PharmaED RESOURCES, Inc.

Extractables & Leachables Summit 2024

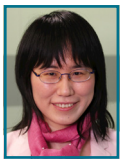
Ensuring Quality, Safety, Suitability and Regulatory Compliance for Drugs, Biologics and Medical Devices

April 18-19, 2024, Philadelphia PA

Featuring Lessons Learned and Case Studies from Industry Experts:

Prabhakar Reddy
USP

Ping Wang
Janssen



Dujuan Lu
SGS

Dennis Jenke
Triad Scientific

Andrey Sarafanov
FDA

Ron Brown
Risk Science Consortium

Marine Lapoutre
GSK

Sherry Parker
SParker Consulting

Ravi Kiran Kaja
USP

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Cherry Shih
Cytiva

Sam Albeke
Element

Gyuri Vas
Intertek

Mike Eakins
Eakins & Assoc

Joe Binkley
LECO

With Comprehensive Coverage On:

- Analytical Assessment of Leachables in Biological Drug Products: FDA Approach and Experience in Reviewing Information
- 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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Thursday, April 18, 2024

7:00 *Registration Check-in & Complimentary Breakfast*

8:00 *Chairperson Michael Eakins' Welcome & Opening Remarks*

8:05 **Cumulative Effect vs Lego Mode: How to Simplify an Extractables Approach**

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

The goal of this presentation is to illustrate how to manage the cumulative effect and to explain which simplifications can be implemented for extractable studies and patient exposure scenarios. Key takeaways include:

- Why extractable studies are not always representative
- How to deal with the cumulative effect described in regulations
- The concept of a Lego approach to simplify cumulative evaluation
- How to use digital tools to support your extractables approach and to simplify patient exposure scenarios and minimize toxicological risk

Regulatory Perspectives for the Analytical Assessment of Leachables

8:45 **Analytical Assessment of Leachables in Biological Drug Products: FDA Approach and Experience in Reviewing Information**

Dr. Andrey Sarafanov, Principal Investigator, US Food and Drug Administration, Center for Biologics Evaluation and Research

Biological drug products (biologics, i. e. therapeutic proteins, vaccine-, gene-, and cell therapy-based products) are produced via multi-step processes involving multiple materials contacting intermediates and sourcing numerous leachables into final drug products (DP). Such steps involve (i) purification of intermediates using chromatography, centrifuging, dialysis, filtering, and filling in final container closure system, etc., and (ii) shelf-life storage and in-use hold of DP. The respective leachables-producing contact materials involve chromatography resins, filtering/dialysis membranes, tubing, collecting containers, gaskets, valves, etc. By these, the assessment of leachables risk in biologics is the most challenging compared to other types of DPs. However, current guidances are generally focused on assessment of the leachables only from single manufacturing components, scored to be high-risk for leachables, and by this, underestimate other components scored to have the lower risk. Following these directions, manufacturers typically perform assessments only for the high-risk individual components and underestimate the contribution of other materials to the overall (cumulative) leachables profile in final DP. Other typical issues involve (i) non-validation of analytical methods, resulting in ambiguity in Analytical Uncertainty Factor (AUF) used for calculation of the Analytical Evaluation Threshold (AET; or reporting limit in an assay), (ii) missing the assessment of elemental (ionic) leachables, or (iii) incorrect leachables study design; altogether also resulting in potential underestimation of the leachables risk. Such issues usually cause multiple back-and-forth communications between the FDA and Sponsor during the application review, typically ending up with post-marketing commitments/requirements (PMC/PMR) that puts an unnecessary burden on both sides. This presentation overviews an FDA experience in reviewing information for analytical assessment of leachables, including examples of the issues, altogether aimed to reduce the efforts of both sides in the submission/review process and facilitate proper evaluation of the leachables risk.

9:30 *Morning Coffee & Networking Break*

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

10:00 **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.

10:40 CASE STUDY

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

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.

11:20

Nelson Labs Presentation

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

Abstract Coming Soon

12:00 *Complimentary Lunch, Sponsored by*

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1:05

Extractable and Leachable Risk Assessment for a Pharmaceutical Manufacturing Train Utilizing USP <1665> and <665>

Vicki Ward, Sr. Manager, Analytical R&D, Catalent

Catalent has a systematic process in place to incorporate E&L risk assessments in its pharmaceutical manufacturing train. The primary goal of this process is to ensure product safety and compliance with USP <1665> and <665> throughout all stages of manufacturing. This systematic approach involves an initial assessment, identification and quantification of risks, and the assignment of characterization levels to develop a robust risk mitigation strategy. Catalent uses risk dimension scores and clinical mitigation factors to evaluate the risk of leachables in systems used in the manufacture of pharmaceutical products. A case study will illustrate the application of the USP <1665> and <665> framework to perform an E&L manufacturing risk assessment and how this can support drug sponsors in obtaining regulatory approval.

Methodological Spotlight—Improving the Identification of E/L Compounds

1:25

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 separa-

tion 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.

2:05

Accelerating GC/MS E&L Analysis with Advanced Software Analysis Tools

Benjamin Johnson, NSF International (Co-authors: Don Kuehl & Yongdong Wang, Cerno Bioscience)

NSF International provides services for certifying the safety of drinking water equipment (NSF/ANSI 61). With 7000-8000 samples evaluated every year. The deconvolution, identification, and quantitation of Tentatively Identified Compounds (TICs) can require hours (for "clean" samples) to days ("dirty" samples) of tedious manual review from a team of 4 or more highly trained experts. A sample backlog of up to 6 months was common, and hiring and training additional analysts was a lengthy and expensive process. To complicate the problem further, multiple worldwide sites used different instrumentation, and some lacked the expertise to analyze the more complex samples.

To solve this problem, the search for a vendor-neutral software solution was needed to:

- Reduce the level of "expertise" required for the analysis
- Accelerate the analysis time for each sample
- Seamlessly integrate reporting and analysis with in-house LIMS systems

After an extensive review of available commercial software solutions, it was decided to use two commercial software products to address the problems: Thermo Scientific Chromeleon CDS 7.3 (Thermo Fisher Scientific, Waltham, MA) for the quantitation of Target compounds, and GC/ID 5.0 (Cerno Bioscience, Las Vegas, NV) for the identification and quantitation of TICs. GC/ID provided dramatically improved TIC identification through its use of a composite scoring system of unknown compounds that combine conventional Forward and Reverse Library Search, comprehensive Retention Index (RI) matching, and accurate mass/spectral accuracy formula validation key of ions (on single quadrupole analyzers). In addition, an automated spectral deconvolution process eliminated the previous peak-by-peak manual deconvolution necessary for complex samples with many coeluting peaks. A custom Python script fully automated the previous manual NSF analysis process, which is projected to eliminate the 6-month sample backlog. In addition, the review process is greatly simplified, minimizing the need for highly trained expert analysts. Both software can accept data from the three different GC/MS systems used globally and were easily and seamlessly integrated into the corporate LIMS system to efficiently generate internal and external customer reports, further saving time and reducing error. This presentation will describe the current state of the system being implemented in detail.

2:45 *Afternoon Networking & Coffee Break*

Critical Issues—Streamlining Toxicological Risk Assessment of Polymeric Materials

3:15

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.

3:55 CASE STUDY

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.

4:35 CASE STUDY

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

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.

5:15 ***Happy Hour Mixer, Sponsored by***

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Join your colleagues in the hotel bar for informal networking. Complimentary beverage ticket & appetizers provided, courtesy of Boston Analytical.

Friday, April 19, 2024

7:15 ***Complimentary Breakfast***

8:15

USP <665> and <1665>, Extractables from Manufacturing Components: Past, Present and Future(?)

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

USP monographs addressing extractables testing of plastic manufacturing components were developed, debated, and ultimately accepted to ensure that both component users and drug product regulators had the extractables information they needed to establish whether the components are suitable for use, specifically focusing on patient safety. These USP monographs were based on three principles:

1. That the rigor of the extractables testing should be related to the risk of unsafe component-related leachables being present in the manufactured drug product (greater risk = more extensive and rigorous testing),

2. That extractables testing should be performed in a comprehensive and standardized manner to produce data sets that are complete and comparable across component vendors,

3. That properly designed, executed, and justified extractables testing could be used to qualify a component as safe to use without testing of manufactured drug product for manufacturing-related leachables.

Although published with a delayed implementation, these chapters have already resulted in the generation of a significant body of data, which, when considered in the context of other published studies, may dictate how

these Chapters are applied upon their implementation and how they may evolve thereafter.

This presentation re-visits the development of these chapters, discusses their current content and the implications thereof, reviews currently available relevant knowledge, and considers how the chapters could evolve after their implementation.

Roundtable Discussion—USP's System Suitability Standards

8:55

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

Panelists:



Dr. Dennis Jenke, Triad Scientific Solutions

Dr. Ravi Kiran Kaja, US Pharmacopeia

Dr. G. Prabhakar Reddy, US Pharmacopeia

Discussants:

The Audience

Spotlight on Absorbable Med Devices

9:40

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.

10:20 ***Morning Networking & Coffee Break***

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

10:50

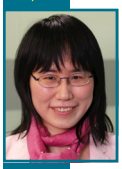
Application of New Toxicology Risk Assessment Principles per ISO 10993-17:2023, and Unique Challenges for Combination Products

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.

11:30 CASE STUDY

Case Studies and Regulatory Expectations in Chemical Characterization of Medical Devices per ISO 10993-18 Guidance



Dr. Dujuan Lu, E&L Global Leader, SGS

Chemical characterization per ISO 10993-18 guidance has become an important component of biocompatibility testing for medical devices. A major revision of ISO 10993-18 "Chemical characterization of medical device materials within a risk management process" was published in the beginning of 2020 and an amendment was published in 2022. This presentation will focus on the recent regulatory expectations regarding chemical characterization of medical devices.

- Strategies of exhaustive extractions for long term or permanent contact devices.
- Discuss the amendment published in 2022 regarding determination of the uncertainty factor (UF) for analytical evaluation threshold (AET) calculation and strategies to navigate AET challenges.
- Method qualification/validation of screening methods and ISO/IEC 17025:2017 accreditation.

12:10 *Complimentary Lunch, Sponsored by*

alcami™

1:15 **Extractables and Leachables: Keys to Success**

Amanda Connor, Principal Scientist—Extractables and Leachables, Alcami, & Chris Williams, Director of Laboratory Operations, Alcami

This presentation will cover important things to consider when selecting an E&L testing partner, keys to success, and an Alcami specialty laboratory services overview. Important takeaways include:

*Partner selection: What to look for in a laboratory partner

*Keys to Success: Timing, strategy, and planning ahead

1:35 **The Impact of Targeted Analysis in Extractables and Leachables on Patient Safety and Drug Stability**

Dr. Rigwed Tatu, Extractables and Leachables Program Lead, PSN Labs

Extractables and leachables testing is a critical component of the drug stability lifecycle. Understanding the E&L profile enables insights into potential drug interaction with degradation or reaction moieties that could lead to patient hazard or cause drug instability. In a chemical characterization program, organic constituents are characterized using discovery analysis where the extract is compared with a library of compounds and a semi-quantitation is performed using a structurally similar surrogate molecule. However, utilizing a semi-quantitation approach can lead to an under-estimation or over-estimation of patient risk. PSN Labs employs targeted analysis for accurate quantitation of compounds of toxicological concern, which provides a binary response—the chemistry is either present or absent. This approach guides decisions on patient safety and additional remediation strategies. Additionally, targeted strategies can also be used as the future state of drug-product interaction studies that are critical for safety and efficacy. Key takeaways include:

- Targeted analysis in E&L and its impact on patient safety and drug stability
- Benefits and criticality of targeted analysis
- Future state of E&L for drug delivery systems

2:15 **Evaluation of Complex E&L Data Packages: Using Science, Expertise, and Common Sense to Streamline Data Processing and Enhance Efficiency**

Dr. Gyorgy Vas, Research Fellow, Intertek Pharmaceutical Services (Co-authors: Louis Fleck, Anna Michelson, Nicole Dunn, Intertek Pharmaceutical Services)

E&L testing is very often complicated by combination of complex matrices and extremely low-level detection requirements, particularly in the case of large volume parenterals or large size implantable devices. Based on the current regulatory standards and industry best practices it is required to use complimentary (and often orthogonal) analytical techniques, to evaluate volatiles, semi-volatiles and non-volatiles in various sample extracts. Elemental impurity testing is more straightforward and less complex, as finite numbers of elemental impurities existing and listed in the standards, allowing well defined targeted approach for testing. The situation is more complex for organic impurities as the potential number of targets are in a range of 10,000-100,000 analytes, which usually requires either a large number of targets on a defined list or use a non-targeted data processing.

This presentation will focus on case studies, illustrating how data obtained from different types of analytical instrumentations can be used as complimentary information, empowering the scientist to make more confident decisions regarding identification and quantitation, and providing evidence for the suitability of the analytical methods used for the testing.

2:55 *Afternoon Break*

3:10 **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.

Abstract Coming Soon

3:50 ***Close of Program***

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Venue Address:	215 S. 16th St. Philadelphia, PA 19102
Venue Phone:	215-735-1525

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