Pre-Filled Syringes Forum 2012

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

JULY 26-27, 2012, 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
- Elastomeric Components
- Syringe Manufacturing
- Extractables & Leachables
- Combination Products

Featuring Representation From:

- Chimera Consulting North America
- Pfizer
- Vetter-Pharma
- Kiang Consultant Services
- Trotter Biotech Solutions
- Abbott
- BD Technologies
- BOSCH
- STELMI
- Zeon Chemicals L.P.
- Eisai Machinery U.S.A. Inc.
- Gerresheimer
- West Pharmaceutical Services, Inc.
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Thursday, July 26, 2012

**8:45**  
Chairperson's Welcome and Opening Remarks

**9:00**  
**FDA QUALITY SYSTEMS UPDATE**

Current State of the FDA Regulatory Framework for Quality Systems and Safety Reporting for Combination Products  
**Michael Gross, Senior Consultant, Chimera Consulting North America**

In 2009 FDA’s Office of Combination Products issued two proposed rules, one on quality systems for combination products and another on safety reporting for combination products. FDA has received a considerable number of comments from the pharmaceutical and medical device industries through direct company and trade association commentary. FDA has indicated that it expects to issue the final rules mid-2012. This presentation will consider the current state of the regulatory framework for quality systems and safety reporting for combination products and will include a discussion of industry concerns expressed in comments and, if issued, a review and discussion of the final rules.

**9:45**  
**MATERIALS CONSIDERATIONS**

Future Materials for Pre-filled Syringe Components  
**Patty Kiang, PhD, Kiang Consultant Services**

Pre-filled syringes are becoming a popular tool for sterile injectable drugs due to its ease of use, enhance of compliance, and reduce waste of expensive drug and marketing differentiation. There are still some drawbacks due to the breakage of glass barrel, silicon coating on inside of glass barrel causing protein aggregation, Tungsten vapor causing Protein degradation, rubber plunger leakable causing toxic effect etc. Due to all these reasons there is a definite need for better syringe construction materials and components. A special clear plastic pre-filled Syringe with Flurotec laminated rubber plunger, without silicone oil lubricant and Tungsten heated needle to eliminate leakable and protein aggregation concerns will be discussed.

**10:30**  
Mid-morning Break

**10:45**  
Glass Delamination: Causes and Effects  
**Michael N. Eakins Principal Consultant, Eakins & Associates**

A number of parenteral drugs have been in short supply in 2011-2012. This is due in part to numerous drug product recalls resulting from the discovery of glass particles or flakes (lamellae) in the product due to delamination of the inner surface. The durability of the inner surface of glass containers is affected both by the conditions under which the glass containers are formed, subsequent handling and treatments and the formulation of the drug product. The USP has proposed a new draft General Information chapter <1660> Evaluation of Inner Surface Durability of Glass Containers that describes the factors contributing to a reduction in inner surface durability and strategies to evaluate/screen batches of glass containers to assess surface durability with individual formulations. The presentation will review these factors that contribute to variability in inner surface durability and screening methods available to assess glass containers.

**11:30**  
Exploring Future Materials for Pre-filled Syringes  
**Toshiro Katayama, Product Manager, Zeon Chemicals L.P.**

There are number of new Pre-filled Cycloolefin polymer (COP) device products in pipeline scheduled to be launched soon. While such products base is expected to expand at accelerated rate, ZEON continues to explore & develop new polymers suited for the medical device field. The presentation will cover:  
1) Key properties of current Medical Cycloolefin polymer (COP) grades, Regulatory Status and Bio-Compatibility, Protein Adsorption study, effect of Gamma/EB/Steam sterilization  
2) Introduction of new products & technologies under development.

**12:15**  
Luncheon and Exhibit Viewing

**1:30**  
Pre-filled Syringes – Update on Material and Quality  
**Dr. Arno Fries, Director Product Management Tubular Glass, Gerresheimer**

The question regarding the ideal primary packaging material for pharmaceutical products is discussed in the industry. Pre-filled syringes from cyclic polyolefin materials have been developed and are applied for specialty drugs and diagnostic agents. Glass syringes are used for the majority of heparins, vaccines and biotech products in the pre-filled syringe market. In this presentation, special focus is placed on the current discussion related to glass as raw material for syringes and other drug containers. The topics covered include:  
• Trends in the pre-filled syringe market  
• Pre-filled syringes from plastic and glass  
• Glass as packaging material for syringes and vials  
• Quality and durability of glass containers

**2:15**  
Innovations in Elastomer Components for Prefillable Syringe Systems  
**Tibor Hlobik, Associate Director, PFS Technologies**

Quality requirements for elastomeric closures continue to be refined and Pharma/Biotech companies expect suppliers to deliver safe and reliable products that minimize patient risk. New standards such as Quality by Design, automated inspection and steam sterilization for finished product are being applied to closures to meet patient needs. A deeper review of specification trends, how suppliers are changing their development and manufacturing strategies and details of new innovative
KEY CONSIDERATIONS AND REQUIREMENTS FOR AN APPROPRIATE “SYSTEM” APPROACH

product solutions will be covered during the presentation. Several case studies will also be included that outline how cost of poor quality, impact of an extractables profile on drugs and poor syringe functionality can be reduced with proper selection of elastomeric products. The benefit of this information will be that packaging decision-makers fully understand material options when selecting syringe platforms and can mitigate potential quality risks during drug development through commercialization.

3:00 Afternoon Break

3:15 Future-Oriented Processing of Nested Syringes, Syringe Filling: Pre-sterilized in Nest and Tub

Jamie Schroetter and Dena Flamm, BOSCH

There is a significant growth in the need for administer- ing drugs thru the use of syringes as well as the need for flexibility. This session will cover fully automated lines with disposable filling systems, interchangeable fill systems and design for easy use within barrier systems to demonstrate flexibility. Aseptic transfer of nested syringes in pre-sterilized and bagged tubs into aseptic filling environment is much discussed due to residual risk of bag integrity. To make use of the increased quality with advanced aseptic processing in barrier systems the transfer of the syringes could be the weak link due to re-contamination of aseptic production environment with bioburden introduced via transfer of the tub. A variety of techniques to keep tub integrity during transfer or rester- lization to the outside of the tub could be applied. Characteristics, benefits and disadvantages of common techniques are introduced.

4:00 Exhibit Viewing

4:30 End of Day One

Friday, July 27, 2012

PRE-FILLED SYRINGE CASE STUDY

9:00 Pre-Filled Syringe Case Study – Determining Decision Factors for Extractables Studies and Testing Laboratory Service Providers

A. Mark Trotter, Trotter Biotech Solutions

The growing use of polymeric materials utilized in Pre- filled Syringes has spurred new investigations into the question of extractable profiles and polymeric materials leaching into finished pre-filled Injectable products. This Case Study attempts to outline and review the necessary decision factors and testing parameters needing consideration when choosing an appropriate syringe and component materials. These newer materials include for example, Cyclic Olefin Polymer (COP), Cyclic Olefin Copolymer (COC), fluoropolymer and elastomeric components, e.g., plungers and tips. The advantages of these new materials making their use desirable may necessitate further investigation into extended stability studies using Arrhenius and Q10 assumptions/calculations, extractables and leachables (E&L) studies, and compatibility testing, when changing syringe and component base materials, e.g., glass, polypropylene, silicone. We will examine the various sta- bility, compatibility and E&L testing parameters required to meet or exceed Regulatory compliance and Industry standards. Additionally, examining the key decision factors such as analytical testing capabilities and analysis will assist in investigating and choosing an appropriate Contract Laboratory Organization (CLO.) The use of spreadsheets and matrices focuses on these key decision parameters resulting in more effective and efficient decision analysis.

10:00 Exhibit Viewing and Mid-Morning Break

10:45 Managing the Impact of a Material Change in Components of Pre-Filled Syringes

Michael A. Ruberto, Material Needs Consulting

The characterization and control of extractables and leachables from the plastic and elastomers used in pre- filled syringes is a formidable task for the pharmaceuti- cal industry. Obtaining information from vendors regarding the composition of container closure system compo- nents can be a challenge, and even when this data is ini- tially supplied, the communication of material changes that can affect the leachables profile of these compo- nents during development or after commercialization can be an issue. The supply chain associated with the fabrica- tion of pre-filled syringe components can be quite

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complex. There are many suppliers of raw materials, such as additives and resins, that are further upstream and not under the direct influence of their downstream pharmaceutical customers. This presentation will provide a comprehensive review of the polymer supply chain for pre-filled syringe components as well as potential areas of concern. Case studies that illustrate the types of changes that can occur, both announced and unexpected, and their chemical and regulatory impact will be discussed. Specific topics will include:

- Introduction to polymers and additives
- Common changes to pre-filled syringe components
- Efficiently dealing with unexpected changes
- Implementation of control measures to evaluate new batches of components
- Partnering with vendors to establish an effective change control process

The following step then consists in installing visual inspection automatic machines at the end of production to control the components. These machines have to be specifically adapted to elastomer plungers and the potential defects identified.

In this presentation we will develop the integration of a 100% automated inspection system for plungers, demonstrating the efficiency of the process, and we will illustrate the impact on quality improvement.

Development and Regulatory Strategies to Effect A Change from a Vial Presentation of a Drug or Biological Product to a Prefilled Injector Presentation

Michael Gross, Senior Consultant, Chimera Consulting North America

This presentation will consider current technical and regulatory requirements and development strategies to effect a change from a vial presentation of a drug or biological product to a prefilled injector such as a prefilled syringe, auto injector, injection pen or microneedle patch. The presentation will consider submission strategies such as a new NDA or a sNDA CMC submission including the possibility of using a comparability protocol. The content of these submissions and acceptance criteria for product comparability will be considered. The use of pharmacokinetic bridging studies and human factors studies to validate the injector design will also be discussed.

11:30 Pre-Filled Syringe Processing with RABS, Isolators, E-Beam & Alternatives and RABS & Total Room Decontamination with H2O2 Vapors

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. Also the latest isolator for aseptic/toxic nested syringe filling. Also, a short presentation on total clean room de-contamination with H2O2 vapors.

- Isolator technology with latest E-Beam design features
- Alternative tub entry system for slow speed production
- Expansion of the areas of nested syringe filling technology to aseptic/toxic
- Comparison of use of RABS to Isolators
- Total cleanroom decontamination using H2O2 vapor

12:15 Exhibit Viewing and Lunch

1:30 Automated Visual Inspection System for Pre-Filled Syringe Plungers

Damien Saleur, Technical Support Manager, STELMI

Evolution in the drug industry and the potential impact of certain defects in the appearance of pharmaceutical elastomer closures require the establishment of ever stricter quality specifications to meet the latest demands of pharmaceutical laboratories. In the absence of a standardized frame of reference for appearance defects that is applicable to elastomer components for pharmaceutical use, the syringe component supplier has to identify the potential defects and can establish its own frame of reference, classifying them into categories from refusal defects to minor ones. As visual quality is first of all the result of a total control of the manufacturing process, the frame of reference has to be associated with a specific production process to eliminate appearance defects at the source.

2:15 Q&A with Conference Faculty and Exhibit Viewing

3:30 Close of Conference
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