PharmaED RESOURCES, Inc.

Extractables & Leachables West 2026

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

November 4-5, 2026, Sheraton La Jolla, CA

Featuring Lessons Learned & Case Studies from Industry Experts:

Ping Wang
J&J

Dennis Jenke
Triad

Chris Houston
Bausch + Lomb.

Siyi Zhang
Abbott Labs

Desmond Hunt
US Pharmacopeia

Huaina Li
B. Braun Medical

Qiu Gan
Intuitive Surgical

Dan Norwood
Feinberg, Norwood

David Weil
Agilent

Kevin Rowland
Jordi Labs

Eric Hill
NAMSA

Dujuan Lu
SGS

Kristin Treece
Nelson Labs

Jim Scull
BA Sciences

Will Parker
West Pharmaceutical Svcs.

Sam Albeke
Element

Sainath Babu
MED Institute

Pranav Mashankar
Gradient

Angela Sanchez
NAMSA

Sandi Schaible
Bonded in Science

With Comprehensive Coverage On:

- **The FDA's New Container Closure System Guidance—Implications for E&L**
- **Generating Clinically Relevant Patient Exposure from Chemical Characterization of Medical Devices and Materials**
- **Extractables and Leachables at USP: Chapters, ICH Q3E Alignment, and Analytical Solutions**
- **How Would a Regulator Evaluate Your E/L Package for Pharmaceutical Products? A Risk Based Approach to Meet Regulatory Expectations**
- **ISO 10993-18—New Technical Specifications and Their Implications for E&L**
- **Will Extractable Profiles of Drug Product Filters Be Altered by Multicycle Sterilization?**
- **Leveraging Best Practices in Food Contact Materials Testing for E&L Chemical Characterization of Medical Devices and Pharmaceutical Materials**
- **Case Study—Application of USP<665> to a Small Molecule Drug Product Manufacturing Process**
- **Trace Analysis of Leachable NDBA and Other Small Molecule Nitrosamines In Infusion Bags by GC-MS And LC-MS**
- **Case Study—Exploring Pathways to Safer Medical Devices Through BDDE Detection**
- **When Biocompatibility Fails: A Risk-based Chemical Approach to Root Cause and Resolution**
- **Beyond Tentative: Machine Learning for MS/MS Interpretation in E&L**
- **Importance of Accurate E&L Identifications and Key Aspects of Structural Elucidation**
- **Read-across Framework for Medical Device Extractables Toxicological Risk Assessment**
- **Exploration of Medical Device Extract Stability: What is an Acceptable Loss of Extractables?**

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Wednesday, November 4, 2026

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

8:25 *Chairperson Christopher Houston's Welcome & Opening Remarks*

Critical Issues—Biocompatibility & Medical Device Qualification

8:30

When Biocompatibility Fails: A Risk-based Chemical Approach to Root Cause and Resolution

Qiu Gan, Material Characterization Lead and Biocompatibility Strategist, Intuitive Surgical

In vitro cytotoxicity failures pose a major hurdle during medical device qualification, frequently triggering material redesigns or costly process overhauls. However, a cytotoxicity failure does not necessarily indicate an unacceptable biological risk. This presentation introduces a structured root-cause investigation framework that integrates failure analysis, Extractables & Leachables (E&L) characterization, and Toxicological Risk Assessment (TRA) to isolate and evaluate chemical driver. E&L and TRA serve as a scientifically robust risk mitigation strategy to determine true patient safety impact. Through representative case studies, this presentation demonstrates how leveraging E&L and TRA transforms unexpected biological test failures into actionable, science-based chemical assessments—supporting regulatory compliance, avoiding unnecessary redesigns, and preserving development timelines.

9:10

Generating Clinically Relevant Patient Exposure from Chemical Characterization of Medical Devices and Materials

Siyi Zhang, Manager Biocompatibility, Abbott Labs

Abstract Coming Soon

9:50 *Morning Networking & Coffee Break*

10:20

Extractables and Leachables at USP: Chapters, ICH Q3E Alignment, and Analytical Solutions

Desmond Hunt, Senior Principal Scientist, US Pharmacopeia

Extractables and leachables (E&L) have become a critical element of pharmaceutical quality, bridging materials science, analytical chemistry, toxicology, manufacturing, packaging, and regulatory science. As the pharmaceutical industry adopts increasingly complex drug products, combination products, biologics, and single-use manufacturing technologies, there is a growing need for globally harmonized, science- and risk-based approaches to E&L assessment.

This presentation will provide an update on the evolving USP E&L framework and its alignment with the emerging ICH Q3E guideline. It will discuss the continued role of USP General Chapters <1663> and <1664> as the foundation for extractables and leachables assessments, the development of dosage-form-specific chapters (<1664.1>–<1664.5>), and the modernization of USP <665> and <1665> to address process equipment-related leachables (PERLs) associated with single-use manufacturing systems. Particular emphasis will be placed on the integration of packaging- and manufacturing-derived leachables into a unified lifecycle risk assessment strategy.

The presentation will also highlight practical implementation tools developed by USP, including recently introduced system suitability standards and analytical reference materials designed to improve consistency and confidence in non-targeted E&L analyses. In addition, it will discuss how risk-based testing strategies and dosage-form-specific considerations influence study design for orally inhaled and nasal drug products, parenterals, ophthalmics, topical and transdermal products, and oral dosage forms.

Industry Spotlight—Meeting Regulatory Expectations Through Risk-based Frameworks

11:00

How Would a Regulator Evaluate Your Extractables & Leachables Package for Pharmaceutical Products? A Risk Based Approach to Meet Regulatory Expectations

Huaina Li, PhD, DABT, Director of Pharmaceutical Research & Development, B. Braun Medical

Extractables and leachables (E/L) studies and assessments are essential for demonstrating the safety and quality of pharmaceutical products. While current guidance documents such as USP <1663>, USP <1664>, PQRI recommendations, and ICH Q3E provide a framework for E/L studies, a successful E/L package for regulatory filing will depend on more than simply compliance with guidance and generating analytical data. Regulators will

evaluate whether the overall E/L program is scientifically justified, risk-based, and demonstrates that patient safety has been adequately addressed.

This presentation will examine E/L submission package per the regulatory review perspective based on industry experiences, highlighting the key questions reviewers may ask when evaluating an E/L package. Topics will include risk assessment, study design, analytical method suitability, Analytical Evaluation Threshold (AET) justification, management of unknown leachable compounds, toxicological assessment, and lifecycle considerations. Common regulatory questions/deficiency and practical approaches for developing a clear, well-supported E/L package will also be discussed incorporating with case studies.

Attendees will gain insight into preparing E/L programs that facilitate and support regulatory review while ensuring patient safety and product quality.

11:40 **What's That You're Doing?**

James Scull, Chief Science Officer, BA Sciences

This presentation will explore the practical applications of extractables and leachables from the patient's perspective.

12:00 *Complimentary Lunch, Sponsored by*

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Critical Issues—Does Multicycle Sterilization Increase Extractable Risk?

1:10 **From Single Use to Smarter Use: Re-sterilizing Un-used DP Filters for Sustainability and Operational Resilience**

Ping Wang, Scientific Director, Johnson & Johnson Innovative Medicine

Sterile and particle filters are critical in the fill/finish process of injectable biologics and synthetic drug products, including monoclonal antibodies. To mitigate potential technical risks during campaigns, additional filters are often sterilized as backups. However, unused sterilized filters are typically discarded due to concerns about increased extractables, leading to significant cost and environmental impact.

This raises an important question: Can previously sterilized filters be safely re-sterilized and reused? Specifically, does multicycle sterilization increase extractables risk? This study compares extractables profiles of six drug-product filters (two lots each) subjected to up to three sterilization cycles—via autoclave or Steam-in-Place (SIP)—against a single cycle. Extractables were assessed using industry-standard analytical techniques, including GC-MS, LC-MS, and ICP-MS.

The presentation will cover:

- Comparative extractables profiles (single vs. multi-cycle sterilization).
- Analytical methodologies and detection limits.
- Variability in impact across different filter types.

Data-driven insights will inform whether re-sterilization is feasible without compromising material integrity, and product quality. The implications are significant:

1. Economic impact: Reducing filter waste can save thousands of dollars per batch and improve resource utilization.

2. Sustainability benefits: Reuse strategies support ESG initiatives and reduce plastic waste from single-use systems.

3. Regulatory considerations: Aligning reuse practices with FDA, EMA, and PDA guidance on extractables and leachables.

Critical Issues—Detecting & Quantitating Small Molecule Nitrosamines in Infusion Bags

1:50 **Trace Analysis of Leachable NDBA and Other Small Molecule Nitrosamines In Infusion Bags by GC-MS And LC-MS**

Dujuan Lu, E&L Manager/Global Leader, SGS

US FDA issued new guidance on leachable N-nitroso-Dibutylamine (NDBA) and other small molecule nitrosamines in infusion bags on August 18th, 2025. NDBA, a small molecule nitrosamine impurity, has been detected in certain drug products packaged in infusion bags with printed pouches. US FDA is concerned that NDBA and other small molecule nitrosamine impurities may leach from the packaging into the drug products. Thus, the FDA is requesting drug manufacturers to provide risk assessments or testing results on this matter. Nitrosamine impurities are of concern because they are probable or possible human carcinogens. Due to their high toxicity, the acceptable intake (AI) limits of nitrosamines are very low. For example, the AI limit of NDBA is 26.5 ng/day. Due to the nature of the large volume parenteral (LVP) products packaged in infusion bags, their maximum daily doses are typically very high (100 mL/day or higher). Therefore, the detection limits of the nitrosamines need to be at sub or low ppb levels. An ultra-sensitive method is needed for detection and quantitation of small molecular nitrosamines.

In this presentation, we report both an ultra-sensitive dynamic headspace GC-MS/MS method and an LC-HRMS method to detect NDBA and other small molecule nitrosamines with a LOQ of 0.1 -0.5 ppb. The methods were also applied to study the solvent extracts of infusion bags with printed pouches. The root causes of the NDBA from infusion bags with printed pouches were investigated and will be presented in this talk.

Bullet Point Outline:

- Understanding the new guidance from US FDA on leachable N-nitroso-Dibutylamine (NDBA) and other small molecule nitrosamines in infusion bags.
- Investigation of the root causes of the NDBA from infusion bags with printed pouches.
- An ultra-sensitive dynamic headspace GC-MS/MS method as well as an LC-HRMS method to detect NDBA and other small molecule nitrosamines with a LOQ of 0.1-0.5 ppb and its application to infusion bags with printed pouches.

2:30 *Afternoon Networking Break, Sponsored by*

Nelson Labs
A Sotera Health company

3:00

Exloration of Medical Device Extract Stability: What is an Acceptable Loss of Extractables?

Kristin Treece, PhD, Principal Scientist, Nelson Labs (Co-authors: Caitlin Keller, Sr. Developmental Chemist, & Sarah C. Campbell, Principal Toxicologist, Nelson Labs)

Holding times for medical device extracts are the allowed period of time from the completion of extraction to instrumental analysis. The holding times for medical device extracts intended for chemical characterization have not been formally established nor listed in ISO 10993-18, leading some regulatory agencies to rely on the ISO 10993-12 holding times for biological testing of ≤24 hours. Recent feedback was received from an FDA CDRH submission which requested a description of extract storage conditions and durations. The feedback referenced the biological testing-based ISO 10993-12 and specified if extract storage was >24 hours then scientific rationale describing why the storage would not result in an unacceptable loss of extractable chemicals was required. From a contract testing laboratory perspective, the regulatory expectation of sample processing and analysis within 24 hours is a high bar that is nearly impossible to achieve routinely.

In an effort to empirically address extract holding times, a stability study was conducted to evaluate potential organic extractable chemical loss at various time intervals over approximately 40 days. Solutions containing the compounds from the FDA's Chemicals List for Analytical Performance (CLAP) were prepared in various solvents (polar, mid-polar, non-polar) and stored in a manner similar to test article extracts prior to sample processing. Storage after sample processing was also considered by preparing the solutions per general industry sample preparation practices with moderate concentration factors. The holding times were considered for semi-volatile and non-volatile organic compounds by analyzing the solutions via GC/MS and LC/MS (ESI and APCI) at routine time intervals. Semi-volatile and non-volatile organic chemical constituents were demonstrated to be relatively stable for storage over 20 to 40 days providing recoveries of >70%. The importance of amber vial storage was demonstrated within the data as UV-sensitive compounds degraded when stored in clear vials despite intentionally limiting UV exposure during storage. The concept of the combined loss of extractables from the two separate holding times (extraction end to sample preparation and sample preparation to instrumental analysis) will be introduced and explored.

Methodological Spotlight—Adapting AI Machine Learning to E&L Analysis

3:40

Beyond Tentative: Machine Learning for MS/MS Interpretation in E&L

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

Identification is the critical step in extractables and leachables. Every downstream conclusion, most importantly the risk assessment, inherits the quality of the identification beneath it, and an incorrect structure propagates silently through the entire assessment.

High-resolution MS/MS fragmentation is the strongest evidence available for structural confirmation when no authentic reference standard exists. The obstacle has never been the data; most labs already run instrumentation capable of collecting high-resolution MS/MS spectra. The challenge is interpretation. Complete manual interpretation of a single high-resolution fragmentation spectrum can take hours or even days, so in practice laboratories may only interpret a handful of spectra per study, and everything else is reported at lower confidence. The confidence gap in E&L datasets is a throughput problem, not an instrumentation problem.

This presentation makes the case that machine learning closes that gap. Predicting expected fragments from a proposed structure and scoring them against the acquired spectrum turns structural confirmation into a tractable, repeatable operation that can be applied to every compound in a dataset rather than a selected few. Model approach, performance, and the failure modes that still require an analyst will be presented candidly.

The discussion will address emerging ISO work on identification confidence levels, and why a rising bar makes

automated fragment interpretation a practical necessity. A brief update on neural-network response-factor prediction closes the session; structure-based quantitation amplifies the cost of a wrong identification.

CASE STUDY

4:20 **Case Study—Exploring Pathways to Safer Medical Devices Through BDDE Detection**

Eric Hill, VP, Global Analytical, & Angela Sanchez, Associate Scientific Director, NAMSA

BDDE (1,4-Butanediol Diglycidyl Ether, CASRN 2425-79-8) is a popular cross-linking agent for use in manufacturing certain types of medical devices, including hyaluronic acid-based hydrogels found in dermal fillers and bone regeneration scaffolds. BDDE can enhance mechanical stability and durability, however the reactive epoxide groups contained in BDDE can pose toxicological risks if they remain in/on the device post-manufacturing. Residual BDDE can interact with tissues in vivo, potentially leading to undesired effects such as cytotoxicity, irritation, or longer-term safety issues. This talk outlines the methodology and findings from research undertaken to explore the challenges of detecting BDDE in medical devices, comparing analytical techniques such as liquid chromatography-mass spectrometry (LC-MS) and gas chromatography-mass spectrometry (GC-MS). Additionally, it examines the impact of solvent selection on analysis accuracy and discusses how these findings could influence future medical device testing, design, and regulatory approval processes.

5:00 *End of Day One*

Thursday, November 5, 2026

Spotlight on ISO 10993-18—New Technical Specifications and Their Implications for E&L

8:30 **Future Path for E&L per ISO 10993-18: A Look at Emerging Technical Specifications**

Sandi Schaible, Founder & President, Bonded in Science

ISO 10993-18 is entering a new phase as several technical specification (TS) documents are developed to address long-standing gaps and confusion in chemical characterization. These TS efforts aim to bring greater clarity to extraction design, identification confidence, quantitation strategies, and quality for better alignment with ISO 10993-17 for toxicological risk assessment. This presentation summarizes the TS documents currently in development, outlines their intended scope, and highlights how they may reshape expectations for E/L study design and reporting. Attendees will gain a concise view of where ISO 10993-18 is heading and practical insight into how these evolving documents may influence regulatory submissions and laboratory practices in the future.

9:10 **That's What's Left of My Test Article now that the Extraction is Finished?!!**

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

During their clinical use, constituents in or on a medical device can be leached from the device and transferred to the patient, with potentially harmful effects. In certain circumstances, medical devices can be directly assessed for leachables while in other circumstances, characterizing a medical device for leachables is challenging because of the practical and ethical challenges of testing human tissue or body fluids. In such cases, leachables are generally addressed by extracting the device under laboratory conditions, chosen to mimic or exaggerate, within a reasonable degree, the clinical conditions of contact.

When medical devices are extracted with solvents, under conditions, and with mechanisms that exaggerate the device's clinical conditions of use, the device could be chemically and/or physically stressed in ways that alter its extractables profile so much that the profile does not match the leachables profile. When a device's extractables profile has been altered by the chemical or physical stress of an exaggerated extraction, a compromised extract is produced.

Establishing that an extract has been compromised is important as the resulting extractables profile is an inappropriate basis for toxicological safety risk assessment.

In this presentation, the presenter introduces the concept of a compromised extract, discusses the collection and use of physical (visual and functional) and chemical evidences to establish whether an extract has been compromised, and recommends practices around the generation and disposition of compromised extracts.

The presenter looks forward to engaging the Summit's participants in a discussion of their experiences and perspectives on this topic, with the end goal of establishing scientifically valid and practically efficient and effective guidelines for recognizing, categorizing, and addressing compromised extracts and overly exaggerated extractions.

9:50 *Morning Coffee & Networking Break, Sponsored by*

element

10:20

Leveraging Best Practices in Food Contact Materials Testing for E&L Chemical Characterization of Medical Devices and Pharmaceutical Materials

David Weil, Master Application Scientist, Global E&L, Agilent Technologies

Abstract Coming Soon

11:00

Importance of Accurate E&L Identifications and Key Aspects of Structural Elucidation

Sam Albeke, Chromatography Manager, Element Materials Technology

When performing extractable and leachable (E&L) studies, there are two components of analytical results that are critical to ensure accurate toxicological risk assessment (TRA). One is the accurate identification of E&L compounds that are used to establish compound-specific permitted daily exposures (PDEs). The other is the concentration E&L compounds are detected at, which allow for assessment of when compounds are approaching levels of toxicological concern.

Using proper analytical thresholds and quantitation techniques have been major focus areas within the E&L industry. This has led to the adoption of several important aspects of E&L workflows, such as the application of analytical uncertainty factors (UFs) and relative response databases for quantitation. However, there has been less E&L industry focus on ensuring the accurate identification of unknowns detected in E&L workflows.

This presentation will go through an assessment of the uncertainty involved in E&L identification vs quantitation to put into context which factor poses the highest risk to TRA accuracy. Application of USP <1663> guidance will be covered to ensure accurate ID confidence level assignments during analytical screening workflows. Additionally, the key aspects of performing accurate structural elucidation of unknown E&L compounds will be covered. Throughout the presentation, structural elucidation case study examples will be used to illustrate how these key aspects can be practically applied to E&L workflows.

Methodological Spotlight—A Framework for Toxicological Risk Assessment of Med Device Extractables

11:40

Read-across Framework for Medical Device Extractables Toxicological Risk Assessment

Pranav Mashankar, Senior Environmental Scientist, Gradient

Toxicological risk assessment of data poor extractables chemicals can necessitate read-across using analog chemicals to fill data gaps. ISO 10993-17:2023 provides only a general description of analog chemical justification with detailed guidance currently lacking. To address this gap, Gradient has developed a robust framework for selecting and evaluating the suitability of potential analog compounds for toxicological risk assessments conducted under ISO 10993-17. This framework evaluates candidate analogues across four weighted domains: chemical similarity and reactive functional groups, physicochemical properties, in silico toxicity predictions, and metabolic profiles. This presentation demonstrates the framework's utility through a case study evaluating 16 candidate analogues for their suitability as an analog for the target compound Irganox 259.

12:20

Complimentary Lunch, Sponsored by

Nitto Avecia Pharma Services

1:30

Updated Recommendation for a Universal Halobutyl Rubber Reference Standard

Will Parker, Manager, Scientific Affairs, West Pharmaceutical Services

Halogenated butyl (or halobutyl) rubber has been a mainstay in the primary packaging of pharmaceutical drugs for decades, and although it is a well-studied material even in the extractables and leachables world, consensus about the parameters for testing it and other materials accurately in E&L studies still eludes our industry. Variability among the myriad labs takes shape in system suitability programs, exact instrument types and detectors, lab environments, development and validation procedures, and reference standard compounds applied at the time of analysis.

However, a logical approach is one where reference standards at the time of analysis include chemicals that are expected to be present in the material being studied. There has been a push in recent years for more universal performance characteristics for methods used in extractables studies from consensus organizations to standardize methodology where possible. Prominent chemists who have been working in this industry for at least twen-

ty years have pointed out the need for greater consensus in the analytical chemistry being employed for E&L studies as the demand for this service keeps increasing. Greater consensus can elevate the quality of the work being performed in general as well as the results of that work, leading to better risk assessments. One way 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 emphasis is being placed on chemical characterization and toxicological evaluation of extractables as the primary result in evaluating biocompatibility.

The presentation will show the conclusion of a continued effort to explore the idea of finding a "universal" reference standard for halobutyl rubber. Previous and updated data mining results along with GC/MS analyses will be shown, along with new LC/MS analyses using varied method parameters, to find the "ideal" compounds that could be included in a reference standard for halobutyl rubber. The presentation will conclude with an overall recommendation and how to apply such a standard in semi-quantitative extractables studies.

CASE STUDY

Case Study Using USP <665>

2:10

A Case Study of the Application of USP<665> to a Small Molecule Drug Product Manufacturing Process

Dan Norwood, Principal Consultant, Feinberg, Norwood & Associates Pharma Consulting

Abstract Coming Soon

2:50

A Toxicologist's Perspective: Reducing Analytical Burden Without Compromising Patient Safety

Sainath Babu, Senior Regulatory Toxicologist, MED Institute

Analytical chemists and toxicologists often encounter unknown extractables during chemical characterization studies, prompting additional studies, repeat testing, and extended timelines. While comprehensive characterization is important, not every unidentified peak or residue represents a meaningful patient risk. Recent updates to ISO 10993-18:2023 and ISO 10993-1:2025 emphasize the integration of chemical characterization, exposure assessment, toxicological thresholds, and risk management into a unified biological evaluation strategy. This presentation will discuss two case studies with how toxicological risk assessment can help determine when additional analytical work is scientifically justified and when it may add burden without changing the biological safety conclusion. In the first case study, exhaustive purified water extraction of a limited-contact oral device identified low-level unknown compounds. Following regulatory discussion, a clinically relevant artificial saliva extraction was performed and showed substantially lower extractable levels, supporting a defensible safety conclusion without identifying every peak. In the second case study, a long-term implantable device undergoing a manufacturing change showed residual extractable mass by gravimetric analysis. Because gravimetric data lack chemical identity, a risk-based assessment incorporated manufacturing knowledge, cleaning agents, potential residual constituents, targeted chemical information, and toxicological thresholds. The evaluation demonstrated acceptable margins of safety and avoided unnecessary additional analytical investigations. Together, these examples demonstrate that the critical question is not whether every peak or residue can be fully characterized, but whether additional analysis would meaningfully change the patient safety assessment.

3:30 *Close of Program*

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