## Monday 9th November

| **Pre-Conference Workshops** |
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| **Workshop 1: E&L vs Food-Contact Compliance: Two Regulatory Worlds, One Packaging Reality** |
| **13:30-15:00 sponsored by Neotron**<br>The workshop will provide a comparative analysis of two regulatory frameworks that are frequently applied to the same packaging materials: pharmaceutical Extractables & Leachables (E&L) assessment and food-contact compliance evaluation.<br><br>• Overview of the regulatory objectives and principles of each framework.<br>• Comparison of risk assessment methodologies, migration concepts, and acceptance criteria.<br>• Discussion of the similarities and differences between food-contact regulations and pharmaceutical E&L requirements.<br>• Evaluation of how food-contact compliance data can support packaging selection for pharmaceutical applications.<br>• Practical case studies illustrating where the two approaches align and where additional E&L investigations are required.<br>• Interactive discussion on decision-making strategies for packaging qualification.<br><br>**Barbara Moretti, Head of Packaging Dept. & Food Contact Materials Specialist, Neotron**<br>**Valeria Mazzoni, E&L Project Coordinator, Neotron** |
| **15:00-15:30 Coffee Break** |
| **Workshop 2: Advanced Toxicological Assessment and Regulatory Decision & Making** |
| **15:30 -17:30 sponsored by Safebridge**<br>Hands-on case studies covering read-across methodologies, grouping of chemically related compounds, identification of unique chemical entities above reporting thresholds, and derivation of Permitted Daily Exposures (PDEs), including complex scenarios involving high-dose drug products and oncology APIs with genotoxic mechanisms of action.<br><br>**Dr Janet Gould, Ph.D, DABT, CIH \| Senior Principal Toxicologist, SafeBridge Europe**<br>**William Hawkins \| Senior Managing Toxicologist, SafeBridge Europe** |
| **17:30 Networking Drinks Reception** |
| 18:00 End of Pre-Conference Workshops |

## Day One – Tuesday 10th November

| **08:00 Registration and welcome refreshments** |
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| **09:00 Chair's opening remarks**<br>**Michael Creese** ***\| Operations Director of Chemistry Medical Device Testing \| Smithers*** |
| **Session: AI & Digital Transformation in E&L** |
| **09:10 Opening Keynote: Accelerating ELSIE Knowledge Base Population: AI-Assisted Ingestion of Multi-Source, Multi-Format Extractables Reports**<br>• AI-driven ingestion of heterogeneous report formats and data sources<br>• Automated extraction and standardisation of extractables study data<br>• Quality control strategies for reliable Knowledge Base content<br>• Impact, lessons learned, and opportunities for broader adoption<br>***James M. Vergis \| Secretariat \| ELSIE Consortium*** |

**09:35 Machine Learning-Driven Solvent Selection for Leachables Studies Using Abraham Solvation Parameters and LogP Optimisation**

- ML enabled solvent selection using Abraham parameter–based solvent selection for E&L
- Predictive optimisation of extractables coverage while minimising API co-extraction
- In silico solvent ranking reduces experimental burden without compromising regulatory expectations
- Practical AI driven decision for efficient, risk-based E&L studies

***Minh Khoa Ta | Scientist | Resolian***

***Blagovesta Tomova | Senior Programme Manager in E&L | Resolian***

**10:00 Predictive Polymer Degradation Modelling for E&L Risk Assessment: The A2P2-AI Platform**

- Why predictive polymer degradation modelling is emerging as a valuable tool for extractables and leachables (E&L) risk assessment
- How polymer formulation and exposure conditions can be used to forecast degradation pathways and potential leachable profiles
- Integrating computational predictions with experimental ageing data to prioritise targeted E&L testing
- Supporting risk-based material selection and product development through earlier prediction of degradation behaviour
- Future applications of AI-assisted predictive modelling for E&L and regulatory science

***Nazli Ozdemir | Founder | Gulsine***

**10:25 Networking break**

**11:05 The Place for AI in E&L Studies in 2026: Is it Ready to Replace You and Me?**

- How AI is reshaping data management in E&L, what it is getting right and where human oversight still matters
- From training tools to knowledge transfer, exploring AI's growing role in building the next generation of E&L expertise
- Beyond the hype: which AI-generated models are actually delivering value in real-world E&L workflows
- Can AI truly replace the experienced consultant, and where would you be mad to let it try?
- An honest snapshot of AI in 2026, its genuine strengths, its stubborn limitations, and what that means for your practice

***Jason Creasey | Managing Director | Maven E&L Ltd***

**11:30 Panel Discussion: From Promise to Practice – Where does "digital transformation" Sit in the E&L Workflow?**

Panellists will explore where automation can improve efficiency and consistency, how predictive and machine-learning approaches could support study design and risk-based decision-making, and what is needed for scientifically and regulatorily acceptable use.

- How do we connect data, models, automation and human expertise effectively?
- How ready are organisations for this transition?
- And what could the digitally enabled E&L workflow look like in 12 months, five years and ten years?

Moderator: ***Michael Cresse | Operations Director of Chemistry Medical Device Testing | Smithers***

Panellist:

- ***Minh Khoa Ta | Scientist | Resolian***
- ***Blagovesta Tomova | Senior Programme Manager in E&L | Resolian***
- ***Nazli Ozdemir | Founder | Gulsine***
- ***Jason Creasey | Managing Director | Maven E&L Ltd***
- ***James M. Vergis | Secretariat | ELSIE Consortium***
- ***Helen Lewis I Manager Project Management I Smithers***

**Session: Clearence of Leachables and Risk Mitigations**

**12:30 E&L in Practice: Case Studies in UF/DF Siloxane Clearance and AOV Vial Lifecycle Strategy**

***Elizabeth Looney | Senior Principal Scientist | Pfizer***

**12:55 Ultrafiltration/Diafiltration (UF/DF) Clearance of Leachables from Mixed-polymer Extracts**

- Traditional spiking studies often misrepresent UF/DF clearance of organic compounds, highlighting the need for more realistic assessment strategies

- Use of mixed polymer plastic extracts (from household items) under intended use conditions to study leachables clearance during UF/DF
- Application of untargeted LC HRMS to identify and follow a broad range of leachables through UF/DF processing
- Development of an in silico semi-quantitation and QSPR-based modelling approach to predict clearance behaviour
- Insights from clearance data across multiple monoclonal antibodies on the robustness and predictability of UF/DF

***Dr Aidan Sexton | Senior Principal Scientist, Material Sciences at Biotherapeutics Development & Supply (BTDS) | Janssen***

***Noemi Dorival Garcia | Senior Research Scientist | NIBRT***

**13:20 Networking Lunch**

**14:30 Clearance of Organic Compounds in UF/DF: Beyond Sieving and Binding Effects**

- Why previous UF/DF studies on clearance of leachables may have missed a critical piece of the puzzle, and what it means for your process confidence
- How spiking studies and mass balances can distinguish between clearance by permeation, material sorption, and protein association
- How existing UF/DF models can be extended with material sink terms
- A more complete framework for interpreting UF/DF results

***Maximilian Bossong | Material Specialist | Uni Mainz & Sartorius***

**14:55 Extractables & Leachables Challenges in CAR-T Cell Therapies**

- Why CAR-T cell therapies present a distinct and more complex E&L challenge than conventional biologics, and what makes them fundamentally different to assess
- The case for extending E&L evaluation across the entire manufacturing process, not just final container closure systems
- How early-stage, risk-based strategies can make E&L testing more feasible and scientifically defensible under real development constraints
- Why CAR-T E&L success demands more than expertise, harnessing true interdisciplinary collaboration to turn complexity into a strategic advantage

***Angelica Artasensi | Project Leader | Eurofins***

**Session: Medical Devices & Combination Products**

**15:20 What is Leaching in Your Child's Hospital Nebuliser**

***Rick Reiley | Chief Scientific Officer | Extractus Ltd***

**15:45 Networking break**

**16:15 Pushing Sensitivity Limits: MS Screening Strategies for Trace Extractables**

- How to build an ISO 10993-18-ready MS screening strategy that spans targeted, suspect, and non-targeted analysis and why all three are needed for comprehensive extractables coverage
- Achieving broad chemical coverage at trace levels in large-volume devices, where sensitivity demands push formerly established workflows to their limits
- A robust, fully qualified screening workflow stress-tested across a diverse range of materials — with the real-world data to back it up
- What pushing sensitivity limits actually looks like in practice, and the practical implications for laboratories aiming to meet evolving regulatory expectations

***Rita Beel | Group Lead Extractables & Leachables | Fresenius Medical Care***

**Virtual Session: Medical Device Toxicology & Regulatory Expectations**

**16:40 Thresholds in Chemical Analysis of Medical Device Extracts and Toxicological Risk Assessments**

***Berk Oktem I Chemist I FDA***

**16:55 Toxicological Risk Assessment of E&L for Medical Devices and Regulatory Expectations**

- What's changed in ISO 10993-1:2025 and what it means in practice for the biological safety evaluation of your medical devices

- How toxicological risk assessment now sits at the heart of biological risk assessment, and how to integrate it effectively into your existing frameworks
- The current regulatory landscape for E&L TRA in medical devices, including the latest developments from ISO/TC 194 working groups and ICH Q3E that will shape expectations in the near term
- Where the guidance is heading, emerging trends and practical implications for toxicologists and regulatory teams working at the intersection of E&L and device safety

***Alina Martirosyan | Senior Scientific Manager Toxicology, Medical Scientific Affairs | B.Braun Melsungen***

**17:10 Joint Q&A**

**17:20 End of day**

**17:20 Networking drinks reception**

## Day Two – Wednesday 11th November

**08:00 Registration and welcome refreshment**

**08:30 Chair's opening remarks**
**Helen Lewis, Manager of Project Management, Medical Device Testing, Smithers**

**Session: Single-Use Systems**

### 08:40 E&L USP <665>: Experiences, Challenges and Best Practices

- What USP <665> really means in practice — how it shifts E&L evaluation toward a material- and lifecycle-based framework, and what that demands of your existing programmes
- Honest lessons from implementing USP <665> in both development and commercial biopharmaceutical settings — where interpretation gets difficult and where the guidance leaves gaps
- The particular challenge of low-risk component characterisation under USP <665>, and how to navigate data availability and evaluation without over- or under-testing
- Best practice approaches for risk-based testing strategies and supplier collaboration that have proven effective in real-world USP <665> implementation
- How to move beyond treating USP <665> as a compliance checkbox — and use it as a strategic tool to build more robust, efficient, and sustainable E&L programmes

***Julia Vincenz | MSAT Specialist | VTU Engineering Wien***
***Annabel Fritz I A&M STABTEST***

### 09:05 Bridging USP 665 to Other Industry Frameworks for Smoother E&L Risk Assessment

- Bridging key E&L frameworks including USP <665>, ICH Q3E, BioPhorum, PQRI and ISO 10993
- A risk-based approach to single-use system qualification, aligning extractables data with patient safety considerations
- Developing harmonized E&L control strategies to reduce redundant testing and support global regulatory submissions

***Samuel Kikandi | Deputy Director-Principal Engineer | Sanofi***

### 09:30 USP <665>/<1665> in Practice: Analytical Methods, Risk Frameworks and Lessons from Across the Industry

- Designing extractables studies for low-, medium- and high-risk manufacturing materials
- Case studies from a range of production materials and single-use systems
- Common testing challenges and practical approaches to overcoming them
- Applying risk-based frameworks to support USP <665>/<1665> implementation

***J. Susanne Becker | Head of E&L Lab | Intertek (Schweiz) AG***

### 09:55 Real E&L Profiling of Single-Use Systems: From Thawing to Final Filling

- End-to-end leachable profiling of a real commercial single-use biomanufacturing line, tracked from frozen drug substance thawing through to final filling across multiple formulations and batch sizes
- Where leachable burden peaks across the manufacturing process, and what that means for where risk-based attention should be focused

- Real-world data on the impact of filling interruptions on leachable profiles, and why process holding time deserves greater scrutiny in your E&L strategy
- How formulation variables such as surfactant type and process scale act as critical drivers of leachable profiles, with data to demonstrate their significance
- A practical framework for linking observed leachables directly back to specific single-use components, hold times, and process scale, making safety assessments more targeted and defensible

***Diane Hohenester | R&D Principal Scientist | F. Hoffmann-La Roche AG***

**10:20 Networking break**

**11:00 Potential Leachable Migration of Labels and Components into Bioprocess Bags**

- Labels on single-use bioprocess bags are an underrecognised source of leachables — face stocks, adhesives, and inks all contain low-molecular-weight compounds capable of migrating under bioprocess conditions
- Understand why bag film and label compatibility is a more critical variable than commonly assumed — with migration behaviour varying significantly across EVA bag types and label combinations
- Adhesives and label substrates are the primary drivers of label-related leachables; ink migration was not observed under any tested condition, offering some reassurance on that front
- Walk away with clear, data-driven guidance on when a new E&L study is — and isn't — required when changing label components
- Why label materials deserve a formal place in your E&L risk assessments, and what the consequences of overlooking them could mean for regulatory compliance and patient safety

***R V Praveen Kumar | Consultant Scientist | Johnson & Johnson***

**Session: E&L Case Studies & Harmonisation**

**11:25 Understanding Leachables in Drug Products as Cumulative: U.S. FDA Experience in Leachables Assessment in Biological Products and a Representative Review Case**

- Biological drug products are manufactured through multi-step processes that involve multiple contact materials
- Even materials considered low risk contribute to the cumulative leachables profile of the finished product, where specific compounds, when summed, may exceed safety thresholds
- Therefore, leachables assessment should encompass all contact materials and be evaluated through real-time studies that cover manufacturing, shelf-life storage, and clinical preparation of the product, as reflected in USP <1664> and ICH Q3E draft guidance
- A representative review case will be presented

***Andrey G Sarafanov I Chemist, Acting Team Lead, Principal Investigator I FDA***

**11:50 Panel Discussion: Global Harmonisation in Extractables & Leachables – Are We Getting Closer?**

- The evolving global E&L landscape: the role of ICH Q3E and its potential to establish a harmonised international framework
- Alignment and differences across key standards, including USP <665>, USP <1665> and emerging chapters such as USP <383>
- Practical implications for industry: reducing complexity, leveraging risk-based approaches, and preparing E&L programmes for future regulatory convergence across pharmaceuticals, biologics, combination products and medical devices

**Moderator:**

**Michael Cresse** ***| Operations Director of Chemistry Medical Device Testing | Smithers***

**Panellists:**

***Andrey G Sarafanov I Chemist, Acting Team Lead, Principal Investigator I FDA***

***Carsten Worsøe I Scientific Director I Novo Nordisk***

***Elizabeth Looney | Senior Principal Scientist | Pfizer***

**12:35 Networking Lunch**

**Session Chair: Michael Cresse** ***| Operations Director of Chemistry Medical Device Testing | Smithers***

**Session: Toxicology, Risk Assessment & In Silico Approaches**

### 13:35 Implication of ICH Q3E for Toxicological Risk Assessment in Parenteral Biopharmaceuticals

- The impact of ICH Q3E on E&L safety assessment
- High-dose parenterals: challenges for current approaches
- From TTC to SCT – evolving threshold concepts
- Key innovations: potency classes and F7 factor
- What Q3E means in practice for toxicologists

***Nina Macho | Senior Toxicologist | Octapharma***

### 14:00 Route-to-Route Extrapolation for PDE Development: From Toxicological Data to Defensible PDEs

- Evaluating available toxicology data and determining when route-to-route extrapolation is scientifically justified for PDE development
- Providing interpretation of ICH Q3E route-to-route considerations using toxicokinectics
- Case studies demonstrating route-specific adjustment factors and approaches for intravitreal and intrathecal administration

***Dr Janet Gould I Senior Principal Toxicologist I SafeBridge Europe***

**Session: Advanced Analytical Chemistry & Unknown Extractables**

### 14:25 Pharmaceutical-Grade Elastomers: Navigating the Evolving PFAS Landscape

- The evolving global regulatory landscape on PFAS: what current and upcoming restrictions actually mean for elastomeric components used in pharmaceutical systems
- Separating fact from concern: how PFAS regulations relate specifically to coated products, and where the real supply continuity risks lie
- How Datwyler is actively monitoring, evaluating, and responding to these developments in the framework of a proactive risk management approach

***Tine Hardeman | Manager Material Development Healthcare | Datwyler***

**14:50 Coffee Break**

### 15:00 Rethinking E&L Quantification: Opportunities and Limitations of Relative Response Factor Databases

- Introduction to the Relative Response Factor concept and its growing relevance for the quantitative analysis of Extractables and Leachables
- Evaluation of over 110 E&L-relevant compounds to establish a representative RRF database covering diverse chemical structures and physicochemical properties
- Comparison of GC-FID and GC-MS performance and assessment of RRF versus response factor approaches for quantitative E&L analysis
- Investigation of key factors influencing RRF values, including chemical functionality, molecular weight, branching, and structural characteristics
- Practical evaluation of RRF-based quantification compared with conventional external calibration using certified reference materials
- Discussion of the opportunities, current limitations, and future potential of RRF databases for more efficient and resource-saving quantitative E&L workflows

***Brian Schüttrumpf I Subject Matter Expert E&L I SGS – Institute Fresenius GmbH***

***Dr. Renate Rohlmann I Operational Laboratory Manager & Customer Service Representative I SGS – Institute Fresenius GmbH***

### 15:25 A Strategic Framework to De-Risk Unidentified Organic Extractables

- Why unidentified NTA compounds are more than an analytical inconvenience, the real risk when unknowns may belong to Cohorts of Concern or ICH Q3E Class 1 substances
- A structured three-phase framework to systematically de-risk unidentified extractables, from structural class definition through to spectral library expansion

- A purpose-built database of ~133 reference CoC compounds enabling high-confidence identification and semi-quantification directly within NTA workflows
- How SciFinder and commercial spectral libraries unlock identification of over 700 additional CoC compounds within routine GC/MS and LC/MS analysis
- A more defensible, science-based approach to demonstrating that high-risk unknowns above the AET have been adequately characterised and addressed

***Philippe Verlinde | Principal Scientist | Nelson Labs Europe***

**15:50 End of conference**