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PharmaED's

Pre-Filled Syringes Forum 2010

Strategic Development, Inspection, Safety & Regulatory Compliance and Commercialization of Pre-Filled Syringes

JULY 22-23, 2010, SHERATON LA JOLLA HOTEL, LA JOLLA, CA

Featuring Case Studies and Lessons Learned from Industry Experts!

- MATERIALS, DESIGN & CONSTRUCTION OF PRE-FILLED SYRINGES
- SAFETY CONSIDERATIONS & REQUIREMENTS
- NUMEROUS DEVELOPMENT CASE STUDIES
- MANUFACTURING & FILLING SOLUTIONS
- REGULATION & INSPECTION OF PRE-FILLED SYRINGES
- FUTURE MATERIALS FOR PRE-FILLED SYRINGE COMPONENTS

Including Special Coverage On:

- Syringe Plunger Movement
- Development Case Studies
- Manufacturing Solutions
- Visual Inspection
- Container Closures
- Stopper Movements
- BUBBLE-FREE FILLING®
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- Extractables & Leachables
- Combination Products

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Zeon Chemicals L.P.
West Pharmaceutical Services, Inc.
Vetter Pharma-Fertigung GmbH
Schott North America, Inc.
PFS Technologies
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Thursday, July 22, 2010

8:15 *Chairperson's Welcome and Opening Remarks*

MATERIALS, DESIGN & CONSTRUCTION

8:30 **Managing the Polymer Supply Chain for Materials**

Dr. Michael A. Ruberto, President, Material Needs Consulting, LLC

The characterization and control of extractables and leachables from the plastic and elastomers used in pre-filled syringes is a formidable task for the pharmaceutical industry. Obtaining information from vendors regarding the composition of container closure system components can be a challenge, and even when this data is supplied, peaks corresponding to unknown compounds are often detected in chromatograms associated with extractable and leachable studies. The source of these unexpected migrants can often be traced back to the fabrication of the components of the syringe and are usually polymer additives that have unintentionally been added to the manufacturing process or degradation and transformation products that result from the active chemistry that occurs during the polymer processing. This presentation will provide an overview of the issues associated with the materials used in the construction of pre-filled syringes with regards to extractables and leachables as well as discuss proactive measures for managing the risks associated with these container closure systems. Topics covered will include:

- Materials commonly used in pre-filled syringes
- Potential extractables from syringe components
- An overview of the polymer supply chain
- Best practices for managing the supply chain for raw materials
- Recommendations for establishing in-house quality control programs

9:15 **Exploring Future Materials for Pre-filled Syringes**

Toshiro Katayama, Product Manager, New Business Development, Zeon Chemicals L.P.

Cyclic olefin copolymers (COPs) continues to demonstrate as one of most suitable plastics for pre-filled syringe application and the demand is steadily rising as the customer base expands. The presentation will cover the basic properties of COPs and the effect of ethylene oxide, steam and gamma radiation, including a color shift study after gamma radiation. Other areas to be covered are regulatory status and biocompatibility including protein adsorption and a comparison of COPs with cyclic olefin copolymers.

10:00 **Pre-filled Syringe Applications for Biotech and Devices**

Arno Fries, Head of Sales USA Syringes, Gerresheimer

The use of combination products of drugs, syringes and autoinjectors is rising. This trend is driven by strong growth in the home care sector. Pre-filled syringes have initially not been designed for such applications. Potential interactions between product contact materials and sensitive biopharmaceutical formulations need to be controlled. In addition, dimensional and functional syringe attributes have to be aligned with the requirements of injection devices. The development of efficient systems can be accomplished through close partnership between biopharma company, suppliers and CMOs. This presentation provides an overview of

- methods to control the interface between syringes and biopharmaceuticals,
- technologies to achieve functionality of syringes in autoinjector devices and
- principles for the design of syringe-based combination products.

10:45 **Q&A**

11:00 *Refreshment Break*

11:15 **Pre-fillable Polymer Syringes: Review of Design Flexibility**

Christian Helbig, Manager of Business Development, Schott North America, Inc.

Ready-to-fill syringes with their advantages in terms of convenience and safety of administration showed significant market growth over the last few years and are expected to grow even further. While prefillable syringes made of glass have been established for decades, those made of plastic, the cyclic olefin polymer family in particular, have just made the transition from an interesting innovation to an accepted parenteral drug packaging as indicated by the increased availability from multiple suppliers. This presentation reviews the properties of the different cyclic olefin polymers and their use in primary parenteral packaging applications such as prefillable syringes.

Clearly, the knowledge base has advanced in the past few years. More companies have included the cyclic olefins in their packaging evaluations, and there is a much higher confidence level on leachables & extractables, as well as regulation of plastics. Beyond this, choosing cyclic olefins has become a valid option to address drug-container interaction topics like tungsten residues, metal ion leaching or reduction of free silicone lubricant or even total lubricant free systems.

While initially targeting to be an exact copy of the prefillable glass syringe, developments now exploit the extra design space that is given from injection moulding of plastic over the forming of tubular glass. The integration of primary polymer container with a safety device or autoinjector or the realization of customized sizes or multi chamber designs can be realized in a much simpler way. By extending the product range from standard products to highly customizable systems, prefillable polymer syringes can help to fulfill the unmet needs of the pharmaceutical industry.

12:00 *Pre-lunch Exhibitor viewing*

12:30 *Lunch*

ELASTOMERIC COMPONENTS

1:45 **Selecting Elastomeric Components for PFS Applications**
Lisa Yoest, Technical Support Manager, Helvoet Pharma
When compared with traditional elastomeric components for pharmaceutical packaging, namely vial stoppers, it is clear that elastomeric components for PFS applications have some key differences, both in terms of form and function. The goal of this presentation is to educate the audience on important factors to consider when selecting elastomeric components for PFS applications. Topics covered will include the following:
- Key ISO & Pharmacopoeial Standards
- Standard PFS Plunger Designs
- Standard PFS Tipcap & Needle Shield Designs
- Typical Rubber Compounds for PFS Components
- Special Concerns for PFS Components

2:30 **Machineability of Gamma Irradiated Pre-filled Syringe Plungers**
Pierre Poulain, Technical Support Manager, STELMI
Sterilization by gamma rays has increased in popularity as a sterilization process for medical devices, pharmaceutical processes, and packaging. However, gamma irradiation not only sterilizes but can also trigger complex reaction within the elastomer matrix. A comprehensive functional analysis has to be performed after gamma radiation to ensure that the closure properties have not been damaged in regards to mechanical, physical and chemical properties, bio-compatibility, container/content interaction and machinability.
This presentation will emphasize on the machinability study of sterile rubber plungers performed in collaboration with a worldwide aseptic filling machine manufacturer. Results will be presented regarding aging, gliding properties and process parameters (speed, sorting, conveying, assembly).

DEVELOPMENT CASE STUDY

3:15 **Next Generation Quality for Prefillable Syringes and Primary Components**
Tibor Hlobik, Associate Director, Marketing, PFS Technologies
New Regulatory guidelines, Quality by Design (QbD) initiatives and drug manufacturer efforts to reduce cost of poor quality are driving innovations and continuous improvement with prefillable syringes. It is important to understand the entire supply chain of components and to form a supplier partnership for success. The presentation will provide participants with a detailed understanding of market requirements, how primary packaging materials can improve drug product compatibility, and overview new trends in supplier manufacturing technologies and process controls. Zero defects reliability from concept to industrialization is the expected standard.

4:00 *Refreshment break*

4:15 **Minimizing Risk of Sterility Breach from Stopper Movement**
Shawn Kinney, President, Hyaluron Contract Manufacturing
Stopper movement due to the gas bubble inside a syringe allows the potential for breach of product sterility. There are several approaches to eliminate stopper movement most of which require additional packaging and cost. A simple approach to controlling stopper movement is to control the size of the gas bubble inside the syringe. This presentation will explain how to determine the maximum allowable gas bubble for a given syringe and stopper combination using a risk based approach.

5:00 **Panel Discussion**

5:30 *Close of Day One*

Friday, July 23, 2010

8:15 *Chairperson's Day Two Opening Remarks*

8:30 **Understanding Quality System Requirements for Pre-filled Syringes**
Dr. Michael Gross, Senior Consultant, Biologics Consulting Group
Until recently there has been no specific regulation or guidance describing FDA's expectations for a combination product quality system. Recently, a long anticipated proposed rule on good manufacturing practices for combination products was published. For pre-filled injection devices, it suggests that compliance with a drug-device quality system hybrid will be required. FDA is expected to issue additional guidance describing how manufacturers can design and implement a quality system that combines elements of the drug the drug and device GMPs. Manufacturers should to prepare for the day when the proposed rule becomes a regulation. Six months later it will be an enforceable regulatory requirement. The presentation will discuss the proposed rule and actions that manufacturers of drug pre-filled injection devices will need to take in order to comply with the new regulation.

9:15 **Application of 2D Bar Codes to Pre-filled Syringes – Methods and Progress Towards Regulatory Requirement**
Dr. Michael N. Eakins, Principal Consultant, Eakins & Associates
The presentation will review methods to add 2D barcodes to syringe components. On the regulatory front, measures to implement serialization of pharmaceuticals and establish electronic pedigree (e-pedigree) are proceeding slowly in the USA. The current situation will be discussed including the FDA Amendment Act of 2007 and individual state initiatives requiring the establishment of drug pedigrees.

10:00 **Q&A**

10:15 *Refreshment Break*

MANUFACTURING CASE STUDIES

10:30 **EZ-fill Vials and Cartridges: Standard Sterile Packaging Solution Suitable for Small Batches in a Ready to Use Format**
Howard Drake, R&D Manager, Glass Division, Nuova Ompi

The pharmaceutical market is moving towards complex and specialized drugs where manufacturing small-scale commercial batches on flexible production is mandatory in providing more effective treatments targeting specific diseases. Time to market and shorten development cycles are key factors in driving the investments of new drug developments. This paper illustrates an integrated packaging solution in a standard format. Leveraging from the experience of nest & tub pre-filled syringes, EZ-fill vials and cartridges are ideal for Isolator/RABS production and biotech products; the concept covers the growing trend to choose combined packaging and devices. The paper will include overview of the following aspects:

- Quality of ready to use vials and cartridges and sterilization procedures compliance
- Delivery on the market based on a standard packaging format (nest, tub, tray)
- Partnership with equipments vendors in order to provide support on handling procedures and filling operations

11:15 **Daikyo Crystal Zenith® Packaging Systems for Parenteral Administration of Biopharmaceuticals and Biological Products**
Dr. Vinod Vilivalam, Director of Strategic Market and Technical Development, Daikyo Crystal Zenith, Innovation, West Pharmaceutical Services, Inc.

The number of drug products packaged in injection devices is increasing, especially in the area of biopharmaceutical drug delivery. Newer proteins are characterized by higher doses, and are extremely sensitive to packaging materials. As a result, optimization of drug product stability in an injection device becomes critical in the early stages of the drug development process. Choosing inert, less reactive packaging materials is essential for maintaining stability over the drug's shelf life.

The discussion will focus on West and Daikyo products that address various scientific and market needs. The presentation will include attributes of the Daikyo Crystal Zenith (CZ) 1 mL long pre-fillable syringe, which is made from a cyclic olefin polymer that is break resistant, silicone oil free, and tungsten free, as it relates to drug storage systems for biopharmaceuticals, and that lends itself to a consistent performing delivery system when combined with an auto-injector. The discussion will also include sterile CZ vials and bulk container systems that are proven to be effective for low temperature storage for biopharmaceutical and cell therapy products.

12:00 *Pre-lunch Exhibitor viewing*

12:30 *Lunch*

1:45 **Pre-filled Syringe Processing with RABS, Isolators, E-beam & Alternatives**
Jim Spolyar, Sales and Technical Director, SKAN US, Inc.

This presentation will highlight the aseptic processing lines that have been installed for pharmaceutical syringe filling around the world. There will be an analysis of RABS and Isolator technology, as well as the use of E-Beam for tub entry, with some alternatives for low speed production.

- Isolator technology with latest E-Beam design features
- Comparison of RABS vs Isolators
- Alternative tub entry system for slow speed production
- Expansion of the areas of application of syringe technology

FILLING & INSPECTION CASE STUDIES

2:30 *Refreshment Break*

2:45 **Visual Inspection of Pre-filled Syringes**
Andreas Rothmund, Vetter

- Why do we inspect? – The legal side
- Inspection basics
- Defects – classification and defect evaluation list(s)
- Inspection methods – pros and cons
- Automated visual inspection of syringes – scope and limitations
- Some newer developments

3:30 **Strategies for Pre-Filled Syringes Inspection**
Peter Spinelli, Sales, Eisai Machinery USA, Inc.

EISAI's 600 per minute inspection of pre-filled syringes, including the technology used for both particulate matter detection and cosmetic defects such as cracks on the barrel, stopper defects and tip cap and needle shield areas will be presented. In addition, latest software features such as Regressive Testing will be described.
Attendees can benefit by topics covered such as:

- Methods used to qualify automated inspection
- Best practices and sources for the development of test kits
- Typical challenges found in developing a project for automating the inspection process

4:15 **Q&A**

5:00 *Close of Conference*

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Strategic Development, Inspection, Safety & Regulatory Compliance and Commercialization of Pre-Filled Syringes

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