PharmaED RESOURCES, Inc.

Extractables & Leachables Summit 2025

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

April 23-24, 2025, Philadelphia PA

Featuring Lessons Learned and Case Studies from Industry Experts:

Ping Wang
J&J

Dennis Jenke
Nelson Labs

Adeyma Arroyo
Roche

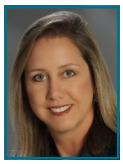
Shuliang Li
FDA

Chris Houston
Bausch + Lomb

Marine Lapoutre
GSK

Prabhakar Reddy
USP

Ravi Kiran Kaja
USP



Sherry Parker
SParker Consulting

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Nelson Labs

Dan Norwood
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Kevin Rowland
RQM+/Jordi Labs

Cherry Shih
Cytiva

Michael Ruberto
Material Needs

Gyuri Vas
Intertek.

Sam Albeke
Element

Mike Eakins
Eakins & Assoc

With Comprehensive Coverage On:

- **Biocompatibility Testing in FDA's Accreditation Scheme for Conformity Assessment—an FDA Overview**
- **The FDA's Draft Guidance on Topical Ophthalmic Drug Products & A Case Study in ODP Impurities**
- **Post Approval Material Changes for Container Closure Systems**
- **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)**
- **Managing New Requirements Alongside USP 665 Compliance**
- **Charting the Universe of Organic Extractables—Implications for Best Practices Moving Forward**
- **Mass Transport Models for Extraction Efficiency and Clinical Exposure—Benchmarking Alternative Screening and Simulated Use Solvent Selection**
- **Addressing Analytical Challenges in HS-GC-MS: From Response Factors to Matrix Effects**
- **Using Fatty Acid E&L Profiles to Indicate the Origin of Fatty Acid Additives in Packaging and Device Components**
- **Overcoming Common Analytical Challenges in E&L Study Design**
- **And More!**

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Wednesday, April 23, 2025

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

8:30 *Chairperson Michael Eakins' Welcome & Opening Remarks*

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

8:35

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.

9:15

Biocompatibility Testing in FDA's Accreditation Scheme for Conformity Assessment

Dr. Shuliang Li, Biocompatibility Test Lab Lead, FDA-CDRH

The FDA encourages medical device manufacturers to cite recognized standards in medical device submissions. This session will introduce participants to the FDA's Accreditation Scheme for Conformity Assessment, or ASCA, a program in which manufacturers may contract with ASCA-accredited test labs to perform testing to certain consensus standards, reducing burden and streamlining the conformity assessment elements of device review. The FDA offers ASCA Accreditation to qualified test labs, who may then offer testing to manufacturers. Since the FDA has confidence in ASCA-accredited test labs' methods and results, less documentation and time are needed for FDA review of the ASCA testing. This program will focus on the biocompatibility testing scope in ASCA and the dramatic results achieved through the program.

10:00 *Morning Coffee & Networking Break*

Hot Topics—Evaluating E&L Risks in Cell Therapy Drug Products

10:30

DMSO Extractability Investigation for Single Use Systems (SUS) Used in Advanced Therapy Medicinal Products (ATMP) and Antibody-Drug Conjugates (ADCs)

Ping Wang, Scientific Director, Johnson & Johnson Innovative Medicine

The impact of detrimental leachables to the cell growth in the biomanufacturing has been extensively studied. Major suppliers of cell bags and single use bioreactors do understand the impact of leachable bDtBPP to cell growth, originated from Irgafos 168. To promote their products, the suppliers have started providing the extractable data showing the low level of bDtBPP in their bags. Though that information is nice to have, it has little use to evaluate if those bags are truly suitable for any particular application due to the following facts: 1) the bDtBPP was generated after the bags went thru gamma irradiation and the level of bDtBPP level are highly relied on the age of the bags after gamma irradiation, 2) the detrimental impact of bDtBPP to cell growth is highly dependent on the cell lines, certain cell lines are sensitive, and others are not, 3) the quantitative level of bDtBPP thru chemical testing is highly variable depending on the testing assays, age of bags, and extraction methods. Therefore, it is almost useless to rely on suppliers claim that their bags are suitable for cell growth application. We will present a holistic strategy to evaluate multiple bags. All bags are gamma irradiated at the same facility at the same time, and extraction studies are performed at the same lab at the same day and the extracts analyzed with same assays at the same day on same instrumentation. Cell growth testing of multiple

cell lines in those bags were performed at the same time to determine the impact of leachables. The apples-to-apples comparison of bDtBPP levels and cell growth impact of those bags will be presented.

11:10 **TBA**

Adeyma Arroyo, Network Expert, E&L Standards, Global Manufacturing Sciences & Technologies, Roche/Genentech

Abstract Coming Soon

11:50 ***Complimentary Lunch, Sponsored by***

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1:05 **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?"

1:45 **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.

2:25 ***Afternoon Networking & Coffee Break***

Roundtable Discussion—USP's System Suitability Standards

2:55 **Update on the Finalized System Suitability Standards Proposals from USP for the Analysis of Organic E&Ls**

Panelists:

Dr. Dennis Jenke, Nelson Labs

Dr. Ravi Kiran Kaja, US Pharmacopeia

Dr. G. Prabhakar Reddy, US Pharmacopeia

Discussants:

The Audience

3:35 **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.

Spotlight on Analytical Methods

4:15 **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).

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

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

Friday, April 24, 2024

7:15 ***Complimentary Breakfast***

Spotlight on USP <665> Compliance

8:15 **Managing New Requirements Alongside USP <665> Compliance**

Marine Lepoutre, Global Subject Matter Expert for GSK Vaccines, and Etienne Michel, Global Quality Expert for GSK Vaccines

The goal will be to present how to effectively handle additional new requirements in parallel with USP 665 (including USP 661.1, 661.2, 662, 382, 383, and EP 4.2.35) and transition from strategy to a fully implemented and operational USP 665 compliance program.

Strategy Program: From Presentation to Implementation:

- Key Learnings: Insights gained from the transition of the strategy program from its presentation at the previous conference to its current implementation and usage.
- Key Difficulties Faced During Implementation: Challenges encountered while putting the strategy program into practice.
- Management of Labs and Testing: Approaches and methods used to manage laboratory operations and testing procedures.
- Workload Management: Strategies employed to handle and distribute workload effectively.
- Digitalization as a Key Element: The role of digitalization in enhancing the efficiency and effectiveness of the strategy program.
- Managing Additional Requirements in Terms of E&L: How to address and incorporate additional requirements related to Extractables and Leachables (E&L).

- **Additional Testing for Cured Silicone Elastomers (USP 383): Specific testing protocols for cured silicone elastomers as per USP 383 standards.**

- **Plastic Packaging Systems vs. Physicochemical Testing (USP 661.2): Comparison between plastic packaging systems and physicochemical testing requirements outlined in USP 661.2.**

- **Glass Container Requirements in Terms of Extractables (Future USP 660): Anticipated requirements for glass containers concerning extractables, as per the upcoming USP 660 standards.**

- **Metallic Packaging Systems (USP 662): Standards and testing requirements for metallic packaging systems according to USP 662.**

Critical Issues—Risk Mitigation in Post Approval Materials Changes for CCS

8:55

Efficiently Dealing with Post Approval Material Changes for Container Closure Systems

Dr. Michael Ruberto, President, Material Needs Consulting

It happens all the time! After spending significant resources to perform extractables and leachables testing for a drug product container closure system (CCS), pharmaceutical companies receive a notification from a supplier that a material change has occurred in one or more of the components of the packaging system. Sometimes the magnitude of the change is obvious, such as a utilizing a completely different polymer in a primary packaging component. However, a change that can often seem minor (for example, changing a catalyst used in the production of the polymer), may have a potentially significant impact on the leachables profile for the CCS.

Additional extractables testing certainly can be used to qualify the "new" packaging component subjected to the material change as suitable for use, but this route can be resource intensive. Are there more efficient strategies to address these changes? Often, vendors conduct relevant chemical and mechanical property testing on the new material that can sometimes be used in lieu of extractables testing to determine the leachables risk for the material change. A step-by step process for evaluating the leachables risk for a post approval material change will be outlined. Proven strategies for efficiently managing post-approval material changes in CCS will be presented.

9:35 ***Morning Networking & Coffee Break***

Evaluating FDA's CLAP List for Biocompatibility Assessment for Med Devices

10:05

The Use and Value of FDA's CLAP-list to Support Scientific Quality in Extractable Testing

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

The "Chemical List of Analytical Performance" (CLAP) published by the FDA (CDRH), represents an attempt to significantly improve and harmonize chemical analyses and Non-Target Analytical Methods (NTA-Methods) that are used for Biocompatibility assessment of medical devices. These methods inherently come with a high level of variance and uncertainty and henceforth the CLAP can be considered a large step forward to address these inter- and intra-lab variability issues. Although the list could be further expanded, it could set the basis for:

- **Optimizing analytical methodologies to minimize gaps and addressing the uncertainty in detectability of a relevant set of compounds.**

- **Understanding variability of responses per technique**

- **Providing the basis to calculate Uncertainty Factors (UF) based on a reference set of compounds.**

- **Calculating the coverage for a methodology, using the derived UF.**

- **Providing the basis of a new way of generating Quantitative data: the RRF-approach.**

- **Minimizing inter-lab variability in Chemical Characterization results.**

In the presentation we will show how a lab could make use of this CLAP list and what kind of conclusions can be drawn with respect to the above to support a higher level of scientific quality in extractable testing.

10:45

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

Targeted & Non-targeted PFAS Screening

11:25

Simultaneous Targeted and Non-targeted PFAS Screening as Part of the Extractables Screening for Pharmaceutical Packaging, Manufacturing Components and Medical Device Materials by LC-HRMS

Dujuan Lu, E&L Global Leader, SGS

The "forever chemicals" Per- and polyfluoroalkyl substances (PFAS) are known for their persistence in the environment and in the human body, leading to potential health issues. Regulatory agencies like the FDA and EPA have set stringent guidelines and limits for PFAS in various products and matrices. However, there is still no regulatory guidance on PFAS levels present in pharmaceutical products and medical devices, which could compromise product safety and efficacy for drug products and devices. As such, medical device and pharmaceutical manufacturers should be proactive by staying up to date with current and future regulation and develop risk mitigation strategies to avoid costly product recall or delays in approvals. To that end, having the ability to detect and quantitate PFAS in various pharmaceutical packaging and medical device materials is essential.

In this presentation, we report an LC-HRMS based concurrent targeted and untargeted detection of PFAS that could be extracted from manufacturing components and containers as part of extractables screening. Sensitive detection of multiple PFAS of interest at sub-ppb levels could be established using Full Scan data from an Orbitrap system, while collecting data dependent MS2 data for unknown identification of potential PFAS compounds within the same injection. In a case study, targeted PFAS could be detected at sub-ppb levels from Fluorinated Ethylene Propylene (FEP) bottles and tubing, and additional PFAS were revealed from the non-targeted analysis following common E&L practices.

Key points covered in this presentation include:

- Combined targeted quantitation and non-targeted screening for PFAS during a single analysis.
- One LC-HRMS method providing both PFAS-specific and general extractables screening.
- Targeted analysis of a list of PFAS to yield unequivocal identification and quantification down to sub-ppb levels.
- Non-targeted analysis to reveal additional PFAS contaminants in the sample extracts that can be quantified using surrogate standards.

12:05 *Complimentary Lunch*

1:15

Mass Transport Models for Extraction Efficiency and Clinical Exposure

Dave Saylor, Research Materials Engineer, Office of Science and Engineering Laboratories, FDA-CDRH

We have developed tools to facilitate the use of physics-based models to predict patient exposure to medical device leachables (CHemical RISk calculators (CHRIS)). However, these tools have been largely limited to scenarios where the total pool of the leachable is known a priori. To extend the applicability of the exposure models, we have developed an approach to estimate the total pool from extraction testing commonly conducted to support biocompatibility evaluations. This testing is typically performed in aggressive solvents where significant swelling can dramatically increase the rate of release. Based on a model for polymer swelling, we have demonstrated that the extent of increase can be reliably estimated and used to predict the total pool; thus, enabling typical extraction data to be translated to a more clinically relevant exposure estimate. This presentation will cover the formulation, parameterization, and validation of these models. Moreover, the potential to leverage the models to develop benchmarks for alternative screening and simulated use solvent selection will also be discussed.

Exploring Sources of Error in Headspace GC-MS

1:55 **Addressing Analytical Challenges in HS-GC-MS: From Response Factors to Matrix Effects**

Kevin Rowland, Executive Vice President & General Manager, Jordi Labs

Headspace gas chromatography mass spectrometry (HS-GC-MS) stands as a pivotal technique for the detection and quantification of volatile extractable chemicals in medical devices. However, the accuracy and reliability of HS-GC-MS can be significantly impacted by various sources of experimental error. The critical aspects of error in HS-GC-MS analyses will be discussed with a focus on understanding the critical differences in errors that occur due to headspace sampling contrasted with liquid injection methods.

A key source of error in all techniques applied to chemical characterization that rely on quantification with surrogates (relative quantification) is response factor variation. The E&L industry is grappling with this issue with an effort to understand and address errors and avoid underreporting of chemicals. Depending on methodology, HS-GC-MS is subject to additional problems that, in some cases, can be more significant than response factor variation. We will explore these challenges in detail and discuss strategies to minimize their impact.

2:35 ***Afternoon Break***

Case Study in Simulated Use for E&L Risk Assessment

2:50 **Using Simulation Solutions to Bridge the Gap in Extractable and Leachable (E&L) Risk Assessment**

Sam Albeke, Chromatography Manager, Element Materials Technology

According to USP <1664>, leachable studies should ideally be conducted on an actual drug product for toxicological assessment. Additionally, FDA guidance on medical device biocompatibility and ISO 10993-18 recommend use of exhaustive or exaggerated extractable testing using solvents ranging from polar to non-polar for chemical analysis of biocompatibility. However, there are certain pharmaceutical and medical device applications in which performing a simulated use or simulated leachable study can be instrumental for extractable and leachable (E&L) risk assessment.

This presentation will cover a case study in which a simulated leachable approach was utilized for evaluation of a pharmaceutical application where the final drug product was unavailable for testing. The presentation will address the use of simulation solutions in other extractable and leachable (E&L) applications, as well as properly designing solutions to simulate a contact product's extraction propensity.

3:30 **Impact of Novel Modalities on Application of Industry Standard Extractables Data: What works and Future Needs**

Cherry Shih, Principal Scientist, Cytiva

Abstract Coming Soon

4:10 ***Close of Program***

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