5th Annual Summit

Extractables & Leachables for Pharma

ONLINE | FEBRUARY 27TH- 28TH, 2025 CET

Key Speakers:

Will Parker, USA
E&L Technology Manager
West Pharmaceutical Services

Tine Hardeman, BE
Manager Material Development
Datwyler

Ana Kuschel, DE
Principal Scientific Affairs
West Pharmaceutical Services

Erika Udovic, CH
Senior Principal Scientist
Novartis Pharma AG

Dujuan Lu, USA
E&L Manager/Global Leader
SGS Health Science

Clemens Guenther, DE
Former Senior Expert Nonclinical Safety at Bayer AG
Independent Lecturer

Katherine Lovejoy, DE
Application Chemist
Thermo Fisher Scientific

Steve Zdravkovic, USA
Research Scientist II
Baxter Healthcare

Divya Regulagedda, ES
Manager (Global SME)
Chemo Group

Dvir Doron, PhD, ERT, IL
Director, Chemical Toxicology Team Leader
Teva Pharmaceutical Industries Ltd.

James Hathcock, USA
Sr Director, Regulatory and Validation Strategy
Cytiva

Eric Hill, USA
Chief Scientific Officer - Chemistry and E&L Labs
BA Sciences

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CONFERENCE OVERVIEW

The assessment of extractables and leachables is a critical step in the biopharmaceutical development process. The interactions between pharmaceutical products and drug delivery systems, bioprocess manufacturing systems, and container closing systems are of special concern for regulatory bodies. Therefore, it is necessary to carefully examine the migration of mobile molecules from the materials and components utilized in the production and storage of pharmaceuticals.

We organize a virtual conference to facilitate discussion on the most recent analytical techniques, regulatory updates, risk-based E&L programs, chemical characterization and toxicological risk assessment among scientists, toxicologists and E&L managers. We also cover ISO 10993-18, medical device materials, analytical and safety thresholds and customized systems for different product types.

Participate in our event to learn about the latest methods for testing and analyzing extractables and leachables. This can help you significantly reduce the risks associated with E&L while also assuring patient safety and product quality.

WE WILL TALK ABOUT

- leachables and extractables as an essential component of product development and launch.
- accurate analytical methods for the identification, measurement, and screening of E&L compounds.
- exchanging knowledge from experts about how to plan, execute and publish E&L studies.
- examining revisions to regulations to keep regulatory approvals compliant and cost-effective.
- industry guidelines for toxicological risk assessment and chemical characterization.
- comprehensive E&L evaluations for complex materials, products and processes.

ABOUT US

Uventia Global s.r.o. is a modern conference and business information company. To help businesses advance, we carry out in-depth research and establish connections with risk-takers and deal-makers throughout Europe & US and emerging markets. With cutting-edge strategies, products, procedures, and technology, our conferences, events, and training programs are created for senior decision-makers operating at the top of their respective sectors.

We believe that delivering timely topics and facilitating person-to-person interaction make a sustainable change.

WHO ATTENDED THE EVENT 2024

• Agilent Technologies Deutschland GmbH • AnaBioTec • Bacthera AG • Baxter Healthcare • Baxter International Inc. • Bayer AG • BBraun Avitum Italy • Becton Dickinson • BSP Pharmaceuticals S.p.A. • Catalent Pharma Solutions • Charles River • Chattam (Sanofi) • Chemical Characterization Solutions, LLC • Chemo Group • CleanControlling Medical GmbH & Co. KG • Crossject • CSL Vifor • Dalia Global Services • Dalton Pharma • Eli Lilly • Estée Lauder Companies • GE HealthCare • GE Healthcare AS • GlaxoSmithKline Biologicals Kft. • GSK (Pharma) • GSK Vaccines • Instem • Intertek (Schweiz) AG • Lausanne University Hospital • Lhasa Limited • LIQVOR CJSC • Maven E&L Ltd • Medline Industries LP • Merck KGaA • Mirum Pharma • Nattrmann (Sanofi) • Norgine • Novartis • Novartis d.o.o. • Novartis Pharma AG • Opella (Sanofi) • Pharmacelsus GmbH • Pharmaceutical company Darnitsia • Philips Electronics Nederland B.V. • Preclintox Services, LLC • Quinta-Analytica, s.r.o. • ResMed • Safetree Consulting e.U. • Sandoz Development Center • Sartorius Stedim Biotech GmbH • Septodont • SEQENS • SGS Health Science • Takeda Manufacturing Austria AG • TEVA branded pharmaceutical products R&D, Inc. • Teva Pharmaceutical Industries Ltd • Teva Pharmaceuticals Ireland • Thermo Fisher Scientific • Vimta Labs Limited • West Pharmaceutical Services • Westlake Compounds Italy S.r.l. • Zoetis Belgium SA

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FIRST DAY

1 2

11:50 - 12:00 Registration

12:00 - 12:10 Opening Address from the Chairman

REGULATORY UPDATES AND EFFECTIVE E&L PROGRAMS

12:10 - 12:40

[AVAILABLE] **Updated regulatory guidelines for E&L testing**

- Regulatory criteria for pharmaceuticals and medical devices.
- How are the E&L data viewed by EMA and FDA?
- E&L testing recommendations from PQRI, ICH, and USP.

12:40 - 12:50 Short Break

12:50 - 13:20

Katherine Lovejoy, DE
Application Chemist
Thermo Fisher Scientific

Aerosol-based detectors (CAD) as a solution to analytical challenges in the evaluation of E&L: troubleshooting and practical answers

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13:20 - 13:40 Break

ANALYTICAL METHODS, E&L STUDIES, AND DATA INTERPRETATION

13:40- 14:10

Divya Regulagedda, ES
Manager (Global SME)
Chemo Group

How to implement effective E&L study designs

- Sample preparation, extraction studies and quantification.
- Classifying and identifying targeted substances.
- Risk assessment and profiling for extractables.
- Assessment of stability studies and leachables.

14:10 - 14:20 Short Break

14:20 - 14:50

Dvir Doron, PhD, ERT, IL
Director, Chemical Toxicology
Team Leader
Teva Pharmaceutical Industries Ltd.

Risk assessing extractables and leachables in topical ophthalmic drugs: case studies and lessons learnt

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14:50 - 15:10 Break

15:10 - 15:40

Steve Zdravkovic, USA
Research Scientist II
Baxter Healthcare

ELSIE's Lab Practices Working Group's Proposal for Best Practices to Improve the Consistency of Extractable Screening Data Between Laboratories

- Inconsistencies in the execution of extractable screening studies between laboratories can result in differences in the qualitative and/or quantitative aspects of the extractable profiles obtained.
- Given that such differences can have a significant impact on the validity of the safety assessments performed, it is critical that they be understood and minimized.
- The "lab practices" working group within the Extractable/Leachable Safety Information Exchange (ELSIE) conducted two industry surveys that uncovered numerous areas associated with the execution of extractable screening studies where labs were not well aligned that may be impacting the data generated.
- To that end, this presentation will summarize the best practice recommendations proposed by the ELSIE lab practices working group to address the discrepancies in extractable study design.

15:40 - 15:50 Short Break

E&L TOXICOLOGICAL ASSESSMENT

15:50 - 16:20

Clemens Guenther, DE
Former Senior Expert
Nonclinical Safety at Bayer AG
Independent Lecturer

Toxicological Risk Assessment on Extractables and Leachables

- Introduction: why do we need to care about E&L?
- How to perform a Toxicological Risk Assessment.
- The concept of Permitted Daily Exposure (PDE).
- The concept of Threshold of Toxicological Concern (TTC).
- Compounds of specific concern: Nitrosamines.

16:20 - 16:30 Short Break

16:30 - 17:00

Erika Udovic, CH
Senior Principal Scientist
Novartis Pharma AG

Safety assessment of E&Ls: toxicology assessment workflow and challenges with different administration routes

- Introduction to general safety and regulatory considerations for extractables/ leachables (E&Ls) in pharmaceutical products.
- Considerations for different administration routes, including (topical) ocular.

17:00 - 17:10 Chairman's closing remarks and end of day one

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SECOND DAY

1 2

11:50 - 12:00 Registration

12:00 - 12:10 Opening Address from the Chairman

E&L ANALYSIS FOR COMPLEX MATERIALS, PRODUCTS AND PROCESSES

12:10 - 12:40

Eric Hill, USA
Chief Scientific Officer - Chemistry and E&L Labs
BA Sciences

Extractables testing of Single Use Systems (SUS)

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12:40 - 12:50 Short Break

12:50 - 13:20

[AVAILABLE] E&L assessment of biologic drug products

- Concerns for large-molecule parenteral formulations.
- E&L testing for biopharmaceutical packaging systems.
- Considerations while manufacturing biological drugs.

13:20 - 13:40 Break

13:40 - 14:10

Tine Hardeman, BE
Manager Material Development
Datwyler

Effect of X-ray vs. gamma on the extractables profile of rubber closures

- Investigation towards the effect of X-ray irradiation on the extractables profile of rubber closures.
- Comparison of X-ray irradiation with gamma irradiation and their effect on extractables.
- Changes in the extractables profiles of rubber closures at the end of shelf life.

14:10 - 14:20 Short Break

14:20 - 14:50

Dujuan Lu, USA
E&L Manager/Global Leader
SGS Health Science

E&L testing for medical devices

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14:50 - 15:10 Break

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SECOND DAY
1 2

15:10 - 15:40

James Hathcock, USA
Sr Director, Regulatory and Validation Strategy
Cytiva

Aligning expectations and risk assessment strategies for bioprocess equipment

- What is needed and what is not. Updated overview of standards relevant to bioprocess resk assessment and qualification.
- Case study examples of different single-use applications, supporting data, and risk assessment.
- Clearance of PERLS in lipid nanoparticle genomic medicines as well as traditional biologics manufacturing processes.

15:40 - 15:50 Short Break

15:50 - 16:20

Ana Kuschel, DE
Principal Scientific Affairs
West Pharmaceutical Services

Will Parker, USA
E&L Technology Manager
West Pharmaceutical Services

Testing for E&L in packaging materials

- Reviewing USP packaging criteria.
- Relating chemical characterisation of components.
- E&L examination of glass, plastic and elastomer components.

16:20 - 16:30 Short Break

16:30 - 17:00

[AVAILABLE] E&L assessment of cell and gene therapies

- Unique challenges with E&L studies for CGTs.
- Analyzing E&L risks in plans for product development.
- Studies on simulation and material characterization.
- Data analysis and toxicological assessment.

17:00 - 17:10 Chairman's closing remarks and end of day two

WHO IS IT FOR?

- Extractables and Leachables/ E&L
- Analytical Chemistry/ Analytical Development/ Analytical Science
- Product Characterisation/ Risk Assessment
- Drug Development/ Drug Substance
- Drug Safety/ Compound Safety/ Toxicolog
- 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

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Will Parker, USA
E&L Technology Manager
West Pharmaceutical Services

Will Parker earned a B.S. in chemistry in 2004 from Penn State Erie where he will soon be serving on a School of Science alumni advisory board and will be earning a master's degree in data analytics from Penn State in May 2024. Will has over 18 years of analytical chemistry professional experience with 13 of them in extractables and leachables labs as both a lab scientist and manager. He has spent the past nearly 8 years in lab management roles, mostly in E&L, with his current role as the E&L technology manager at West where he assists Services and Solutions in meeting industry expectations and our clients' needs. Will has designed and executed hundreds of various E&L studies comprising the breadth of the field including studies of drug product packaging, manufacturing in-process contact materials, single-use systems, and medical devices.

Tine Hardeman, BE
Manager Material Development
Datwyler

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.

Erika Udovic, CH
Senior Principal Scientist
Novartis Pharma AG

Erika is currently working as a Senior Principal Scientist at Novartis, with experience in human health hazard and safety evaluations of pharmaceutical impurities, including extractables and leachables. Her main responsibilities include providing scientific, toxicological, and regulatory support to ensure appropriate risk management. She conducts safety assessments for various administration routes, using computational and read-across methodologies as needed. Erika is a member in internal cross-functional teams and committees, as well as external consortiums such as the Safety Working Group within ELSIE. Previously, she worked as an occupational toxicologist, compiling 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.

Katherine Lovejoy, DE
Application Chemist
Thermo Fisher Scientific

Katherine Lovejoy is an Application Chemist at the Thermo Fisher Scientific production site for HPLC and for the charged aerosol detector. She has 7 years of experience in that role and enjoys helping others get the best possible CAD results. She earned a PhD in Inorganic Chemistry from the Massachusetts Institute of Technology and has a h-index of 15. Her experience also includes time as a chemist reviewer at the FDA and a scientist at Los Alamos National Laboratory.

Ana Kuschel, DE
Principal Scientific Affairs
West Pharmaceutical Services

As Principal Scientific Affairs Europe, Ana is providing technical support relating to West's packaging components and delivery systems for injectable drugs and healthcare products. As well as bridging scientific information through industry outreach. This is complementing her previous role as Manager Material Development, where she worked on both existing and new rubber formulations.
Ana holds a PhD in macromolecular chemistry and is an active member of the ISO TC 76 and PDA Packaging Science groups.

Dujuan Lu, USA
E&L Manager/Global Leader
SGS Health Science

Dr. Dujuan Lu serves as the manager for the extractables and leachables (E&L) team at the SGS Health Science Fairfield New Jersey USA facility as well as the global leader amongst the global E&L centers of excellence. Dr. Lu obtained her PhD in analytical chemistry from the University of Pittsburgh and has extensive CRO and pharmaceutical/medical device industry experience with more than 500 E&L projects. She was named one of the top 60 most influential people working in the pharmaceutical industry in the Medicine Maker's 2020 power list.

Clemens Günther
Former Senior Expert Nonclinical Safety
at Bayer AG
Independent Lecturer

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 Director and Head of Global Preclinical Development at Intendis GmbH, branded later-on as Bayer Dermatology. 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 including human DMPK for development and life cycle management projects.
After integration of Intendis into Bayer in 2013, he became Director Nonclinical Safety Consumer Care and later-on Senior Expert Nonclinical Safety within the Division of Bayer Pharmaceuticals. He held this position until June 2024 and is acting now as independent lecturer.
Dr. Clemens Günther gained about 35 years of 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 including Transdermal Therapeutic Systems. His expertise includes also the Toxicological Risk Assessment of impurities as well as extractables and leachables.

Divya Regulagedda, ES
Manager (Global SME)
Chemo Group

Divya Regulagedda is analytical person from technical perspective and have experience in the field of E & L for 11+ years. She has hands on experience with LC-MS/MS, LC-QTOF, GC-MS/MS, ICP-MS and IC.
Previously, she worked with a CRO and was responsible for the work of E &L.
Currently, she is responsible for the E & L work in Insud Pharma for Pharmaceutical products and medical devices.
Also, she has experience with risk assessments and toxicological evaluations.

Dvir Doron, PhD, ERT, IL
Director, Chemical Toxicology Team Leader
Teva Pharmaceutical Industries Ltd.

Dvir Doron has been working at Teva Pharmaceutical Industries Ltd. since 2014 in the Nonclinical Safety Department of the Global R&D Division. The Chemical Toxicology team, under his leadership, is responsible for providing risk assessments and qualifications of process-related impurities, degradation products, residual solvents, elemental impurities, as well as extractables and leachables, along with other types of contaminants and foreign materials.
Dvir is a European Registered Toxicologist (ERT) since 2020. He earned a Ph.D. in Computational Chemistry from Bar-Ilan University, Israel (2013), where he studied enzyme-catalyzed hydrogen-transfer reactions using Quantum Mechanics/ Molecular Mechanics (QM/MM) simulations and explored the temperature dependence of kinetic isotope effects in these systems. Prior to his doctoral studies, Dvir received a B.Sc. (summa cum laude) in Medicinal Chemistry (2006) and an M.Sc. (summa cum laude) in Medicinal and Organic Chemistry (2008), both from Bar-Ilan University.

Eric Hill, USA
Chief Scientific Officer
BA Sciences

Eric Hill has more than 20 years of experience in the contract testing laboratory space, including the last 8 at BA Sciences. His experience includes new laboratory start-ups, laboratory management, technical leadership, and consulting. Eric came to BA Sciences to build the Extractables & Leachables service line and has since assumed the role of Chief Scientific Officer. In this role, Eric assists BA Sciences' clients by providing technical guidance and consulting for analytical strategy and project scope definition for the Chemistry Laboratories. Eric regularly speaks at technical conferences, and also serves on various USP working groups and expert committees developing new testing standards. Eric has a Master's degree in Chemistry from Central Michigan University and an M.B.A. from the University of Michigan.

Steve Zdravkovic, USA
Research Scientist II
Baxter Healthcare

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.

James Hathcock, USA
Sr Director, Regulatory and Validation Strategy
Cytiva

James Hathcock, PhD is Senior Director of Regulatory and Validation Strategy at Cytiva, responsible for strategy to support the safe and successful end-user implementation of technologies enabling pharmaceutical manufacturing. He is currently an active supporting member to BioPhorum, BPSA, ASTM, ASME-BPE, PDA and ISO. He also leads the BPSA initiative on X-ray security of supply for single-use disposables, the BioPhorum Community of Practice for Extractables and leachables, and the ASME-BPE task group on single-use biocontainers; and has previously served as an expert manel member for USP <665> & <1665>. Since joining Pall in 2008, now a part of Cytiva, James has supported business continuity and security of supply challenges, led material and performance qualification of medical and biotech components, and delivered relevant technical packages supporting regulatory filings. Prior to joining Pall, James served as professor of hematology at the Mt. Sinai School of Medicine in New York City, where he directed the protein purification laboratory related to drug characterization and discovery.

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REGISTRATION DATE:

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UVENTIA	Full access to the 2 days online event.	Full access to the 1 day online event.	Recording of 2 days event sessions.
	Digital certificate, List of participants.	Digital certificate, List of participants.	List of participants.
	Recording of 2 days event sessions, PDF.	Recording of 1 day event sessions, PDF.	PDF presentations.

1st Attendee

Full Name:
Job Title:
Company:
Country: Phone:
Email:

2nd Attendee

Full Name:
Job Title:
Company:
Country: Phone:
Email:

3rd Attendee

Full Name:
Job Title:
Company:
Country: Phone:
Email:

4th Attendee

Full Name:
Job Title:
Company:
Country: Phone:
Email:

SEND

INVOICE DETAILS

Full Name:
Job Title:
Company:
Country: City:
Address:
Postcode: Phone:
EU VAT #:
Email:

PAYMENT METHOD

Bank Transfer: ☐ Credit Card: ☐ PayPal: ☐

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

TERMS & CONDITIONS

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Recognition in chairman's opening address		◊	◊	◊