Extractables & Leachables Summit 2026

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

April 22-23, 2026, Omni Hotel Providence, RI

Featuring Lessons Learned and Case Studies from Industry Experts:

Ping Wang
J&J

Dennis Jenke
Triad

Dujuan Lu
SGS

Ravikiran Kaja
US Pharmacopeia

Subathra Ramamoorthy
Veranova

Christopher Houston
Bausch + Lomb

Prabhakar Reddy
US Pharmacopeia

Sandi Schaible
Bonded in Science

Cherry Shih
Cytiva

Kevin Rowland
Jordi Labs

Eric Hill
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Philippe Verlinde
Nelson Labs Europe

Jim Scull
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Will Parker
West Pharmaceutical Svcs.

Michael Ruberto
Material Needs Consulting

Gyuri Vas
Intertek

Sam Albeke
Element

Kurt Moyer
Pine Lake Labs

Dennis Xu
Nitto Avecia

With Comprehensive Coverage On:

- Overview & Discussion of the New ICH Q3E Guideline for Extractables and Leachablest
- USP <665>: Update on the New Standard and its Implications for Risk-based E&L Assessments
- From FDA Deficiency to Regulatory Resolution: A Risk-Based Extractables and Leachables Framework
- Trace Analysis of Leachable NDBA and Other Small Molecule Nitrosamines in Infusion Bags by an Ultra-Sensitive Dynamic Headspace GC-MS/MS Method
- Extractables in ADC (antibody drug conjugates) Manufacturing: Real-case Insights Across Process Components
- Challenges in Assessing Impurity and E&L Risk Across Uncommon Routes of Administration
- Sharper Quantitation: What We've Learned Since the ML Quantitative Leap
- A Strategic Framework to De Risk Unidentified Organic Extractables as Potential Cohorts of Concern in GC/MS and LC/MS Analysis
- Quantitative Aspects of Non-targeted Analysis Applied to Organic Extractables/ Leachables
- Will Extractable Profiles of Drug Product Filters Be Altered by Multicycle Sterilizations?
- Exploring Compounds That May Be Used in a Universal Reference Standard Mixture for Extractables Studies of Butyl Rubber Components
- Strategies for Managing the Leachables Risk of Admixtures and Infusion Equipment Used to Administer Parenteral Drug Products
- Identification of GC-MS Chromatographic Peaks: How to Handle a Common Situation of the Spectra Not Being Present in a Commercial Database?
- Identification of Unknown Compounds in Extractable and Leachable (E&L) Workflows
- Future Path for E&L per ISO 10993-18: A Look at Emerging Technical Specifications
- Overcoming Common Analytical Challenges in E&L Study Design
- And More!

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Pharma Ed's Extractables & Leachables Summit 2026 is Sponsored by

Wednesday, April 22, 2026

7:15 *Registration Check-in & Complimentary Breakfast*

8:10 

Chairperson Christopher Houston's Welcome & Opening Remarks

Critical Issues—Does Multicycle Sterilization Increase Extractable Risk?

8:15 **Will Extractable Profiles of Drug Product Filters Be Altered by Multicycle Sterilizations?**

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. multicycle 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—Supporting FDA Approval Through Risk-based E&L Frameworks

8:55 **From FDA Deficiency to Regulatory Resolution: A Risk-Based Extractables and Leachables Framework**

Subathra Ramamoorthy, Associate Principal Scientist, Veranova

Extractables and leachables (E&L) evaluations are particularly challenging for high-risk products due to complex delivery systems, formulation–material interactions, and significant patient exposure considerations. Regulatory deficiencies issued by the U.S. Food and Drug Administration often reflect gaps not only in data generation, but also in the scientific rationale used to interpret E&L findings and support regulatory decision-making.

This presentation introduces a structured, risk-based E&L framework developed and implemented in response to FDA deficiencies, resulting in successful regulatory resolution. A representative drug–device combination product case is used to demonstrate the systematic characterization and control of unknown impurities through product-specific risk assessment, scientifically justified thresholds, response factor considerations, and targeted, fit-for-purpose analytical strategies integrated with toxicological assessment to support regulatory approval.

9:35 *Morning Coffee & Networking Break, Sponsored by*

element

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

10:05 **Trace Analysis of Leachable NDBA and Other Small Molecule Nitrosamines in Infusion Bags by an Ultra-Sensitive Dynamic Headspace GC-MS/MS Method**

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 an ultra-sensitive dynamic headspace GC-MS/MS method to detect NDBA and other small molecule nitrosamines with a LOQ of 0.1 ppb and a linearity range of 0.1 to 10 ppb. Results showed better sensitivity compared to static headspace GC-MS/MS and direct injection GC-MS/MS. The method was 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. Key takeaways include:

- 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 to detect NDBA and other small molecule nitrosamines with a LOQ of 0.1 ppb and its application to infusion bags with printed pouches.

Hot Topics—Extractables in Antibody Drug Conjugates Manufacturing

10:50

Extractables in ADC (antibody drug conjugates) Manufacturing: Real-case Insights Across Process Components

Cherry Shih, PhD Principal Scientist, Cytiva

ADC manufacturing introduces unique solvent challenges for single-use systems (SUS). Whereas standardized extractables studies per USP <665> and BioPhorum protocols typically employ solvent sets such as 50% ethanol, real-world ADC processes often expose components and filters to various concentrations DMSO or DMA—and in some limited steps, up to 100% solvent. This raises a critical question: Do current standardized datasets sufficiently bracket these harsher conditions, or do gaps remain that warrant targeted evaluation?

We present real-case datasets designed for high-level understanding across more than 15 SUS components—including connectors, bags, tubing, TFF device and filters—tested under ADC-relevant solvent in worse conditions (50% ethanol, 30% DMA, 30% DMSO). Comparative analysis highlights solvent-driven extractables trends, possible incompatibilities observed, and risk implications. We will share whether existing standardized data adequately covers ADC solvent exposure, identify gaps critical for regulatory compliance, and propose a forward path for addressing extractables for ADC process components.

11:30

Case Study - Exploring Pathways to Safer Medical Devices Through BDDE Detection

CASE STUDY

Eric Hill, VP, Global Analytical, 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.

12:10 *Complimentary Lunch*

1:15

Exploring Compounds That May Be Used in a Universal Reference Standard Mixture for Extractables Studies of Butyl Rubber Components

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

Pharmaceutical packaging components manufactured from butyl and halogenated butyl rubber have been a mainstay in the parenteral 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, 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 This may lead to increased data quality directly contributing to product quality and patient safety. 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.

Being a continuation from previously presented work, this presentation will first show the results from GC/MS testing

performed in 2025, along with the initial database exploration comparing physicochemical properties. New headspace GC/MS and updated direct injection GC/MS results will then be presented to explore further what may be "ideal" compounds to be used in reference standards for butyl rubber. Also, some discussion will be had on non-volatile compounds that are typically analyzed via LC/MS techniques, including a more in-depth look at database compounds that fall within that category.

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

1:55 **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.

2:35 *Afternoon Networking Break, Sponsored by*

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Methodological Spotlight—Adapting Machine Learning to E&L Analysis

3:05 **Sharper Quantitation: What We've Learned Since the ML Quantitative Leap**

Kevin Rowland, Executive VP & 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 continue the conversation on the use of, and improvements to, a tool that can better predict relative response factors. The aim of is to increase accuracy and speed up the quantitation process. Trained on a broad range of compounds based on their physicochemical properties, predictive models were developed and refined 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 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.

3:45 **Strategies for Managing the Leachables Risk of Admixtures and Infusion Equipment Used to Administer Parenteral Drug Products**

Kurt Moyer, PhD, President, Pine Lake Laboratories

Most manufacturers of parenteral drug products are well aware of the E&L testing requirements on the drug product container closure system. However, an additional risk of leachables may arise if the parenteral drug product is reconstituted and/or diluted in an IV bag of diluent to form an admixture and then delivered to the patient by infusion. Even though the extractables profile of the IV bags and infusion devices were evaluated by their manufacturers, the drug admixture can potentially extract unique leachables not previously observed. Therefore, the parenteral drug manufacturer is responsible for evaluating this risk. Choosing the IV bags and infusions sets to study can be an additional challenge when they are not specified as part of the drug label. In this presentation I will show a strategy for how to select the IV bags and infusions sets and then discuss how to design the E&L study of these IV bags and infusions sets.

4:25 **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.

5:05 *End of Day One*

Thursday, April 23, 2026

Critical Issues—Non-targeted Analysis of Organic Extractables & Leachables

8:30

A Strategic Framework to De Risk Unidentified Organic Extractables as Potential Cohorts of Concern in GC/MS and LC/MS Analysis

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

Non Targeted Analysis (NTA) of organic extractables using orthogonal and complementary chromatographic methods often reveals compounds that cannot be conclusively identified, raising concern that some unknowns may belong to highly potent toxicological groups such as ICH Q3E Class 1 substances or broader Cohorts of Concern (CoC). To address the uncertainty surrounding unidentified compounds, Nelson Labs developed a structured three phase framework designed to systematically de risk the possibility that such unknowns belong to a CoC class.

In Phase 1, Nelson Labs defined 12 CoC structural classes relevant to extractables and leachables drawing on international regulatory standards and scientific guidance to establish a clear alert framework. Phase 2 focused on direct identification using empirical data. Nelson Labs analyzed authentic reference standards for approximately 90 frequently encountered CoC compounds, selected to represent the full range of the 12 structural classes. For each compound, mass spectra, retention times, and Relative Response Factors (RRFs) were experimentally determined and compiled into the Nelson Database. This enables accurate identification and semi-quantification of these CoC compounds whenever they appear in NTA datasets, ensuring high-confidence characterization of known high-risk analytes. Phase 3 expanded the safety net beyond these 90 substances. Using SciFinder, Nelson Labs identified the 100 most frequently reported compounds within each CoC class, using publication frequency as a proxy for relevance. Cross checking these compounds with NIST and WILEY mass spectral libraries showed that more than 600 CoC compounds are already represented in these commercial databases. When these libraries are included in NTA workflows, many additional CoC compounds become identifiable. Furthermore, applying RRF data from the Nelson Database across related classes allows conservative assessment of these compounds at or above the analytical evaluation threshold (AET).

Although absolute certainty is unattainable, this three phase framework provides a robust scientific basis for minimizing the likelihood that unidentified extractables are unrecognized CoC compounds, thereby strengthening the safety evaluation of medical device extracts.

9:10

Quantitative Aspects of Non-targeted Analysis Applied to Organic Extractables/Leachables; Implications Secured via a Consideration of CLAP List Compounds

Dennis Jenke, Founder & Principal, Triad Scientific Solutions

A critical aspect of a leachable (or extractable) is its concentration, as a leachable's concentration is used to establish a patient's exposure to that leachable during the clinical use of a drug product or medical device.

There are two issues to consider in the quantitation of extractables or leachables detected during non-targeted analysis: when is quantitation necessary, and how is quantitation accomplished? Considering when, quantitation for the purpose of toxicological safety risk assessment is necessary if the compound is present in the test sample at a level that exceeds the Analytical Evaluation Threshold (AET). To address compound-to-compound variation in analytical response, the AET is adjusted lower via an Uncertainty Factor (UF).

Estimating an identified leachable's concentration can be performed accurately if either a reference standard is available for the leachable or the leachable can be linked to a surrogate reference compound. However, these approaches are not applicable to an unidentified leachable (a leachable that is only partially identified or is established to be an unknown).

In this presentation, the means for calculating the UF are considered. Furthermore, the use of a universal quantitation surrogate, specifically the median relative response factor (RRF) of a data set of compounds, to estimate the concentration of unidentified leachables is considered. Using the FDA Clap list as a reference data set, this manuscript concludes that the proper means of calculating the UF is by considering the relationship between the mean response factor and the response factor at the 84% percentile. Furthermore, this manuscript establishes that methods coupling ultra-high performance liquid chromatographic separations with mass spectrometric detection are inherently inaccurate when quantifying unidentified leachables given the large variation in RRF values among the CLAP compounds. However, as RRF values for GC/MS are less variable, concentrations estimated for unidentified leachables using RRFmedian can be both accurate and protective.

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

Updates from USP

10:20

Updates from USP: Finalized System Suitability Standards, New Leachables Chapters and USP <665> Chapter Implementation

Prabhakar Reddy, Senior Director, US Pharmacopeia, & Ravi Kiran Kaja, Senior Principal Scientist, US Pharmacopeia

Abstract Coming Soon

11:05

Identification of GC-MS Chromatographic Peaks: How to Handle a Common Situation of the Spectra Not Being Present in a Commercial Database?

Gyuri Vas, Business Technical Scientific Liaison, Intertek Pharmaceutical Services

Chemical evaluation is an essential part of a biocompatibility assessment of medical devices and leachables testing during the shelf life of pharmaceutical products. One of the most critical parts of the assessment is the proper identification of the observed chemical species present as chromatographic peaks in the chemical analysis. It is a complex analytical chemistry task that requires multiple analytical techniques (or tools). The identification results unfortunately often impacted by chemical interferences, the observed quantity of the analytes, and the experience and the skills of the chemist, in addition to the instrumentation being used for the testing. It is important to emphasize that false identification would lead to an improper toxicological risk assessment with both the nature and the quantity of the chemical species being impacted, and that, in turn, could pose unacceptable risk to patients.

The applicable standards for the E&L and biocompatibility testing are either lack of providing identification workflow (ISO 10993-18) or lack of providing helpful and detailed support for identification, resulting in improper interpretation of the identification categories (USP <1663>). This presentation will focus on case examples for the different identification categories listed in USP <1663>, and illustrate the level of support each category would provide for the toxicological risk assessment. Key considerations include:

- Tentative identification category will be discussed in details providing recommendations how to use the results of the library-based assignment, and how to deal with the situation when the spectral similarity to a library is low. Case examples will be presented illustrating when tentative identification is not acceptable or not justifiable.

- Data support for confident identification will be discussed based on examples of elemental composition, sub-structure assignment, and other supportive spectral information.

11:45

Strategies for Extractables & Leachables Programs to Meet Global Regulations

Dennis Xu, PhD, Senior Manager of Analytical Research & Development, Nitto Avecia Pharma Services

This presentation will discuss a risk-based E&L study design aligned with global regulatory expectations. The presentation will cover material characterization, simulation studies, targeted and untargeted analytical workflows considerations to ensure product quality and patient safety. It will highlight practical approaches to method development using advanced chromatographic and mass spectrometric techniques. Attendees will gain insights into overcoming analytical challenges such as trace-level detection, unknown identification, and data interpretation, as well as strategies for integrating E&L programs into broader CMC development timelines. This session will provide actionable guidance for pharmaceutical and biopharmaceutical professionals seeking robust, compliant, and efficient E&L solutions.

12:05 *Complimentary Lunch, Sponsored by*

Nitto Avecia Pharma Services

1:15

Identification of Unknown Compounds in Extractable and Leachable (E&L) Workflows

Sam Albeke, Chromatography Manager, Element Materials Technology

When performing extractable and leachable studies (E&L), there are two aspects of analytical results that are critical to ensure accurate toxicological risk assessment (TRA). The first is the identification of E&L compounds, which are used to establish compound-specific permitted daily exposures (PDEs). The second is the level E&L compounds are detected, to ensure concentrations are not 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.

During this presentation, guidance will be provided to ensure proper compound identification during E&L screening workflows. Additionally, key aspects of performing structural elucidation of unknown E&L compounds will be discussed. Throughout the presentation, insightful examples of structural elucidation will be shown to demonstrate effective approaches for identification of unknown compounds within E&L workflows.

1:55

Pragmatic Approach to Extractables and Leachables Assessments for Oral Drug Products Based on New Guidance Documents

Michael Ruberto, President, Material Needs Consulting

The regulatory landscape is changing for performing E&L risk assessments for lower risk drug products. Both USP <1664.5> and ICH Q3E take risk based approaches regarding the leachables risk assessment for container closure systems used to package oral drug products. In many cases, a reference to the appropriate regional food contact regulations (such as to 21 CFR 174-186) may be sufficient. This presentation will provide a step-by-step approach for utilizing the food contact regulations for assessing the risk of primary and secondary packaging components for solid oral and liquid drug products. It will also discuss the higher leachables risk for "fast acting" orally disintegrating drugs (ODDs) that utilize a sublingual and/or buccal route of administration. Examples of performing assessments in the form of "paper exercises" versus E&L testing will be presented. Case studies will include:

- **Determining if the leaching propensity of the drug product is similar or less than those listed in a referenced food contact regional regulation**
- **How to efficiently determine the leachables risk of adhesive labels**
- **When is E&L testing required**
- **Risk assessments for associated and auxiliary packaging components**
- **Testing strategies for ODD container closure systems**

2:35 *Close of Program*

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