PharmaED RESOURCES, Inc.

Extractables & Leachables West 2025

Quality, Safety, Biocompatibility and Regulatory Compliance for Drugs, Biologics and Medical Devices

November 4-5, 2025, Sheraton La Jolla CA

Featuring Lessons Learned and Case Studies from Industry Experts:

Ping Wang
J&J

Dennis Jenke
Nelson Labs

Richard Hutchinson
Janssen

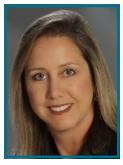
Silvia DePaoli
FDA (pending approval)

Chris Houston
Bausch + Lomb

Ting Cheng
J&J

David Weil
Agilent

Michael Rush
Edwards Life Sciences



Sherry Parker
SParker Consulting

Kevin Rowland
Jordi Labs

Eric Hill
BA Sciences

Philippe Verlinde
Nelson Labs

Sainath Babu
MED Institute

Dan Norwood
Feinberg Norwood & Assoc.

Will Parker
West Pharmaceutical Svcs.

Isaac Mohar
Gradient

Gyuri Vas
Intertek

Sam Albeke
Element

Mike Eakins
Eakins & Assoc

With Comprehensive Coverage On:

- Overview & Discussion of the New ICH Q3E Guideline for Extractables and Leachables
- The FDA's Draft Guidance on Topical Ophthalmic Drug Products & A Case Study in ODP Impurities
- Recent Advancements in E&L Compound Identification: Leveraging EPA's Analytical Met hods and Open Spectral (AMOS) Database in Combination with NIST and Sirius MSMS Search Programs
- Assessment of E&L Migration from Label Components into Final Drug Product Bags in Cell Therapy
- Could a Universal Reference Standard Mixture Exist for Extractables Studies of Butyl Rubber Components?
- Toxicological Considerations for Self-Curing and Light Curing Polymerized Devices: Risk Assessment and Regulatory Challenges
- An Overview of Polyfluoroalkyl Substance (PFAS) Toxicology, Regulation, and Biocompatibility
- Case Studies: Practical Application of ISO 10993-18 and Regulatory Guidance Documents for Performing Chemical Characterization
- Biological Evaluation Strategies for Evolving Medical Device and Combination Product Requirements
- Update on the Finalized System Suitability Standards Proposal from USP for the Analysis of Organic E&Ls
- Standard Selection for E&L Data Packages—How to Use Response Factor Databases Efficiently
- DMSO Extractability Investigation for Single Use Systems (SUS) Used in Advanced Therapy Medicinal Products (ATMP) and Antibody-Drug Conjugates (ADCs)
- Overcoming Common Analytical Challenges in E&L Study Design
- And More!

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Tuesday, November 4, 2025

7:30 *Registration Check-in & Complimentary Breakfast*

8:25 *Chairperson Michael Eakins' Welcome & Opening Remarks*

Evaluating E&L Risks in Cell Therapy Drug Products

8:30

DMSO Extractability Investigation for Single Use Systems (SUS) Used in Advanced Therapy Medicinal Products (ATMP)

Ping Wang, Scientific Director, Johnson & Johnson Innovative Medicine

Dimethylsulfoxide (DMSO) solvent is widely used in ATMP such as cell gene therapy manufacturing processes. USP 665 and Biophorum E&L study protocols have not included DMSO as a standard extraction solvent for testing the E&L risks from SUSs. The discussion from pharmaceutical industry and material suppliers on whether DMSO should be included in the standard extraction solvent panel for ATMP is ongoing. This presentation will discuss the DMSO extractability based on more than 14 controlled extraction studies (CESs) including filters, tubing, bags and assemblies from various suppliers. It is concluded that DMSO does not generate unique or higher concentration extractables when compared to the extraction results of other organic solvents, such as ethanol or 50/50 ethanol/water. Organic extraction solvent such as ethanol shows a significantly higher extractability than DMSO. Therefore, it may not be necessary to include DMSO in the extraction solvent panel while designing an extraction study of SUS for ATMP.

9:10

Assessment of Extractables and Leachables Migration from Label Components into Final Drug Product Bags in Cell Therapy

Dr. Ting Cheng, Principal Scientist and Group Leader, Johnson & Johnson Innovative Medicine [Co-authors: Praveen Kumar and Ping Wang, J&J Innovative Medicine]

In cell therapies, printing inks and labels applied to final drug product bags are becoming emerging sources of extractables and leachables, due to limited packaging barrier properties. This presentation explores the potential migration of ink, adhesives, and other label components into extraction solvents using a simulation study of the final drug product bags. It also examines whether a new extractable and leachable study is needed when label materials or ink are changed.

9:50 *Morning Coffee & Networking Break*

Hot Topics—Spotlight on ICH Q3E

10:20

Overview of ICH Guideline for Extractables and Leachables (Q3E), Step 2 Guideline

Richard Hutchinson, Global Group Leader, Nonclinical Safety—CMC Support Group, The Janssen Pharmaceutical Companies of Johnson & Johnson, and Silvia DePaoli, Regulatory Reviewer, Pharmacology/ Toxicology and CMC, FDA

This presentation will provide an overview of the guideline on management of Extractables and Leachables (E&L). This guideline was written by an International Conference on Harmonization (ICH) sponsored expert working group (EWG). The purpose of the guideline is to provide a holistic framework whereby leachables-associated risk can be identified, assessed, and controlled to protect the safety, efficacy, and quality attributes of the finished drug product.

While the guideline includes materials characterization and process understanding, its primary purpose is to protect patient safety and product quality through assessment and control of leachables in the drug product. Due to rapid advances in materials engineering, device innovations, new manufacturing paradigms and novel therapeutic modalities, the aim is to provide principles and concepts that are forward looking within the scientific and regulatory landscape.

The step 2 guideline document is currently under public review and comments from this process will be addressed by the EWG prior to finalizing the guideline. Within the presentation, the difference in leachable risk and qualification for container closure systems (CCS) and production systems will be discussed. Furthermore, the process for developing leachables relevant qualification thresholds (QT's) will be provided.

11:05

Charting the Universe of Organic Extractables; Further Explorations

Dennis Jenke, Principal Consultant, Nelson Laboratories, Europe

There has been much speculation and discussion of the universe of organic extractables; its size, its constituents, the nature of those constituents, etc. Knowledge about the universe is critical as the E&L community of practice seeks to establish best practices that require that generalizations be made about the universe. For example, in considering the size and composition of a database that is representative of the universe, surely one must first establish the nature of the universe before one can judge the effectiveness with which the database represents that universe.

Last year, Nelson Labs addressed the question of "what do we know about the universe from experience within that universe?" by presenting the results of its retrospective review of the many extractables studies that it has performed in the last several years (representing the "modern age" of E&L), specifically considering compounds with confirmed identities. Since then, Nelson's data review has been expanded to include confidently identified, most probable (MPC) compounds. Study results were reviewed to establish what organic extractables had been reported in the studies performed over that period of time and how often the individual extractables were reported. Additional information about these extractables, including the methods they were detected with and their key analytical and chemical characteristics, were compiled.

The results of this data collection and analysis process will be discussed and the use of the information to establish best practices will be considered.

11:45 **Eurofins EAG Presentation**

Speaker TBA

Abstract Coming Soon

12:05 ***Complimentary Lunch, Sponsored by***

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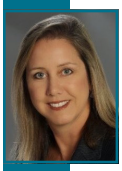
Critical Issues—Biocompatibility Testing for Med Devices & Combination Products: Navigating the Regulatory Landscape

1:10 **Staying Ahead of the Curve: Adaptive Biological Evaluation Strategies for Evolving Medical Device and Combination Product Requirements**



Dr. Sherry Parker, Founder & Principal, Sparker Consulting, LLC

Biological evaluation of medical devices includes a comprehensive biological evaluation plan (BEP), to address the knowledge gaps either by biocompatibility testing or other evaluations that appropriately address the risks. Guidance on biological evaluation is provided in ISO 10993-1, which has been substantially revised and is now in the final draft stages. There are proposed changes to device classification and endpoints to be evaluated that could impact your strategy. For most devices, the plan includes chemical characterization and toxicological risk assessment to address some biological endpoints, and biological testing to address other endpoints. The presentation will cover proposed changes to ISO 10993-1 and the impact on your biological evaluation (with examples). Approaches to chemical characterization continue to evolve, and associated changes to toxicological risk assessment should follow the requirements and guidance of the recently updated ISO 10993-17; and consider the FDA's current thinking presented in the 2024 Draft Guidance on Chemical Analysis for Biocompatibility Assessment of Medical Devices. For combination products, where both medical device requirements and pharmaceutical impurities requirements apply, there will be upcoming changes to both USP and ICH standards and guidance that will impact your test plan, and there are different toxicological risk assessment approaches expected. Examples of differences between evaluations for drug and device components will be presented, in addition to strategies for addressing current and anticipated requirements.

1:50 **Practical Application of ISO 10993-18 and Regulatory Guidance Documents for Performing Chemical Characterization**

Sam Albeke, Chromatography Manager, Element Materials Technology

The recent medical device chemical characterization guidance documents, including ISO 10993-18 and the related FDA draft regulatory guideline, provide more prescriptive requirements for study design, execution and interpretation of results. These updates provide a more defined road map for medical device manufacturers and testing laboratories. While the guidance documents help provide some standardization and increase the structure of studies, several critical industry decision points remain.

This presentation will explore medical device chemical characterization case study examples, where the practical application of the guidance documents will be illustrated. These case studies will be used to highlight regulatory expectations and key challenges encountered during study design and data analysis.

2:30 ***Afternoon Networking Break, Sponsored by***

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Methodological Spotlight—System Suitability Standard Mixtures

3:00

Case Studies in the Evaluation of the New USP System Suitability Standard Mixture

Eric Hill, CSO, Chemistry and E&L Labs, BA Sciences

A stimuli article was published in the USP PF titled Proposals for the Development, Composition, and Routine Use of System Suitability Standard Mixtures in Support of Chromatographic Screening for Organic Extractables and Leachables in early 2024. The purpose of this article was to discuss specific reference standard mixtures, as well as the overall goal and importance of properly demonstrating system suitability in E&L studies. A round robin laboratory study was conducted by the USP following the procedures in this stimuli article, and a summary of this data was presented at the PharmaEd E&L meeting in November of 2024. Current work is underway by the USP to develop a system suitability standard mix for use by laboratories when conducting E&L studies. This mix will be evaluated with various instrument parameters and conditions. Instrument parameters were presented in the stimuli article as well, however adoption of new or alternate instrument methods can create challenges for laboratories. Existing databases and libraries for uncertainty factors and retention time indices were built using internal laboratory methods, and changing instrument methods can require extensive rework to rebuild them. The suitability mix will be evaluated across various instrument conditions, to demonstrate the applicability of the mix and important parameters to consider when using the mix in real-world applications. These data will be generated with a goal of better understanding the impact on E&L study data with proper (or improper) system performance and set up.

3:40

Could a Universal Reference Standard Mixture Exist for Extractables Studies of Butyl Rubber Components?

Will Parker, Technology Manager, Extractables & Leachables, West Pharmaceutical Services

Pharmaceutical packaging components manufactured from butyl and halogenated rubber have been a mainstay in the pharmaceutical industry for decades. For nearly as long, knowing the extractables of these components has been central in understanding their impact on compatibility by way of thoughtfully designed extractables studies, followed by relevant leachables testing of finished drug products. However, another mainstay during the past 25 years has been the great variability in approaches labs have taken for their extractables studies, and a general difficulty in finding consensus among them.

In the past five years, however, there has been a greater push for more universal performance characteristics for methods used in extractables studies and a desire from consensus organizations (e.g., USP) to standardize methodology where possible. One of the ways that this philosophy can be applied is through the selection of appropriate reference standards for organic analyses to demonstrate both method and system suitability and to provide more accurate semi-quantitation. The latter especially has become of greater importance in medical device testing as more emphasis is being placed on chemical characterization and toxicological evaluation of extractables as a major endpoint.

The presentation will show initial data exploration of a database of extractables results with a comparison of physicochemical properties of detected compounds compared to those of compounds that have been proposed by other industry sources. Also, results will be shown from experiments designed to test different standard mixtures to explore what might be the "ideal" compounds to be used in reference standards for butyl rubber. Finally, recommended system suitability criteria will be applied to these compounds to see how a proposed mixture of compounds might perform with current methods.

4:20

Toxicological Considerations for Self-Curing and Light Curing Polymerized Devices: Risk Assessment and Regulatory Challenges

Sainath Babu, PhD DABT ERT, Regulatory Scientist, Toxicology, MED Institute

Self-curing and light-curing polymer medical devices pose unique extractable and leachables testing and toxicological challenges due to the presence of reactive monomers, catalysts, and other degradation products. Unlike traditional polymers, these polymers undergo in situ polymerization, which can lead to variations in the degree of polymerization and the presence of any unreacted monomers or oligomers. Slight variations in polymerization can lead to a range of biological responses which are difficult to predict using conventional testing methods. Several unknown variables may influence factors like cytotoxicity, immune response, and irritation. Understanding the biocompatibility results and the biological behavior of these devices requires careful consideration of the curing processes and their material properties. The presentation will highlight two case studies, each on self-curing and light-curing polymerized devices. The toxicological concerns associated with surface contact and implant devices differ significantly due to the variations in duration, material properties, and interaction with the biological tissues. Moreover, standard biocompatibility tests may not fully mimic long-term real-world exposure, particularly for chronic toxicity testing. These case studies will present key challenges and considerations related to extractable testing and toxicological assessment, highlighting the complexities in evaluating the safety and biological responses of self-curing and light-curing polymer devices.

5:00 ***Happy Hour Mixer***

Join your colleagues in the hotel lobby for informal networking. Complimentary appetizers provided.

Wednesday, November 5, 2025

7:15 *Complimentary Breakfast*

Hot Topics—Retention Index Evaluations

8:15 **Practical Considerations of How Retention Index Evaluations Can Contribute to the Quality of Identifications in GC/MS**

Dr. Philippe Verlinde, Sr. Technical Advisor, Nelson Labs Europe

The identity of an extractable or leachable is a critical foundation of toxicological risk assessment, as it is through the identity that the risk assessor obtains information about the compound's toxicological profile and ultimately establishes a tolerable intake (TI). It is therefore of utmost importance to have identifications of compounds with the highest level of confidence achievable.

The typical "generic" approach that laboratories are taking to identify compounds that are detected by GC/MS is to perform mass spectral matching using library search algorithms with commercial databases (e.g. NIST23, Wiley, etc). The resulting identity of a compound is often based upon the expert evaluation of the quality of the mass spectral match. However, the identification of a compound that is solely based on its mass spectrum may not offer sufficient confidence that this interpretation is correct. To increase the interpretation's confidence, a second piece of completely independent corroborating information can be necessary and can be obtained by the evaluation of the compound's chromatographic behavior. For GC this can be achieved using Retention Index (RI) data if the information is sufficiently accurate.

Practical use of RI matching requires that acceptance criteria be established to define when an acceptable RI match has been achieved. The presentation will evaluate the correlation of Retention Index information included in the commercially available NIST23 (RI) database with the retention data present in the Nelson Database. A confusion matrix-based strategy will be presented that can be used to establish acceptance criteria for RI matching for supporting, rejecting, or accepting proposed identities. Once acceptance criteria have been derived, we will present how such criteria can be put into practice to contribute to the quality of mass spectral identifications using several case studies.

8:55 **Lessons Learned by Using FDA's CLAP List in Practice: Quality Impact of the Internal (Surrogate) Standard Selection for E&L Data Packages—How to Use Response Factor Databases Efficiently**

Gyorgy Vas, Business Technical Scientific Liaison, Intertek Pharmaceutical Services (Co-authors: Louis Fleck, Anna Michelson, Emre Seyyal, Megan Flohl, Intertek Pharmaceutical Services)

The concept of using an Internal (surrogate) Standard in E&L testing is proposed to be the best industry practice since the PQRI recommendation published in 2006. It has been widely accepted and highlights the practical use of Internal Standards (ISs) during extractables and leachables evaluation for the following purposes:

- Establishes relative response factors (RRF) for a wide range of analytes to support RRF databases
- Establishes instrument/method performance at the Analytical Evaluation Threshold (AET) level in the samples via visualization
- May compensate for injection associated variations
- May compensate/establish recovery for sample preparation such as solvent exchange

However, a detailed description was not provided regarding internal standard selection, the appropriate concentration level needed to be used, and number of internal standards appropriate for high quality testing data. Since those criteria are not standardized, the industry uses multiple "best practice" approaches.

This presentation will provide some guidance regarding:

- Importance of setting a framework for database use
- Selection of internal standards and appropriate concentration levels to be used
- Impact on the IS to the RRF database
- Limitations of RRF databases

9:35 *Morning coffee & networking break, Sponsored by*

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Spotlight on E&L for Ophthalmics

10:05 **When Is a Migrant not a Migrant? An Impurity Investigation for an Ophthalmic Drug Product**

Christopher Houston, Research Fellow & Group Leader, Bausch+Lomb

This presentation will include an updated review of regulatory expectations for extractables and leachables (E&L) in ODP with a discussion of the December 2023 draft guideline published by the US-FDA. Additionally, the presentation will focus on an impurity investigation of an unexpected ODP impurity that arose after completion of E&L studies. The case study will include how the novel impurity was identified, how newer technology can mitigate recurrence of the impurity, and ultimately answer the titular question of "when is a migrant not a migrant?"

10:45 **Recent Advancements in E&L Compound Identification: Leveraging EPA's Analytical Methods and Open Spectral (AMOS) Database in Combination with NIST and Sirius MSMS Search Programs**

David Weil, Master Application Scientist, Agilent Technologies

Abstract Coming Soon

11:25 **Alcami Presentation**

Speaker TBA

Abstract Coming Soon

12:05 ***Complimentary Lunch, Sponsored by***

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Spotlight on PFAS

12:50 **An Overview of Polyfluoroalkyl Substance (PFAS) Toxicology, Regulation, and Biocompatibility**

Isaac Mohar, PhD, DABT, Principal Toxicologist, Gradient

Polyfluoroalkyl substances, commonly known as PFAS, have had broad applications in consumer, industrial, and medical applications for decades. Recently, the recognition of the propensity for certain PFAS compounds to persist environmentally (and in humans) has led to increased regulatory attention to this class of chemicals and potential human health effects. This presentation overviews the chemistry, toxicology, environmental fate, and regulatory status of this broad and varied class of PFAS chemicals generally, and the safety profile of PFAS substances most commonly used in medical device applications.

Critical Issues—Novel Approaches to RRFs in Chemical Characterization

1:30 **The Quantitative Leap: Machine Learning for E&L Response Factors**

Kevin Rowland, EVP & General Manager, Jordi Labs, an RQM+ Company

When it comes to ensuring the safety of medical and pharmaceutical products, chemical characterization plays a key role, particularly through the analysis of extractables and leachables. One of the ongoing challenges in this area is the wide variability in how different compounds respond during mass spectrometry analysis. These differences can make accurate quantitation difficult and error prone.

This talk will look into how machine learning can be used as a tool to better predict relative response factors, with the aim of increasing accuracy and speeding up the quantitation process. By selecting a broad range of compounds based on their physicochemical properties, predictive models were developed using neural networks for both positive and negative ion modes in LCMS, and GCMS.

The focus is on how these models can help address the common challenge of response factor variability, an issue that can otherwise create large errors in extractables and leachables assessments. While the models are still in early development, they represent a step toward building smarter, more adaptable tools for analytical chemists. As more data becomes available, there's potential to refine these approaches further, making it easier to handle complex mixtures and unknowns with greater confidence and efficiency.

2:10 *Afternoon Networking & Coffee Break, Sponsored by*

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2:25 **Challenging the Database: Improving RRF Reliability in Chemical Characterization**

Michael Rush, Distinguished Chemist, Edwards Life Sciences

Accurate quantitation of extractables and leachables (E&L) is essential for ensuring the safety of medical devices, yet the variability of relative response factors (RRFs) - a key element of uncertainty factor (UF) - remains a critical challenge. This study systematically investigates the sources and magnitude of RRF variability across compound classes and analytical platforms, including GC-MS and LC-MS. We demonstrate that RRFs are influenced by ionization efficiency, instrumental conditions, dynamic range, quantitation model, and other variables, resulting in significant uncertainty in semi-quantitative analyses. We propose a calibration strategy that incorporates real-time RRF and uncertainty factor determination, as opposed to reliance on an external database model, to support analytical evaluation thresholds (AETs) - showing fit-for-purpose and fit-for-use. Our findings provide a practical framework for improving semi-quantitative methods in complex analytical workflows by moving away from an external database model.

3:05 **Fatty Acid Extractables/Leachables Profiles as an Indicator of Technical Grade Stearate Acid Additive Origin**

Daniel L. Norwood, MSPH, PhD, Principal Consultant, Feinberg Norwood Pharma Consulting

Medium-chain fatty acids are used extensively as additives to plastics and elastomers. Plastics and elastomers are in turn used in the fabrication of components which then are used in the fabrication of drug product container closure-delivery systems and medical devices. As a result, these medium-chain fatty acids routinely appear in extractables profiles from these components as well as in leachables profiles of drug products. The most commonly used medium-chain fatty acid additive is "Technical Grade Stearic Acid" either as the free base or salt (e.g., Mg, Ca, Zn). Technical Grade Stearic Acid contains a mixture of fatty acids, with Palmitic (C16) and Stearic (C18) acids being the most abundant. These fatty acid mixtures are of biological origin, either plant or animal derived (bovine). It is well established in the scientific literature that the ratios of C16/C18 in fatty acid mixtures vary with origin. This presentation focuses on the use of extractables and leachables profiles to indicate the origins of fatty acid additives in packaging and medical device components. Data will be presented from both GC/MS and LC/MS analyses of various extractables/leachables profiles and compared with the chromatographic profiles of fatty acid mixtures of known origin. It will be shown that plant and animal derived C16/C18 ratios can be distinguished by either analytical technique, alerting the analytical chemist to the possibility of a bovine sourced additive with the potential of carrying Bovine Spongiform Encephalopathy (BSE).

3:45 *Close of Program*

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