PharmaED RESOURCES, Inc.

Extractables & Leachables West 2024

Ensuring Quality, Safety, Suitability and Regulatory Compliance for Drugs, Biologics and Medical Devices

November 13-14, 2024, La Jolla CA

Featuring Lessons Learned and Case Studies from Industry Experts:

Kimberly Ehman
WuXi AppTec

Prabhakar Reddy
USP

Ping Wang
Janssen

Dennis Jenke
Triad Scientific Solutions

Sherry Parker
SParker Consulting

Ray Colton
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David Weil
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Ravi Kiran Kaja
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Diego Zurbriggen
West

Chongming Liu
SGS

Kevin Rowland
RQM+

Eric Hill
BA Sciences

Casey Chamberlain
Eurofins EAG Laboratories

Ron Brown
Risk Science Consortium

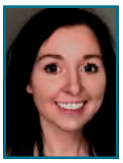
Isaac Mohar
Gradient

Joe Binkley
Leco

Cherry Shih
Cytiva

Sam Albeke
Element

Michael Ruberto
Material Needs Consulting



Molly Haan
WuXi AppTec

Mike Eakins
Eakins & Assoc

With Comprehensive Coverage On:

- **USP Update on the Revised System Suitability Standards Proposals for the Analysis of Organic E&Ls**
- **USP <665> and <1665>, Extractables from Manufacturing Components; Past, Present and Future**
- **How to Simplify an Extractables Approach—Managing the Cumulative Effect**
- **Case Studies and Regulatory Expectations in Chemical Characterization of Medical Devices per ISO 10993-18 Guidance**
- **Application of New Tox Risk Assessment Principles per ISO 10993-17:2023, and Unique Challenges for Combination Products**
- **Holistic Strategies to Evaluate the Impact of Detrimental Leachables to Cell Growth of Multiple Cell Bags**
- **Accelerating GC/MS E&L Analysis with Advanced Software Analysis Tools**
- **Using Chromatography, Databases and Mass Spectral Data to Improve Compounds Identification**
- **Case Study: Migration of PFAS from Fluoropolymers used as Single-Use Processing Components in the Manufacture of Cell & Gene Therapy Products**
- **Managing AETs in Extractables Testing of Med Devices**
- **Chemical Characterization in Biocompatibility for Med Devices**
- **Overcoming Common Analytical Challenges in E&L Studies**
- **And More!**

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Wednesday, November 13, 2024

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

8:30 *Chairperson Welcome & Opening Remarks*

Hot Topics—Evaluating E&L Risks in Commonly Used Cell Media & Biopharmaceutical Manufacturing Components

8:35

How to Evaluate the Suitability of a Cell Bag: Holistic Strategies to Evaluate the Impact of Detrimental Leachables to Cell Growth of Multiple Cell Bags

Dr. 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.

9:15

Case Study: Migration of PFAS from Fluoropolymers used as Single-Use Processing Components in the Manufacture of Cell & Gene Therapy Products

Sam Albeke, Chromatography Manager, Element Materials Technology

CASE STUDY

In the rapidly advancing field of Cell & Gene Therapy (CGT) manufacturing, the use of single-use processing components is integral for efficiency and flexibility. Fluoropolymers, such as FEP, have been commonly used as materials of construction for these components and commonly known for being inert. However, concerns have emerged regarding the potential migration of Per- and Polyfluoroalkyl Substances (PFAS) from fluoropolymer contact materials into therapeutic products. When PFAS are detected in E&L studies, they require thorough investigation to ensure the safety and efficacy of CGT products.

This presentation will dive into a case study for the identification of PFAS from a commonly used single-use material, FEP. The case study will cover factors influencing migration, potential impacts on patient safety and regulatory feedback received with regards to PFA detection in CGT E&L studies. This presentation seeks to facilitate a collaborative dialogue within the CGT community, fostering awareness, and encouraging the development of industry-wide standards to ensure the continued success and safety of Cell & Gene Therapy products.

9:55 *Morning Networking Break, Sponsored by*

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Critical Issues—Refining Uncertainty Factor Methodology and Application

10:30

Practical Application of the Uncertainty Factor

Kevin Rowland, PhD, Executive Vice President & General Manager, Lab Services, RQM+

Proper management of the analytical uncertainty involved in chemical characterization of Extractables and Leachables is critical to ensure patient safety. The recommendations in ISO 10993-18:2020 describe an uncertainty factor (UF) that should be used to ensure that the uncertainty related to response factor variation does not cause omission of weakly responding compounds present above the analytical evaluation threshold (AET). The recommendations include descriptions of how the UF can be derived, and one possible method for the application of the UF is implied. The equation provided implies that UF could be applied to the AET in units of concentration. This method has some technical problems that can cause significant errors in the chemical characterization results. The authors will present an alternative methodology, the application of the UF to the direct instrumental

signal (peak area). Both methodologies were performed and compared for a laboratory study performed with chemicals known to be present near AET in a simulated extract. The complete results from a medical device extractables study were also compared following application of these two UF application methodologies. The potential pitfalls of these UF application methods were explored and will be highlighted.

11:10 **Case Studies Simplifying SUS Risk Assessments Based on Industry-standard Protocols, Simulation Studies, and Leachables Evaluation**

Chien-Ju (Cherry) Shih, PhD, Principal Scientist, Regulatory and Validation Strategy, Cytiva

Increasing availability of extractable datasets aligned to industry-standard protocols (BioPhorum and USP <665>) have made it possible to risk assess complex single-use systems (SUS) consisting of multiple components and materials of construction less laboriously as an on-paper exercise. In this evaluation, we examine the on-paper approach for complex assemblies and compare to case study evaluations using simulation solvents or leachables assessment, including examples for end-to-end production of self-amplifying RNA-lipid nanoparticles intended for genomic medicines. The benefits, challenges, and learnings of these different approaches will be shared.

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

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Regulatory Perspectives for the Analytical Assessment of Leachables

1:00 **Considerations in Processing and Interpretation of Extractables Data**

Casey Chamberlain, PhD, Manager, Analytical Chemistry, Medical Device TestingEurofins EAG Laboratories

Proper collection and interpretation of extractable data are critical to ensure the output of a chemical characterization study accurately reflects the potential patient exposome resulting from a medical device. However, due to lack of defined expectation from both regulatory bodies and in ISO 10993:18 regarding data handling, there is currently a spectrum of approaches that exists throughout the industry, many of which are insufficient to adequately capture the extractable profile. In this presentation, we will cover three pillars of state-of-the-art chemical characterization data analysis: data deconvolution, high-resolution mass spectrometry, and reference material databases. Each of these items will be discussed with respect to the essential information they provide, along with the chemical insights which are lost in an analytical platform lacking these tools.

1:40 **Journey from Extractables to Leachables: Importance of Material Selection**

Diego Zurbriggen, Sr. Manager Strategic Studies & Analytical Lifecycle, West Pharmaceutical Services

The complexities of pharmaceutical drugs begin with development of the molecules and extend through the manufacturing processes and final delivery to patients. Chemical and physical properties of a containment and delivery system for parenterals may affect the product quality, and patient safety.

The risk associated with extractables and leachables is particularly high in primary packaging components that are in direct contact with the drug product, such as container closures. These components are commonly manufactured from elastomer formulations. These elastomer formulations may contain various additives and processing aids that could migrate from the elastomeric component into the drug product during storage.

The potential impact of elastomeric components on product quality and patient safety is well established and addressed by a variety of compendia chapters and regulatory guidance documents. Assessment of Extractables and Leachables are a common part of assessing suitability for intended use of container closures.

This presentation will explore sources of extractables in elastomeric components along with key considerations during the selection process of suitable for intended use container closures. Employing a holistic approach to elastomeric component selection allows for risks to patient safety and product quality to be mitigated.

A simulated lyo cake leachables study was performed using lyo stoppers manufactured from three distinct elastomer formulations. The data obtained from this study will illustrate the impact of material selection on the observed leachables profile and its potential impact to product quality and patient safety.

Critical Issues—Streamlining Toxicological Risk Assessment of Polymeric Materials

2:20

Grouping Extractable and Leachable (E&L) Compounds with a Common Mechanism of Action for Toxicological Risk Assessment

Dr. Ron Brown, Owner & Principal, Risk Science Consortium

The toxicological risk assessment of E&L compounds is typically conducted on a compound-by-compound basis; however, for compounds that lack toxicity data, it may be useful to group compounds together that have similar structural and physical-chemical properties, as well as a similar toxicological mechanism of action, to derive a class-specific Tolerable Intake (TI) or Permitted Daily Exposure (PDE) that is applicable for all compounds in that group. This talk explores ways to group compounds based on their structural and toxicological similarity and how to use computational models to identify a proposed toxicological mechanism of action for compounds in a group. The presentation will also review methods to conduct a cumulative risk assessment of the compounds in the assembled group. This approach of first assembling a group of compounds with a common toxicological mechanism, then conducting a risk toxicological assessment of the compounds in the group, has the potential to streamline the toxicological risk assessment process when large numbers of extractable or leachable compounds are released from a polymeric material and provides a science-based method for setting TI/PDE values that is presumably less conservative than the use of Threshold of Toxicological Concern (TTC) values as default TI/PDE values for the individual compounds.

3:35 *Afternoon Networking Break, Sponsored by*

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3:45

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 can often seem minor (for example, changing a catalyst used in the production of the polymer), but may have a potentially significant impact on the leachables profile for the CCS. Additional extractables testing can certainly 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. Key considerations will include:

- What constitutes a material change?
- What supporting data and information should be provided by the material supplier?
- What material properties impact the diffusion of extractables and leachables?
- What other factors should be considered in determining the leachables risk for a material change? For example:
  - Primary vs Secondary Packaging
  - Barrier properties of the primary packaging
  - Regulatory compliance for the new material
  - Dosage form and route of administration for the drug product
  - Storage conditions and shelf life for the drug product
- When additional E&L testing is necessary, what is the most efficient manner to perform this testing?

Proven strategies for efficiently managing post-approval material changes in CCS will be presented, offering practical solutions to these complex challenges.z

Critical Issues--E&L Qualification of Combination Products

4:15

Qualification of Extractables and Leachables for Combination Products

Eric Hill, CSO, Chemistry & E/L Labs, BA Sciences, and Isaac Mohar, Principal Scientist/Toxicologist, Gradient

Drug-device combination products provide patients and healthcare providers with ready access to reliable treatments. The combination of drug with device, however, can present unique challenges for ensuring patient safety. Among these challenges, qualification of extractable and leachable (E&L) constituents often requires meeting the varied and divergent expectations of drug and device health authority reviewers. This talk will contrast the standards for E&L chemical characterization and toxicological qualification, and propose

a dual-purpose approach for a drug/device E&L program that integrates ISO 10993-12/-18 and USP <1663/1664> chemistry with ISO 10993-17 and ICH/PQRI-based toxicological qualification.

4:55 *Happy Hour Mixer, Sponsored by*

Join your colleagues in the hotel bar for informal networking. Complimentary beverage and appetizers provided, courtesy of BA Sciences.

Thursday, November 14, 2024

7:15 *Complimentary Breakfast*

8:30 ### Is Swelling an Indication of Polymer Incompatibility?

Dr. Ray Colton, Director of E&L Services, Nelson Labs—North America

The FDA-CDRH does not consider swelling during extractable testing with semi-polar and non-polar solvents to be a sign of incompatibility. How does swelling affect the extractable analysis? Is swelling related to the level of extractables? This presentation will answer these questions by studying the swelling phenomena with different grades of silicon and polyurethane followed by High Resolution Mass Spectroscopy (LC-Orbitrap). The results will inform about the challenges of swelling in polymer/solvent interactions and recommend mitigation steps to navigate device approval and patient safety.

9:10 ### Extractable/Leachable Analysis: Using Chromatography, Databases and Mass Spectral Data to Improve Compounds Identification

Dr. David Weil, Master Application Scientist, Agilent Technologies

As drug formulations move from small molecule (API's) to Biologics, the complexity and the impact of potential extractable and leachable compounds on stability and safety continues to increase, from manufacturing with single-use-systems, container closure systems (CCS), and drug delivery. Being able to detect potential E/L compounds continues to be a challenge due to the wide range of MW, polarity, hydrophobicity, concentrations, and presence of breakdown/degradation products. In contrast with food and environmental application areas where standardized methods and protocols are set by regulatory agencies, the lack of standardized analytical methods and protocols has inhibited the sharing of public information and increased the difficulty in comparing results from one lab to another.

In the summer of 2023, a stimuli article was published entitled, "Proposals for the Development, Composition, and Routine Use of System Suitability Standard Mixtures in Support of Chromatographic Screening for Organic Extractables and Leachables," by USP-NF. The publication contained GCMS and LCMS separation methods (columns, gradients, sample preparation) linked with GC and LC amenable standards. For the LCMS analysis, the paper provided different methods for Electrospray Ionization (ESI) and Atmospheric Pressure Chemical Ionization (APCI). The publishing of the paper sparked our interest to review the many factors that impact optimal LC separation of E/L related compounds. Using a newly developed Food Contact Materials standards kit from AChemTek, (> 350 compounds) we began to explore how the analytical column (chemistry, diameter, length, pore size); organic mobile phase (MeOH, ACN, IPA), buffers (Formic Acid, Ammonium Formate), gradients and flow rate all impacted the separations. Using these experimental RT values, we investigate the use of theoretical RT modeling software, with high-resolution mass spectral data (MS and MSMS), downloadable third-party information managed using ChemVista the database management software to improve the identification of suspect and unknown E&L Compounds from extracts obtained from various commercially available catheter samples.

9:50 *Morning Networking Break, Sponsored by*

10:20 ### Charting the Universe of Organic Extractables

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.

In an effort to at least start the process of charting the organic extractables universe, Nelson Labs addressed the question of "what do we know about the universe from experience within that universe?" by performing a retrospective review of the many extractables studies that it has performed in the last five years. 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 characteristics [e.g., relative response factors, retention indices (for GC/MS compounds) were abstracted from the compiled data and physiochemical characteristics of the extractables were collated from various sources.

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.

Roundtable Discussion—USP's System Suitability Standards

11:00 **Update on the Revised System Suitability Standards Proposals from USP for the Analysis of Organic E&Ls**

Panelists:



Dr. Ray Colton, Nelson Labs

Dr. Ravi Kiran Kaja, US Pharmacopeia

Dr. G. Prabhakar Reddy, US Pharmacopeia

Discussants:

The Audience

Spotlight on Absorbable Med Devices

11:40 **Approaches and Challenges with Chemical Characterization and Toxicological Risk Assessment for Absorbable Medical Devices**


Dr. Kimberly Ehman, Director of Regulatory Toxicology & Consulting, WuXi AppTec, & Molly Haan, Senior Technical Customer Support Scientist, WuXi AppTec

Absorbable medical devices pose unique concerns for both chemical characterization and toxicological risk assessment (TRA). This presentation will provide a high-level overview of chemical characterization studies for absorbable medical devices, including exhaustive extractions, dissolution studies, and simulated-use approaches. The associated challenges will be addressed with specific case studies and proposed approaches for evaluation in the TRA. Additionally, chemical characterization and TRA may not always provide the full story for assessment of an absorbable device. Situations where additional data would be helpful (e.g., in vivo biocompatibility data) will also be discussed.

12:20 *Complimentary Lunch*

Critical Issues—Practical Considerations for Implementing ISO 10093-17 & -18 Standards

1:30 **Application of New Toxicology Risk Assessment Principles per ISO 10993-17:2023, and Unique Challenges for Combination Products**

Dr. Sherry Parker, Founder & President, Sparker Toxicology Consulting, LLC

The new revision of ISO 10993-17 is substantially changed from the last version, with new requirements and guidance for exposure dose estimation, use of toxicological thresholds, and derivation and evaluation of Margins of Safety for medical device constituents. An overview of new requirements, recommendations, and tools will be presented to facilitate the conduct of toxicological risk assessment of medical devices. Application of toxicological screening limit (TSL) may now be used to prioritize chemicals for toxicological risk assessment. New guidance for estimating the exposure dose for extractable chemicals based on assumed release kinetics now provides more relevant information for evaluating short-term vs. long term toxicological risks. Risk Acceptance Criteria are available to determine when a risk is tolerable and when it needs to be further evaluated and managed. For combination products, where both medical device requirements and pharmaceutical impurities requirements apply, 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 both sets of requirements.

2:10 **Concurrent Detection of PFAS Combined With Non-targeted E&L Screening Testing by UHPLC-HRMS for PFAS Analysis in Fluorous Pharmaceutical Packaging, Manufacturing Components and Medical Devices**

Chongming Liu, Supervisor – E&L Testing, SGS (Co-authors: Rajesh Chennam Shetti, Dujuan Lu, SGS, & Sven Hackbusch, Sebastien Morin, Jon Bardsley, Thermo Fisher Scientific)

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 materials, such as the detection of PFAS in drinking water by EPA methods 537.1 and 533. 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. As such, it is desirable to investigate approaches to detect PFAS in these components. This presentation will highlight several aspects of the concurrent targeted and untargeted detection of PFAS as part of non-targeted E&L screening

testing by UHPLC-HRMS, and its application to E&L testing of fluorous pharmaceutical packaging, manufacturing components, and medical device materials.

- Instead of sample pre-treatment like SPE, which discriminates compounds with less affinity to the cartridge materials, minimum sample preparation or direct injection is acceptable for testing. In addition, as it is critical to mitigate against system background PFAS compounds, the PFC free kit and a delay column were installed in the UHPLC system.
- 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.

2:50 *Afternoon Break*

3:05 **Case Study—Employing a Novel Sample Work-up and Analysis by GC-TOFMS for Improved Target and Non-target Detection of Leachables in Cream/Gel Drug Products**

CASE STUDY

Eric Hill, CSO, Chemistry and E&L Labs, BA Sciences, & Joe Binkley, Director of Separation Science Applications NA, LECO Corporation

Topical creams and gels are commonly used to treat diseases and conditions of the skin. These formulations introduce the active ingredient of the drug through the dermis and typically take the form of an oil-in-water emulsion, which presents a challenging matrix for analysis. Extractables studies involve extraction of the packaging components (usually comprised of tubes or pumps) with neat solvents, which are selected to mimic the chemistry of the oil-in-water emulsion matrix. Leachables studies require analysis of the cream or gel material directly for the presence of analytes from the packaging materials. As the emulsion cannot be analyzed directly, novel sample preparation and/or exchange workflows must be developed for the leachable studies. In addition to this sample preparation challenge, topical products also often have low analytical evaluation threshold (AET) values, due to the high recommended dosages for these product types. Here, sample preparation workflows are presented that involve concentration and clean-up to simultaneously achieve the low AET value and reduce matrix interference.

Two different sample preparation methods were evaluated in this work, and each sample preparation type included an unspiked and blind spiked sample for analysis. Extracts were analyzed by GC-MS using a non-targeted analysis workflow to discover the spiked analytes. The use of time-of-flight MS also helped to address the sample complexity and sensitivity requirements for these analyses. TOFMS data is optimal for mass spectral deconvolution algorithms that can uncover coeluting analytes in complex matrices, and it has the sensitivity needed for low-level detection. This pairing of hardware and software designed for MS deconvolution allows compounds of interest to be detected and identified, even in the most challenging of matrices such as cream and gel drug products. A workflow using GC-MS with some unique software tools to simplify both targeted and non-targeted analyses will be presented.

3:45 *Close of Program*

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