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PharmaED's

Extractables & Leachables 2010

Strategies to Ensure Safety and Compliance in the Packaging and Processing of Drugs and Biologics

MAY 3-4, 2010, RADISSON HOTEL FISHERMAN'S WHARF, SAN FRANCISCO, CA

Featuring Case Studies and Lessons Learned from Industry Experts!

- Examine Case Studies and Best Practices for Extractables and Leachables
- Manage Extractables and Leachables Resulting from Packaging Materials, Closures and Excipients
- Review Toxicology Considerations and Risk Mitigation Strategies
- Trace Level Compound Indentification and Extractables and Leachables from Disposable/Single Use Systems

In-Depth Pre-Conference Workshop:

Aligning Safety Assessment and Product Development Activities to Reduce the Risks Associated with Extractables and Leachables: A Case Study Review

Dennis Jenke, Ph.D, Principal Scientist, Physical and Chemical Sciences, Baxter Technology Resources

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Monday, May 3, 2010

8:00 *Registration and Coffee*

PRE-CONFERENCE WORKSHOP

8:30

Aligning Safety Assessment and Product Development Activities to Reduce the Risks Associated with Extractables and Leachables: A Case Study Review

Dennis Jenke, Ph.D, Principal Scientist, Physical and Chemical Sciences, Baxter Technology Resources

Interactions between systems and products are well known and well documented and it is incumbent on the producers and users of such systems to demonstrate that any interaction that occurs between a system and a therapeutic product has no consequential effect on the composition of that product. While regulations and standard practices have been developed to accomplish the task of demonstrating "no impact", such regulations and practices are either general, high level, or strategic in nature and/or are part of a fragmented general literature on the topic of system/product compatibility. Members of the regulatory and industrial communities who find it necessary to assess system/product interactions struggle to develop, implement and report effective, efficient, standardized and scientifically sound strategies and tactics for performing such compatibility assessments.

This juxtaposition establishes the driving force behind this presentation, which considers two major questions; "what do we have to do?" and "when do we have to do it?" This presentation considers the multiple aspects of both safety assessment and therapeutic product development and notes that if safety assessment and product development were to start at the same time, there are logical time connections between the two. Thus the presentation is loosely constructed around a timeline that delineates the major activities associated with both the development of pharmaceutical products and the safety assessment of extractables and leachables. Key topics covered in this presentation include:

I. An introduction to the topic of the safety assessment of extractables and leachables and an overview of pertinent regulations.
II. Key nomenclature that is used with extractables and leachables.
III. Understanding the link between the product lifecycle and the major activities associated with E&L safety assessment.
IV. The process of material characterization, screening and selection.
V. Components of the simulating extraction study and its associated preliminary toxicological assessment.
VI. Components of the leachables migration study.
VII. Strategies for disaster management.
VIII. The E&L section of a Registration Dossier.
IX. Dealing with Reviewer Feedback.
X. Post Launch E&L Activities including change control and ongoing QC.
XI. Product retirement and disposition of E&L information.
XII. Ongoing activities in E&L, including manufacturing and container/closure systems.

The points made in this presentation are illustrated via numerous case studies.

12:00 *Luncheon*

1:00 *Chairperson's Welcome and Opening Remarks*

1:15

Best Practices for Extractables and Leachables Pharmaceutical Development Studies: PQRI and Beyond

Dr. Daniel L. Norwood, Distinguished Research Fellow, Boehringer Ingelheim Pharmaceuticals, Inc.

Extractables and leachables studies can be some of the most complex and vexing in all of pharmaceutical development, no matter whether the dosage form is considered to be "high risk" (e.g., inhalation drug products) or "low risk" (e.g. solid oral dosage forms). Over the past two decades a scientific/regulatory consensus has evolved regarding pharmaceutical development "best practices" as applied to extractables/leachables issues. Consensus continues to develop in areas such as the conduct of laboratory controlled extraction studies on container closure system critical components, drug product leachables testing and control, routine testing and control of component extractables, and safety qualification of individual leachables. A milestone in the consensus building process is clearly the qualification and best practices for extractables/leachables pharmaceutical development in Orally Inhaled and Nasal Drug Products (OINDP). The purpose of this presentation is to describe the PQRI recommendations in terms of philosophy and content, present and discuss other consensus building efforts, and consider the extrapolation of the PQRI recommendations to other drug product types and dosage forms.

- Current consensus around best practices in pharmaceutical development for extractables/leachables.
- Consensus building activities around extractables/leachables pharmaceutical development.
- Understanding what's next in the evolution of consensus best practices for extractables/leachables pharmaceutical development.

CASE STUDY

2:00 **Risk-based Testing and Control Strategies for OINDP Materials**

Cheryl L.M. Stults, Ph.D.
Novartis Pharmaceuticals Corp.

Orally inhaled and nasal drug products (OINDP) are generally categorized as having a high level of concern for patient safety and require high quality materials and controlled processes throughout the supply chain. Development of appropriate control and testing strategies begins with selection and qualification of materials. Throughout the lifecycle of the product a risk-based evaluation of the product, components and supply chain can be used to determine appropriate testing strategies and establish relevant controls that may include leachables and/or extractables. This presentation will include: a brief review of expectations for OINDP, a discussion of risk-based approaches with illustrative examples and appropriate management strategies for extractables in OINDP materials.

This can be accomplished by extensive testing or reduced to a paper exercise, but typically is some combination of the two. The strategy employed depends on several factors including but not limited to: the risk level associated with the dosage form of the product, life cycle stage, experience with similar materials and pedigree of the material. A few examples will be used to compare and contrast various testing and subsequent control strategies for different OINDP materials.

2:45 **Mitigating Risk and Bridging the Gap between Extractables and Leachables**

Andrea Straka, Technical Account Specialist, West Monarch Analytical Laboratories

Extractables and Leachables are two distinct terms that have been used interchangeably over the past decade. The confusion seemed to stem from the FDA Guidance for Industry published in 1999 "Container Closure Systems for Packaging Human Drugs and Biologics", which was written when the topic was in its infancy, and continued to grow over the years. There are industry leaders with strong opinions, some claiming it is possible to circumvent extractables testing to get to "the real issue" of leachables. However, building a body of extractable information is the key to a scientifically sound study of a container closure system or device. This session will:

- Review the relevance of gathering extractables data for manufacturing equipment, packaging materials, and delivery systems
- Discuss strategies for designing a reasonable but thorough extractable profile study
- Present solutions to determining the risk of extractables becoming leachables in drug products and how to make project decisions backed up by good science

3:15 *Refreshment Break*

3:30 **Best Practices for Design and Execution of Controlled Extraction, Methods Optimization and Validation**

James R. Scull, Ph.D., Executive Director & Managing Member, Pharmalytica Services

Controlled extraction studies can become extremely complex when evaluating multiple components produced from a variety of materials. Thoughtful planning to outline how the study will be conducted improves efficiency, compliance and ultimately provides a more complete and coherent data package. The same concepts can be applied to optimization and validation of the analytical methods used for both qualitative and semi-quantitative analysis. Protocol design, including the implementation of "Executable Protocols" and flow diagrams will be highlighted along with other industry best practices.

TOXICOLOGY CONSIDERATIONS

4:15 **Toxicology Issues in Extractables and Leachables**

William P. Beierschmitt, Ph.D., D.A.B.T. – Associate Research Fellow, Drug Safety Research and Development, Pfizer, Inc.

An essential, critical component of the registration package for a parenteral product that is addressed by the toxicologist is the risk assessment of extractables and leachables. From a toxicology perspective, while extractable data can provide valuable information (i.e. what chemicals might migrate into the drug during storage), formal risk assessments are typically only performed on leachables (i.e. what chemicals did migrate into the drug during storage). The basic premise of this procedure is to assess the potential risk to humans resulting from unintentional exposure to the chemicals that migrate into drug product from packaging. For each chemical, after determining the maximum potential dose a human might receive, the toxicologist uses available toxicology data, including experimentation if needed, to assess the potential risk. The route of administration and duration of potential exposure are just two of many factors taken into consideration when a risk assessment is performed. Overall, involvement of the toxicologist in extractable and leachable studies from the earliest experimental planning stage through the data collection greatly facilitates arriving at a timely and successful assessment of these chemical impurities. While there are no formal regulatory guidelines currently in place addressing the risk assessment of these impurities, safety thresholds for risk assessment of leachables in orally inhaled and nasal drug products (OINDP) have been developed through a joint effort of scientists from the US FDA, academia and industry, and such thresholds will

greatly facilitate the risk assessment process for these chemicals.

IDENTIFYING LOW LEVEL COMPOUNDS

4:45 **Strategies for Identifying Low Level Compounds**
Liagiong Fang, Baxter Healthcare Inc.
A critical aspect for leachable/extractable study is to be able to identify unknown compounds at very low levels. The first challenge is to acquire data at the required levels. Very often the best one can do is the acquisition of incomplete set of data or data of limited quality. The second challenge is then how to extract and utilize information from limited information to derive structures. This presentation will examine ways to maximize data acquisition and to use the data to the fullest extent for structure elucidation. The following topics will be discussed.

- What is special about trace level compound identification
- Data dependent experimental design
- Non-laboratory tools
- Lessons learned from real life issues – case studies
- General approaches

5:30 **Extractables and Leachables from Elastomeric Closures for Parenteral Applications**
Renaud Jansenn, Technical Support Manager, Helvoet Pharma
One of the most highly pursued topics in the parenteral closure area is extractables and leachables. Two of the main reasons are toxicological and drug stability concerns. To minimize the occurrence of these problematic issues, suppliers and pharmaceutical companies invest endless amounts of time and resources into identifying and validating techniques to detect extractables and leachables. With respect to elastomeric closures, the most widely researched extractables and leachables are accelerators (carcinogenic nitrosamine substrates and cytotoxic molecules), volatiles (alkanes, oligomers, and aromatics), carbon black waste (polynuclear aromatic hydrocarbons), and antioxidants (mostly BHT and Irganox). As chromatographic databases of extractables and leachables from elastomeric components begin to develop, the sources, impurities, degradation, and feasible mechanisms have become of great scientific interest. Within this presentation, attempts will be made to discuss topics and define industry questions related to the subject of extractables and leachables with regards to:

- Actual definitions
- Sources of extractables and leachables
- Associated impurities and degradation products
- Elastomeric closure supplier support

6:00 *Close of Day One*

Tuesday, May 4, 2010

8:00 *Chairperson's Day Two Opening Remarks*

INJECTABLES CONSIDERATIONS

8:15 **The Use of Extractable/Leachable Testing in Quality Control Programs: From Raw Materials to Final Product**
Steven Doherty, Technical Manager, TOXIKON
The assurance of the purity of a product begins with the purity of raw materials. The use of extractable and leachable testing can be used as a component of quality control activities. Selected testing conducted at various points of the manufacture, packaging, and storage of pharmaceutical products can be used as part of an overall strategy to ensure product quality, while providing for the early detection and remediation of the introduction of potential impurities. The increased use of disposable components in both manufacture and packaging makes the inclusion of quality control measures addressing extractable and leachable issues of critical importance. Possible source of compounds may be include a number of components such as tubing, gaskets, containers, filters, closures, etc. Example strategies will be presented for the implementation of Extractable/Leachable testing as part of the overall quality control process.

- Points of consideration in designing a study
- Evaluating available information
- An overview of suggested analytical techniques
- Examples of strategies for using E&L studies

8:45 **Appropriate Scientifically-Defensible Approaches to Assessing the Toxicity of Extractables and Leachables in Drug Products: Using All the Tools Available**
Allan W. Ader, Ph.D., DABT, Vice President and Principal Toxicologist, SafeBridge Consultants, Inc., Mountain View, CA
It is quite a challenge to digest all the analytical data developed from extractable and leachable studies just from the analytical side. But what do you do with these data, once you have the information? The FDA and other regulatory bodies and the drug, device, or supplier manufacturer want to ensure that those materials identified do not change the quality of the product or cause toxicity themselves. A risk assessment of the extractables and leachables is needed that will provide scientific support to the safety of the product. This presentation will provide approaches on what analytical data needs to be assessed, what toxicity data needs to be assessed, and how to conduct an appropriate and scientifically-defensible toxicological risk assessment for extractables and leachables into drug products for biopharmaceutical and small molecule products.

CONTAINER CLOSURES

9:15 **Selection of Container/Closure Components: Maximize Functionality, Minimize Patient/User Risks for Single Use Medical Devices**

Patrick O. Tennican, MD, Chief Executive Officer, Hyprotek, Inc.

The selection of materials for containers and closures for single use medical devices is facilitated by grid analyses of device functionality and exposure risks to the patient and caregivers. Incorrect selection of materials may impair operability of the device or interfere with the therapeutic efficacy of the reagents or pharmaceuticals. Material changes may occur during production or sterilization procedures, as in gamma irradiation or autoclaving. Inadvertent contamination in the manufacturing or packaging processes may contribute to toxicity. The reagents, pharmaceuticals, diluents or combinations may create synergistic leachable issues unanticipated by univariate analysis.

This discussion will highlight safety and efficacy considerations from the viewpoint of patients and caregivers. Compliance with FDA guidelines regarding packaging integrity, identification and patient/caregiver instructions should ensure product safety and reduce liability.

9:45 **Materials Used to Fabricate Container Closure Systems and the Impact on Extractables and Leachables**

Michael A. Ruberto, Principal, Material Needs Consulting, LLC

Components of container closure systems and medical devices can be fabricated with a wide variety of materials. Polymers, such as plastic or elastomers (rubber), are commonly used in these applications and represent a very broad class of compounds with many different properties that can provide functionality, security, or aesthetics to the primary packaging. Plastic components are light-weight, flexible, and often more durable than traditional metal or glass and can be modified by the addition of polymer additives to have many of the desirable properties of these conventional materials such as strength and clarity. Although polymers appear to be the material of choice for use in container closure systems and have many advantages over metal and glass, they are not without shortcomings of their own. In the presence of light, heat, oxygen, and other environmental factors, polymers will degrade. Additives and stabilizers commonly added to these polymer systems to minimize this degradation can be sources of leachables, especially if they are not compatible with the polymer. This presentation will provide an overview of the issues associated with the materials used in the construction of container closure systems with regards to extractables and leachables. Topics covered will include:

- An introduction to polymer degradation and stabilization
- Typical extractables profiles for the materials used in container closure systems
- The polymer supply chain and sources of unexpected leachables
- Considerations for managing and minimizing the risk associated with material selection

10:30 *Refreshment Break*

DISPOSABLE PLASTIC COMPONENTS

10:45 **Qualification of Disposable Plastic Components Used in Manufacturing and Filling Processes**

Kurt L. Moyer, Ph.D., Director Analytical & Bioanalysis, Pharmalytica Services

Plastic components used in the manufacturing and filling of parenteral materials should be assessed for potential extractables and leachables that may affect the finished product. During this study, samples of various tubing used on the filling line were extracted using four different solvents by reflux and oven incubation extraction techniques. For each sample, volatile extractables were analyzed by headspace GC-MS, volatile and semi-volatile extractables were analyzed by direct injection GC-MS, non-volatile extractables were analyzed by HPLC-MS, and 65 inorganic extractables were screened for by ICP-MS. Initial semi-quantitative analysis was done on each extractable found. All extractables observed during GC-MS analysis were quantitated against octamethylcyclotetrasiloxane. All extractables observed during HPLC-MS analysis were quantitated against Irganox 1010. Overall, 68 of the 77 organic extractables observed were identified. An overall comparison among the various tubing types was conducted to select those to be used in the manufacturing process.

SINGLE USE SYSTEMS

11:30 **Extractables/Leachables from Integrated Single-Use Systems in Biopharmaceutical Manufacturing**

Weibing Ding, Ph.D., Technical Manager, Pall Life Sciences

This talk presents a new set of results of the systematic study of extractables from single-use systems into water and ethanol via novel concepts, practical design, and analytical detection using advanced techniques. In order to tackle the fairly complex systems, we studied the components first, which included filters, sterile connectors, tubing and biocontainers, and then examined the full single-use systems comprised of filter, tubing, sterile connectors and biocontainers. This approach greatly simplified the identification of the extractable compounds from the integrated systems. The test design was based on actual biopharmaceutical manufacturing process conditions using a worst-case scenario. The complete extractables results were obtained using validated analytical methods, including quantitative non-volatile residue measurement and FTIR for qualitative assessment, headspace GC/MS for volatile compounds and direct-injection GC/MS for

semi-volatile compounds, derivatization GC/MS for fatty acids, HPLC/UV/MS and LC/MS/MS for non-volatile and heat-sensitive compounds, and ICP/MS for inorganic elements. The presentation provides a well-designed method for extractables/leachables study on single-use systems. Thismethod can be directly applied to extractables/leachables study during process validation.

- Learn how to design a suitable E/L test
- Learn what analytical methods are suitable for E/L from process equipment
- Learn how to proceed with process validation on E/L

12:15 *Luncheon*

1:15 **A General Approach to Determination of Extractables from Single Use Systems**
Jerold Martin, Chairman, Bio-Process Systems Alliance (BPSA), Sr. V.P. Scientific Affairs, Pall Life Sciences

Qualification of extractables from single-use process components and systems is a critical requirement for their selection and validation, in particular for risk assessment of potential process-derived leachables in final product. Similarities of many applications for single use systems make characterization of extractables amenable to a common general approach. A joint supplier/user subcommittee of the Bio-Process Systems Alliance (BPSA) has developed an expanded guide to testing of extractables from single use components and systems. Recommendations for harmonizing extraction conditions and extractables analyses are provided to facilitate generic data comparisons and utility.

DISPOSABLE SYRINGE PRODUCTS

2:00 **Analytical Approaches for the Determination of Extractables and Leachables in Syringe Products**
Srini Sridharan, Ph.D., Manager, Research & Development/Materials Technology, BD Medical Surgical Systems

Chemical compounds leaching from a container closure can potentially have significant adverse effects on safety and stability (e.g., incompatibility, toxicity, etc). Knowledge about the presence, nature and potential leaching of chemical compounds from container closures is mandated by Regulatory requirements. The methods and approaches used for the determination of the compounds depend on the specific medical device of interest. In this work, the analytical approaches to determine the potential extractable compounds in disposable syringe products are presented. ICP/MS has been used for the determination of heavy metals and other elements. A screening method for more than 70 elements has been developed. Volatile extractables are determined by Headspace GC/MS. Direct injection GC/MS or in combination with SPME(solid phase mictroextraction) is used for the analysis of semi-volatile extractables. Liquid extractables are determined by LC/MS/MS using APCI (atmospheric pressure chemical ionization) or ESI (electrospray ionization) mass spectrometry. The sample preparation and methods of analysis are presented. Application examples involving the analysis of plastic and elastomeric syringe components are given.

2:30 **TopLyo: Ideal packaging for lyophilized biopharma**
Horst Koller, Head of Regulatory Affairs PP, Schott

The TopLyo container is coated with a hydrophobic layer and has an improved geometric design to offer optimum efficiency for the lyophilisation process (freeze dried). Since the coating is inside and in direct contact with the drug a study regarding the extractable performance was set up and evaluated. The goal of this study was to provide data on the coating stability for regulatory support for customers.

3:00 *Refreshment Break*

CASE STUDIES

3:15 **From Extractables Study to Leachables Assay: A Protein Drug Case Study**
Helmut Schneider, Senior Scientist II, Analytical Sciences, Human Genome Sciences

E&L studies for container-closure systems are essential for drug commercialization, but can be challenging for many biotech companies due to lack of infrastructure and experience. This presentation describes how HGS conducted the studies for an injectable protein drug. With the help of a pharmaceutical service company, extractables studies were performed for Bulk Drug Substance storage containers, for a Phase 3 vial with associated stopper used in Phase 3, and for a dual-chamber cartridge to be used with the commercial product. Aqueous and organic extracts were analyzed by the service company using an array of semi-quantitative assays to cover both volatile and non-volatile substances. To confirm extractables as leachables and to identify substances which had not been missed in the previous study, tests of aged Final Drug Substance and placebo were performed. Criteria were then established to select compounds for toxicological risk analysis from the list of extractables. Based on toxicologicaland product impact risk, a multi-year leachables study for three substances was designed. The presentation will provide a rationale for the chosen leachables assay platforms. Examples are given how results of the validated leachables assays correlated with the preceding extractables study.
The presentation will cover:

- The design of an extractables study for an injectable protein drug
- Approach to cope with the data obtained by the extractables study
- The selection of appropriate leachables assay techniques
- Comparison of leachables study data and extractables study data

3:45

Extractables/Leachables Assessment of an Elastomeric Material for Potential Use as an Injection Site for Flexible Containers

Dr. James Story, Research Scientist, BAXTER HEALTHCARE

The organic extractables profile of a synthetic polyisoprene material being considered for use as a closure on a bag-type packaging system will be discussed. The predominant organic extractables associated with the test material were bis(2,2,6,6-tetramethyl-4-piperidinyl) sebacate (Tinuvin 770), several Tinuvin related substances, fatty acids and antioxdant related compounds. Based on their potential product safety impact, Tinuvin and one of its related substances were chosen as target leachables. In order to establish the accumulation behavior of these target leachables under conditions that simulate the desired application, monobags (100 mL fill volume) and multi-chambered bags (1000 mL fill volume) were constructed with injection sites made from the test material, filled with water and subjected to accelerated aging including multiple sterilization cycles and long term storage at 40C. An electrospray LC/MS/MS method was developed and validated for use in the sub-200 ppb range for the measurement of the selected target leachables. Even under the worse case contact conditions, the accumulation levels of the target leachables were much less than their total available pool in the injection sites. This presentation has the advantage of demonstrating the entire E/L process of:

1. Extractables elucidation
2. Target leachable selection and toxicological evaluation
3. Leachables method development and validation
4. Leachables measurement

4:30

Tackling the Extractables and Leachables Challenge: Managing Extractables Along the Supply Chain

Lee Nagao, Drinker Biddle & Reath, Washington, DC

Control of extractables and leachables in OINDP is a complex challenge involving not just OINDP developers and manufacturers, but the supply chain for OINDP container closure systems and devices. Indeed, a key quality by design concept with respect to extractables and leachables, is to control these chemical entities as far back in the supply chain as is practical and possible. This supply chain is highly complex, involving a number of different suppliers, including those providing raw materials such as resins, those providing specific additives such as colorants and antioxidants up to those supplying the final packaging and device components. Additionally, molding or other forming processes enacted by suppliers can affect extractables profiles, making changes that are not obvious even given initial material composition information.

The IPAC-RS OINDP Materials Working Group is interacting with different areas of the OINDP component supply chain to improve both suppliers' and OINDP manufacturers' understanding of how extractables and ultimately leachables can be best managed along this chain and within OINDP companies. This poster will primarily focus on phase appropriate, risk-based application of extractables and leachables management within the development process, including acquisition of composition information and performance of extractables and leachables studies. The poster will make reference to the supply chain in general, describing key areas that have impact on extractables profiles, examining the roles of suppliers and manufacturers in extractables control, and how these roles are changing within the current regulatory and development environment.

5:00

Migration Study Design and Case Study of Benzophenone Leaching from Packaging Componentry into Drug Product Solution

Alan D. Hendricker, Catalent Pharma Solutions

This talk focuses on a case study to source, quantitate and eliminate a contaminant migrating from the drug product container closure system into a nasal spray formulation during stability storage.

The migration study was performed over eight weeks. Drug product vehicle was added to marketed HDPE bottles and capped. Test articles of commercial secondary packaging labels and next generation labels were applied to individual bottles. In addition, samples were prepared to which marketed and novel tertiary cardboard packaging was added, but without direct contact with the bottles. Control blanks were also employed. The migration study was monitored using GC-MS screening methods in order to confirm detected species for both volatiles and semivolatile leachables. Results of this study will be presented. After sourcing the benzophenone, validated methods were used to confirm and quantitate amounts present in the packaging materials. The packaging materials were subsequently removed from use as a corrective action.

This talk will also focus on migration study design. Migration studies can be used to anticipate potential problems with leachables and provide relatively rapid answers concerning materials compatibility issues. Non-validated screening methods may be used for this purpose which can save cost and time versus encountering a problem after significant amounts of effort have been spent. Linking migration studies to materials characterization studies will also be discussed in terms of understanding which species to focus on and applying appropriate analytical methodology.

5:30

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