaker at events and international conferences (PDA, A3P, ECA, VDI, BioInnovation, CPHI, Smithers RAPRA, IQPC, Vonlanthen Group, Chinese Medical Device Association, Dipartimento di Scienze del Farmaco in Pavia and others) in the fields of Medical Device, Single Use Systems and Finished Packaging safety evaluation.
Companies in regulatory controlled industries are challenged by on-going regulatory systems. Changes must be set in practice and cross-functional teams with different functional expertise must be organized to work toward a common goal.
Andreas wants to motivate experts from Life Industry or organizations working together to realize or achieve a better and effective cross departmental collaboration in order to improve regulatory requirements for safety testing of plastic materials that are used to produce the medical product.

Delphine Brissaud | R&D Staff Scientist | BD, FR

Delphine Brissaud is a Senior Scientist at BD Medical Pharmaceutical Systems with over 20 years of experience focused on extractables and leachables in prefillable syringes. Her main responsibility has been supporting new product development as well as current business on extractable studies. This included definition of extraction parameters, development and validation of analytical methods and laboratory management. She holds a degree in chemistry from Clermont-Ferrand School of Chemistry (ENSCCF – France) and a specialization in drug/packaging interactions from the Faculty of Pharmacy of Paris (France).

Dr. Roberto Menzel | Laboratory Supervisor and Manager Extractables |
Sartorius Stedim Biotech, DE

Dr. Roberto Menzel has a Ph.D. in Chemistry from the University in Jena.
He started his career as an assistant editor in the natural science book section at Wiley VCH, Weinheim followed by a position as group leader for the organic trace analysis in the environmental analytical division at Eurofins Scientific.
In 2015, he joined Sartorius Stedim Biotech where he established and is heading the internal Extractables analysis laboratory.
He is responsible for material and product qualification studies for single-use systems and components for the biopharmaceutical industry.

Dennis Jenke | Chief Executive Scientist | Triad Scientific Solutions, LLC, USA

Dennis got a PhD from Montana State University Bozeman in Analytical Chemistry. He worked over 33 years for Baxter. His primary responsibilities include the development, validation and application of diverse analytical strategies and methods for the discovery, identification and quantification of trace constituents in pharmaceutically relevant solutions and samples. Currently he is Chief Executive Scientist at Triad Scientific Solutions, Inc. which is his own consulting firm.

Markus Obkircher | Director R&D, Head of Reference Materials and
Proficiency Testing | Merck, DE

Markus Obkircher is the head of Merck's Reference Materials Research & Development division with teams in the US and Switzerland. He is responsible for the in-house development of new analytical standards and certified reference materials. Prior to this position he was R&D Manager in Buchs, Switzerland, with a strong focus on synthesis, characterization and certification of reference materials. He joined Merck / Sigma-Aldrich five years ago after heading the development unit for a custom API manufacturer. Before that he completed his post-doctoral studies at Harvard in Boston and his PhD thesis in Basel, Switzerland.

Bram Jongen | Vice President Materials & Surface Technologie |
Datwyler Pharma Packaging International NV, BE

After his Masters in Polymer Chemistry at the University of Louvain, Belgium, Bram Jongen acquired a Ph.D. in Water Soluble Polymers used for advanced drug administration.
Bram started as Technical Support Manager for Datwyler about 14 years ago, supporting customers in a vast area, from Western European countries to countries like India, Korea, and South Africa. Thereafter, he headed the Global Product Introduction & Support team, a global team of highly experienced and educated people, having each their own expertise in the world of pharmaceutical closures. Bram himself acquired profound Extractables & Leachables expertise. His team managed customer projects of technical nature and supported Datwyler's product and portfolio management.
Since end of 2012, he has been acting as Head of R&D, leading a group that focuses on developing new rubber and new coating materials.

SPEAKER'S BIOGRAPHIES

Dr. Christina Reufsteck | Biocompatibility Expert | TÜV SÜD Product Service GmbH, DE

Christina studied Biology and graduated at the University of Cologne. Then she moved to the German Cancer Research Center in Heidelberg, where she worked in cancer research, and received her PhD. Afterwards, she joined BioMedimplant, an accredited biocompatibility test laboratory in Hannover. There she conducted studies of cytotoxicity, hemocompatibitity and implantation according to the ISO 10993 series. Since 2014, she is working as an expert at the notified body TÜV SÜD Product Service GmbH in Munich and assesses the manufacturers' technical documentation with focus on biocompatibility. Christina is a member of the German working committee for ISO/TC 194 (Biological and clinical evaluation of medical devices).

Diego Zurbriggen | Sr. Manager Strategic Studies & Analytical Lifecycle | West Pharmaceutical Services USA

Mr. Zurbriggen has over 20 years of analytical lab experience, 10 of which focused on inorganic trace level analysis. As Technical Account Manager within the Technical Customer Support group of West, the focus of his role is to provide technical support relating to West's packaging components and delivery systems for injectable drugs and healthcare products. He serves as the West subject matter expert on Extractables & Leachables, including elemental impurities.
Prior to this role, he was Supervisor of the Leachables/Stability group in the Analytical Labs division of West Pharmaceutical Services, Inc., the focus of his role was to develop and validate leachables methods. Mr. Zurbriggen holds a Bachelor of Science/Chemistry degree from the Gewerbliche Berufsschule Visp – Visp, Valais, Switzerland.

Dr. Tine Hardeman | Manager Material Development Healthcare | Datwyler, BE

Tine Hardeman studied Polymer Chemistry at the University of Leuven and received her MSc in 2013. She acquired a PhD for her dissertation on the controlled synthesis of conjugated polymers in 2017. After gaining R&D experience at Kaneka Belgium, Tine started her career at Datwyler in 2018 as Manager Material Development. In this role, she is working on the development of new rubber formulations, raw material management, and helping customers with rubber compound-related questions, among other things. Additionally, she has been focusing on the field of Extractables & Leachables, where her detailed knowledge of rubber formulations provides an interesting perspective.

Steve Zdravkovic | Research Scientist II | Baxter International Inc., USA

Steve Zdravkovic is currently a Research Scientist II at Baxter Healthcare, which he joined in February 2021. Prior to joining Baxter, he worked for 16 years in the E/L team at PPD, Inc. In these roles, Steve has been responsible for all aspects of E/L studies with a focus on the design and execution of screening studies using mass spectrometry-based techniques. Steve has published nine peer reviewed journal articles, which pertain to various areas of research within the E/L field, and is a member of the editorial board of the PDA Journal of Pharmaceutical Science and Technology. Steve holds a Bachelor of Science degree in chemistry and mathematics from the University of Wisconsin – Whitewater.

Dr. Candice Johnson | Senior Research Scientist | Instem, USA

Dr. Candice Johnson is a Senior Research Scientist at Instem with over 10 years of experience in computational model development. She holds a Bachelor of Science degree in Biology, and a Ph.D. in Engineering. Her published work includes peer-reviewed manuscripts, and book chapters on procedures to increase confidence in computational evaluations and novel assessment approaches.

Chris Waine | Senior Toxicologist | bibra toxicology advice and consulting, UK

Chris Waine is a toxicologist with 10 years of experience in human health hazard and risk assessment of chemicals. Along with his work on extractables and leachables, he specialises in the evaluation of pharmaceutical impurities, submissions under the EU REACH Regulation and the application of (Q)SAR models for toxicology. He is a member of the BSI and ISO Technical Committees relating to ISO 10993 on the biological evaluation of medical devices.

Ron Brown | Toxicologist | Risk Science Consortium, LLC, USA

Ron Brown is a toxicologist with 35 years of experience in regulatory toxicology and risk assessment. He recently retired from the US FDA after 25 years of service and currently directs a small company, Risk Science Consortium, LLC, that provides consultation and training in toxicological risk assessment and computational toxicology. At the FDA, Ron was the senior toxicologist responsible for developing and reviewing toxicological risk assessments of extractable and leachable (E&L) compounds from medical devices. Prior to his position at the US FDA, Ron served as a Senior Associate at the ILSI Risk Science Institute. He is founding member and former President of the Medical Device and Combination Products Specialty Section of the Society of Toxicology and former President of the Dose-Response Specialty Section of the Society for Risk Analysis.

SPEAKER'S BIOGRAPHIES

Dr. Margherita Monico | E&L Senior Project Manager | Mérieux NutriSciences Italy, IT

Graduated in 2010 in Veterinary Medicine at the University of Padua, Margherita Monico has also obtained a Master's degree in Biotechnology for Business at CUOA Business School. In Mérieux NutriSciences since 2019, she is the Senior Project Manager dedicated to designing and supervising Extractables & Leachables studies, and also provides customized courses and webinars on the subject.

Marine Lepoutre | Global Subject Matter Expert | GSK Vaccines, BE

Marine LEPOUTRE currently holds the position of Global Subject Matter Expert in Extractable & Leachable at GSK Vaccines and is responsible for aligning all GSK Vaccines sites with current regulatory requirements. Before this position, in his role of process expert for Belgium site, she leads process validation as homogeneity, holding time, lifetime and lyophilisation. Marine is a Chemical Process Engineer with a master's degree in Chemistry from CPE Lyon in France.

Etienne Michel | Global Quality Expert | GSK Vaccines, BE

Etienne MICHEL currently holds the position of Global Quality Expert at GSK Vaccines, with an oversight on several expertise areas such as Extractable & Leachable, Cleaning, Bulk processes, Homogeneity and Chemical compatibility. Before that, in his role as Global Cleaning Expert, he has led the development and implementation of new cleaning strategies within GSK. Etienne is a Civil Chemistry Engineer with a master's degree in environmental sciences and management from the Université Catholique de Louvain-la-Neuve in Belgium.

Dr. Andrew Feilden | Director Analytical Sciences | Bicycle Therapeutics, UK

Dr Andrew Feilden joined Bicycle Therapeutics as CMC Director of Analytical Science in October 2022, where he is responsible for regulatory testing.
He has previously held leadership positions at CROs specialising in extractable and leachable testing. 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.
Andrew has presented on the field of extractables and leachables in over 17 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.

Weifeng Lin | Staff Scientist | Thermo Fisher Scientific, USA

Dr. Weifeng Lin a staff scientist in Thermo Fisher Scientific's Single-use Division (SUD). He is currently leading the extractable and leachable (E&L) analysis lab in the R&D division to support the routine E&L analysis and new material research. Dr. Lin received his PhD at UC Davis majoring in analytical chemistry. He is member of BioPhorum E&L workgroup and is a regular speaker at various E&L conferences.

Jianfeng Hong | Sr. Research Scientist | Fresenius Kabi, USA

Jianfeng Hong is a Senior Research Scientist and the manager of the Analytical Chemistry laboratory at Lake Zurich, IL, USA of Fresenius Kabi USA LLC. His major responsibilities include leading a group of analytical chemists to perform extractable and leachable studies for material and container closure systems usd for blood and pharmaceutical transfusion products of Fresenius Kabi. His group uses a wide variety of advanced analytical instrumentation including GC/MS, UPLC/UV, Q-TOF/ion trap mass spectrometer and ICP/MS. He has over twenty years of experience as an analytical chemist with pharmaceutical and medical device industries performing analytical method development/validation. He earned a master degree in Analytical Chemistry from University of Louisville, Kentucky, USA.

Erika Udovic | Principal Scientist II, PCS Impurity Safety | Novartis, CH

Erika is currently working as a Principal Scientist II at Novartis with experience in human health hazard and safety evaluations of pharmaceutical impurities, including extractables and leachables. Her main responsibilities include scientific, toxicological, and regulatory support to ensure risk is appropriately managed. She provides safety assessments for various administration routes, applying computational and read-across methodologies where required. She is a member in internal cross-functional teams and committees, as well as external consortium (e.g., Safety Working Group within ELSIE). Prior to this, she worked as an occupation toxicologist responsible for compilation of risk assessment reports for drug substances, intermediates, and raw materials for worker and patient safety purposes. Erika has a background in Veterinary Medicine and found her passion in Toxicology.

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 Annual Extractables & Leachables Summit | October 11-13, 2023

PARTICIPATION PACKAGES	Register by 30.6.2023	Register by 28.7.2023	Register by 1.9.2023	Standard price
VIRTUAL Ticket - 2 Days	€ 295 (save € 200) ☐	€ 345 (save € 150) ☐	€ 395 (save € 100) ☐	€ 495 ☐
VIRTUAL Group - 2 Days (*2-3 delegates, per person)	€ 245 (save € 200) ☐	€ 295 (save € 150) ☐	€ 345 (save € 100) ☐	€ 445 ☐
VIRTUAL Group - 2 Days (*4+ delegates, per person)	€ 195 (save € 160) ☐	€ 255 (save € 100) ☐	€ 295 (save € 60) ☐	€ 355 ☐
VIRTUAL Ticket - 2 Days (*NPO/Academic, per person)	€ 95 (save € 150) ☐	€ 145 (save € 100) ☐	€ 195 (save € 50) ☐	€ 245 ☐
VIRTUAL Ticket - 2 Days (*Past Attendees, per person)	€ 95 (save € 150) ☐	€ 145 (save € 100) ☐	€ 195 (save € 50) ☐	€ 245 ☐
RECORDING				
RECORDING only - Without live summit attendance (*Each ticket already contains this option)				€ 345 ☐
SPONSORSHIP PACKAGES				
PROMO - € 995 ☐	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: _____

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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 14 days or more before the event start date will be refunded with no charges. Cancellations made less than 13-3 days before the event start date will be refunded 50% of the registration fees. Cancellations made less than 2 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 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 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 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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«I agree to be bound by Terms and Conditions of registration»

SEND

PARTNERSHIP PACKAGES

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.	€ 345

PARTNERSHIP PACKAGES:

BENEFITS	PROMO € 995	PRESENTER € 1.595	PARTNER € 2.595
Included passes	1	2	3
Additional company representatives registration fees	€ 295	€ 245	€ 195
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.

EVENTS **CALENDAR** 2023-2024

3rd Annual Extractables & Leachables Summit | October 11-13, 2023 | VIRTUAL
Registration is Open Now!

https://qepler.com/events/el23.html
https://qepler.com/calendar/el23.pdf

4th Annual Highly Potent APIs Summit | February 20-23, 2024 | VIRTUAL
The Call for Speakers is Open Now!

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

4th Annual Genotoxic Impurities in Pharmaceuticals Summit | March 13-15, 2024 | VIRTUAL
The Call for Speakers is Open Now!

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

4th Annual Extractables & Leachables Summit | June 12-14, 2024 | Prague, Czech Republic
The Call for Speakers is Open Now!

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

5th Annual Highly Potent APIs Summit | September 18-20, 2024 | Prague, Czech Republic
The Call for Speakers is Open Now!

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

5th Annual Genotoxic Impurities in Pharmaceuticals Summit | October 9-11, 2024 | Prague, Czech Republic
The Call for Speakers is Open Now!

https://qepler.com/events/5gti24.html
https://qepler.com/calendar/5gti24.pdf