PharmaED RESOURCES, Inc.

2016 Pre-Filled Syringes Forum:

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

April 4-5, 2016, Racquet Club of Philadelphia, PA

Featuring Lessons Learned and Case Studies From Industry Experts:

Akshay Kamdar
Sr. Consultant Engineer, Lilly

Doug Ball
Research Fellow, Pfizer

Michel Mikhail
Sr. V-P, BioNTech AG

Edmond W. Israelski
Dir. Human Factors, AbbVie

Ian Thompson
V-P, Ypsomed AG

Pharma Ed Resources, an industry leader since 2004 in delivering market-driven research on pre-filled syringes, is proud to announce its 2016 Pre-Filled Syringes Forum. With the global market for PFS expected to top $6.5 billion dollars by 2020, the biopharmaceutical industry is looking for next generation materials, technologies and production strategies to streamline commercialization and to adapt quickly to a changing regulatory environment. That is why you cannot afford to miss this intensive two-day training event. Pharma Ed brings together top researchers and innovators to share best practices and the latest science, enabling you to maximize your organization's leverage in this dynamic and growing market.

Including Special Coverage On:

- **A PFS Case Study—FDA Warning Letter for a Combination Product**
- **Key Factors in Combination Product Development: Regulatory Hurdles in Receiving PFS and Pen Approvals for Human Factors Studies**
- **Next Generation Materials & Design of Pre-Filled Syringes**
- **Applying a Systems Engineering-Based Approach for Developing PFS**
- **Finite Element Analysis Modeling Applications to PFS and Autoinjector System Design**
- **Improving Quality and Cost Control Through Fully Automated Manufacturing of Customized Disposable Pen and Autoinjector Devices**
- **Fully Automated, Semi-Automated, and Manuel Inspection Technologies for Safety and Quality in PFS Manufacturing**
- **Update on USP's General Chapters Revisions on Packaging Components for Pre-filled Syringes**
- **A Complete E&L Qualification Case Study of New Label on Plastic PFS**
- **Managing the Materials used to Construct Pre-Filled Syringes—Selection and Supply Chain Control**
- **Overcoming Complex Requirements for Biologic Drug Delivery**
- **And Much More!**

Featuring Representation From:

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Monday, April 4, 2016

7:45 *Complimentary Breakfast & Chairperson's Welcome*

Critical Issues—Examining the Regulatory Environment for Pre-Filled Syringes & Injector Pens

8:15 **Combination Product Development: Regulatory Hurdles in Receiving PFS and Pen Approvals for Human Factors Studies**

Edmond W. Israelski, Ph.D., Director Human Factors, AbbVie

This presentation examines regulatory hurdles in receiving PFS and Pen approvals for human factors studies. What are the FDA guidances and relevant standards from IEC/ISO and AAMI for human factors? The acceptance criteria for safety related use scenarios and tasks is qualitative for FDA; there are no quantitative usability objectives. In this context, topics to be covered include:

- Minimal sample size of 15 per distinct user group in summative usability testing
- Learning decay included in usability test protocol
- Extensive subjective probing for residual risk
- Use error probability in use FMEA
- Likert rating scale measures of usability satisfaction

We will also explore the differences within the US FDA between CDER and CDRH for Combination Products Including:

- Worst case no training arm in summative validation tests for CDER
- At home use tests often expected by CDER
- CDER sometimes asks for labeling changes even when manufacturer has usability test data to support label design

8:55 **Pre-Filled Syringes Case Study: US-FDA Warning Letter**

CASE STUDY

Dr. Michel Mikhail, Senior Vice President, Global Head Regulatory & Development, BioNTech AG

This case study uses a recent US-FDA Warning Letter to explore the regulatory implications of key definitions established for the industry. These include:

- 21 CFR Part 4 - cGMP for Combination Products

As set forth in part 3 (21 CFR Part3), a combination product is a product comprised of any combination of a drug and a device; a device and a biological product; a biological product and a drug; or a drug, a device, and a biological product.

- Rule 21 CFR Part 4 became final in January 2013 and became effective180 days later

21 CFR part 4 comments and clarification:

A syringe is a device used to deliver another medicinal product (e.g., a drug) (see, e.g., 21 CFR 880.5860). Accordingly, a prefilled syringe is a combination product and subject to this rule. The implications of these and other rules shaping product development and patient safety will be discussed.

9:35 *Mid-Morning Coffee & Networking Break*

Industry Updates—PQRI Best Practices & USP General Chapters

10:00 **PQRI PDP Best Practices: Use of a Classification Strategy to Develop Analytical and Safety Thresholds for Parenteral Drug Products**

Dr. Doug Ball, Research Fellow in Regulatory Strategy and Compliance, Pfizer

Contemporary parenteral drug products make use of the advantages that modern container closure systems and materials provide for technical and functional purposes as well as marketing/brand recognition. Despite the advantages, these systems also present the potential for contributing impurities to the formulated drug product in the form of leachables. As with any impurity, leachables do not provide any therapeutic benefit to the patient using the drug, and their presence only makes for concerns for drug product quality and/or safety as related to inadvertent exposure. As such, the drug developer has an obligation to demonstrate leachables have negligible impact on quality and/or safety when the drug product is used as intended. Leachable qualification can present both analytical and safety evaluation challenges to the scientist involved in the risk assessment process. For example, when the available information for the evaluation is limited in terms of the toxicological potential of any of the substances that emerge as leachables, additional in vitro and/or in vivo studies may need to be conducted to assess potential risk. In recognition of the obstacle that limited data presents, the Product Quality Research Institute (PQRI) Parenteral and Ophthalmic Drug Product (PODP) work team has developed scientifically-justified threshold levels for analytical and safety evaluation of extractables and leachables from parenteral drug products. In addition, the work team has developed a classification strategy to facilitate qualification of extractables and leachables with limited data to conduct a safety evaluation.

10:40 **Revision of USP's General Chapters on Packaging Components for Pre-Filled Syringes**

Michael N. Eakins, Ph.D., Principal Consultant, Eakins & Associates, Inc.

Primary packaging components for pre-filled syringes include both glass and plastic as well as elastomers. The USP published a major revision to chapter <661> under a revised title Plastic Packaging Systems and their Materials of Construction in USP 39 NF 34. The revision of this chapter encompasses concepts detailed in the USP chapter on extractables <1663> Assessment of Ex-

tractables Associated with Pharmaceutical Packaging/ Delivery Systems and ICH Q3D Guideline on Elemental Impurities. The revision will be discussed as it relates to pre-filled syringes, including the addition of new plastic resins and how the revision aligns with the chapters on plastic packaging components in the European Pharmacopoeia. The USP has also begun a revision of <381> Elastomeric Closures for Injections which also will follow concepts provided in <1663> and ICH Q3D and the general approach to this revision will be discussed.

11:20 **Applying a Systems Engineering Based Approach for Developing a Prefillable Syringe System**

Akshay R. Kamdar, Senior Consultant Engineer / Group Leader — Syringes, Eli Lilly & Co.

A delivery/device system requires the integration of three main elements: (1) the drug formulation; (2) the primary container closure system such as prefillable syringes and; (3) the device the patient will use to administer the drug. A fundamental understanding of the interaction between the three elements is very important. Failure to design the system correctly could be detrimental on the overall function of the device, especially for autoinjectors.

The functional performance of prefillable syringes can be impacted by several factors such as protein concentration and viscosity, barrel silicone level and distribution, plunger geometry and siliconization, contact pressures between the syringe barrel and the plunger, and interaction of the drug product with the silicone oil over time. With our advancement in understanding the impact of some of these factors, technical risks around the performance aspects of the existing prefillable syringe device were identified. This drove the need to apply a more robust, systems engineering based approach to develop and implement a next generation prefillable syringe system to meet some of the challenges identified as part of Lilly's continuous improvement efforts.

This presentation will highlight some of the risks identified with the existing prefilled syringe systems, the approach adopted to understand some of these risks and compare the critical quality attributes (CQAs) such as the performance aspects between the existing and the next generation prefillable syringe system.

12:00 ***Complimentary Lunch & Networking Hour***

Spotlight on Next Generation Polymer Syringes for Biopharmaceuticals

1:15 **PLAJEX™ Polymer-Based Prefilled Syringes and its Value with a Novel Tapered Needle Design for its Use in Place of On-Body-Injection Devices for Sensitive, Viscous, Therapeutic Proteins**

Kevin Constable, Senior Director, Technology Development, Terumo Global Pharmaceutical Solutions

The audience shall be presented with an overview of the various features of PLAJEX™ ready to use prefillable syringe system with a novel tapered needle for mitigating the risks of high forces due to viscous products, aggregation due to silicone oil, leachables due to extractables from container materials, and an applied method of sterilization for a reduction in drug degradation due to radicals.

1:55 CASE STUDY **The Preliminary Stability Data of Drugs in a Novel Plastic Safety Syringe**

Robin Hwang, Owner/Director, ICP Consulting Corp., MCI, TheraKine

PFS has many benefits but comes with the risk of needle-stick injury on its own. With the trend of global needle-stick legislation, most drug products in PFS require sharp protection devices driven by healthcare worker safety concerns and the regulatory mandates. While the approach for making syringes safe continues to be dominated by add-on needle cover devices, integrated prefilled safety syringes (in glass and plastic) are now being developed. MCI's MySafety Syringe is a user-activated, automatic needle-retraction safety syringe. At the end of injection, by pushing the collapsible plunger rod, the used needle retracts and is sequestered inside the syringe barrel. MySafety Syringes are already commercialized as empty PP syringes (in 1cc and 3cc) and are turned into an integrated plastic prefilled safety syringe (iPPFSS) in nested tub with COC and COP differentiated by its simple design and container closure system. iPPFSS (aka MySafill syringe) takes advantage of material design flexibility, eliminates glass breakage and provides a great life cycle management tool for drug products in PFS. It could ensure the quality of syringes before fill and would not waste the precious drugs due to assembly process that could occasionally happen to the add-on devices. Its compact design saves costs in cold storage space, transportation and waste disposable. The design of MySafill Syringe is different from all the safety syringes in the market (or under development) and is easier to industrialize as already demonstrated by the commercialized empty PP syringes. We will present preliminary stability data on drug product compatibility with MySafill Syringes and compare against typical glass PFS.

2:35 ***Afternoon Coffee & Networking Break***
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3:00 **Polymer Syringe Systems— Practical Considerations**

Scott Young, Ph.D., Vice President, Daikyo Crystal Zenith Division

Glass syringes remain the standard for primary containment systems for parenteral drug formulations worldwide. With the advent of biopharmaceutical products some inherent characteristics of glass have proved problematic. The biopharmaceutical industry has to cope with certain disadvantages associated with glass containment systems. In particular, issues around glass breakage, incompatibility with silicone oil lubricant, tungsten residue, needle glue or breakage within auto-injectors

and vial glass delamination due to high pH drug or diluent formulations are found with glass systems.

One of the most promising materials to manufacture plastic prefillable syringe system from is Daikyo Crystal Zenith® (CZ). This unique material from the cyclic olefinic polymer (COP) family comprising a unique array of physical and chemical properties suited best to address the unmet needs of biopharmaceutical drug makers. Specifically, the total elimination of silicone oil and lack of tungsten and glue residues in the syringe systems leads to a significant reduction of drug-containment interactions potentially leading to protein aggregation. Furthermore, the Daikyo Crystal Zenith® prefillable syringe system demonstrate high break resistance and leverage the unique combination of Crystal Zenith® material with Flurotec® laminated elastomeric components for low E&L profiles. This session will discuss key attributes of the Daikyo Crystal Zenith container system ideal for today's sensitive biopharmaceutical drug delivery applications.

3:40 **Technical Data Update–Cyclo Olefin Polymer (COP)**

Toshiro Katayama, Product Manager, Zeon Chemicals LP

Cyclic Olefin Polymer (COP) is very pure, amorphous, high transparent and non polar plastic with excellent chemical resistance and moisture barrier. COP can be extruded, injection molded and blow molded and they are EtO, Gamma and steam sterilizable.

This presentation will cover:

- Key properties and features of COP & its benefits for Pre-filled syringe applications
- Mechanical properties after exposure to gamma, steam, EOG and cryogenic temp
- JP, US, EU Pharmacopoeia and ISO 10993 status
- Extractable/leachable test data
- Delamination study data on glass syringe
- Moisture/Gas barrier data
- Residual metal and outgas data
- COP marginal stress data vs. various chemicals
- Protein Adsorption study with BSA. Insulin, IgG
- EB & Gamma irradiation-color shift study

4:20 **Comply to FDA Requirements For Combination Products—Integrating Design Controls Into the Pre-Filled Syringe Development**

Ling Lu,Sr. Principal Scientist, Pfizer Inc

Design Controls used to be device industry vocabulary. Since the Combination Product Final Rule became effective in January 2013, Design Control is required for the combination product development in the pharmaceutical industry. While applying design controls, the pharmaceutical companies experienced challenges which were due to the differences in terminologies, culture, and scientific disciplines between pharmaceutical and device industries.

This presentation will use the pre-filled syringe as an example to:

1. Compare drug and device development processes.
2. Discuss how to integrate the design control activities into the pharmaceutical development; by considering the combo product as a whole, focusing on the interfaces between user and device, drug and device, device and device, and by identifying and filling the gaps.
3. Explore a risk based, value added and more efficient process to apply design controls considering users and use environments; new design or design changes, complexity of device, manufacturing methods, and clinical phases versus commercial.

Panel Discussion

5:00 **What's Next in the World of Pre-Filled Syringes? Re-imagining an Industry Paradigm**

Members of the audience will set the agenda in this open forum discussion of the current state and future of PFS and related injectable devices.

Moderator:

Mathias Romacker, Sr. Director, Device Strategy, Pfizer
Michael Eakins, Principal Consultant, Eakins & Associates, Inc.

Panelists:

Doug Ball, Pfizer
Ling Lu,Sr. Principal Scientist, Pfizer
Robin Hwang, ICP Consulting
Edmund Israelski, AbbVie
Michel Mikhail, BioNTech AG
Ian Thompson, Ypsomed

5:30 ***Complimentary Happy Hour, Sponsored by Terumo Global Pharmaceutical Solutions***

TERUMO

Tuesday, April 5, 2016

8:00 ***Complimentary Breakfast & Chairperson's Remarks***

Technology Spotlight—Automated Manufacture & Inspection of Parenteral Drug Delivery Systems

8:30 **Improving Quality and Cost Control Through Fully Automated Manufacturing of Customized Disposable Pen and Autoinjector Devices**

Ian Thompson, Vice President Business Development, Ypsomed Delivery Systems

Large scale automated manufacture of disposable auto injector subassemblies for multiple customers and customized device versions is a new paradigm for injection device development and manufacturing companies. The

increased quantity demands of disposable injection devices lend themselves to automated manufacture in order to improve their quality and reliability. The presentation covers usability, technical and industrialization aspects for a disposable auto injector system.

9:10 **Pre-Filled Syringe Inspection for Viscous and Non-Viscous Products**

CASE STUDY

Peter Spinelli, Site Manager, Bosch Inspection, Pharma Division

Technologies continue to develop and be applied in the field, with the goal of 100 percent defect detection and 0 percent false rejection as our target. This presentation will explore the latest technologies available to achieve highest detection levels for visible particle and cosmetic defects and container closure integrity and ensure product and patient safety. Automated, semi-automated and manual inspection technologies, including adapting high resolution cameras, vision algorithms, Static Division sensors, high voltage and laser spectroscopy methods will be explored.

9:50 ***Mid-Morning Coffee & Networking Break***

10:15 **Applications of First Principles to Pre-Filled Syringe System Design**

CASE STUDY

Seung-Yil Yoon, Ph.D., Senior Consultant Engineer, Eli Lilly & Co.

Pre-fillied syringe products are becoming more complex due to a proliferation of new drug formulations and injection mechanisms. In a classic approach, available syringe components are tested and the best components are chosen. This design, build and test approach is a time consuming process that makes it difficult to try all possible scenarios needed to optimize design performance, robustness, complexity and cost. First principles modeling of the system can be used to minimize the risk of failures in designing a syringe system that optimally balances the design criteria. This presentation will introduce how first principles and modeling tools have been applied to design a syringe system.

Materials Selection, Characterization and Requirements for PFS and Autoinjector Devices

10:55 **Managing the Materials used to Construct Pre-Filled Syringes – Selection and Supply Chain Control**

Michael Ruberto, Ph.D., President, Material Needs Consulting, LLC

There are many options available when selecting the components for pre-filled syringes including the materials of construction for these components, lubricious coatings, volume, shape, needle configuration, and sterilization pre-treatments. These options must be weighed against the formulation of the drug product that includes its viscosity, solvating power, compatibility, and protection requirements. These choices can be a direct influence on the leachables profile that will ultimately result for the drug in the pre-filled syringe. Proactive selection of the proper components and design of a suitable, efficient E&L testing plan are keys to successful product development. Obtaining information from vendors regarding the composition of container closure system components can be a challenge, and even when this data is initially supplied, the communication of material changes that can affect the leachables profile of these components during development or after commercialization can be an issue. The supply chain associated with the fabrication of pre-filled syringe components can be quite 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 discuss a step-by-step approach for the proactive selection of the appropriate pre-filled syringe components for the conditions of use based on the mechanical and chemical properties of the materials of construction along with their extractables profile. A comprehensive review of the polymer supply chain for pre-filled syringe components as well as potential areas of concern will also be provided. 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:

- Key factors to consider when selecting materials of construction
- Utilizing vendor extractables data to design efficient E&L testing strategies
- Common changes to pre-filled syringe components
- Efficiently dealing with unexpected changes

11:35 **Overcoming Complex Requirements for Biologic Drug Delivery**

Tibor Hlobik, Global Director, Marketing for PFS Technologies, West Pharmaceutical Services

The healthcare market is experiencing rapid growth in the use of self-administration devices with prefilled cartridges and/or syringes to deliver biologic drug products. Ensuring reliability of the drug, container and device as an integrated system becomes even more complex when trying to deliver drugs with higher fill volumes and increased viscosity. Such devices are often associated with more complex user requirements, and may be used to ensure drug brand differentiation. In this talk, we will review component selection strategies being applied by leading companies to mitigate risks associated with defects and particulate, extractables and leachables, and poor device reliability. It is essential that components used to store and deliver drug products be of the highest quality and designed to support combination product needs.

12:15 ***Complimentary Lunch & Networking Hour***

1:15

Methods to Help Control and Distinguish "Inherent", "Extrinsic", And "Intrinsic" Particulate Matter in Pre-Filled Syringes by Membrane Microscopy with Image Directed Raman Spectroscopy

Dr. Olga Laskina, Application Scientist, Rap.ID Inc

Pre-filled syringes are often used for large molecule APIs and are especially vulnerable to silicone oil or tungsten induced protein agglomeration. The USP<1787> chapter "Measurement of Sub-visible Particulate Matter in Therapeutic Protein Injections" defines different particle types: "extrinsic", unexpected foreign material, "intrinsic", from the production environment or primary packaging, and "inherent", from the formulation itself. It is important that the inherent particles be distinguished from the other two types. The revised USP<787> states that membrane microscopy is not the preferred method and is primarily suited for particles other than inherent particles. The gridded filter paper described in USP<787> and USP<788> the MM method cannot isolate fragile or translucent particles, nor can those particles be sufficiently be visualized in a conventional microscope setup. We will show a method that allows the isolation of particles with subsequent enumeration of particles and analysis by means of Raman spectroscopy which is used to obtain fingerprint spectra that allow material identification and differentiation as extrinsic, intrinsic and inherent proteinaceous particles. With a fully integrated database comparison this method gives chemical composition of hundreds of particles per analysis. We will also discuss analysis using a liquid cell that can be used to obtain Raman spectra of suspended particles. These allow the root cause investigation of extrinsic and intrinsic contaminants to avoid further contamination in production as well as characterization of inherent protein particles. The silicone oil syringe barrel coating may affect protein agglomeration and a method for measuring the silicone thickness and distribution will also be discussed.

1:35

PFS Optimization for Biotech Drugs: An Overview of the Most Recent Process Developments Designed to Optimize the PFS for Compatibility With Sensitive Bio-Molecules, as well as the Expanding Use of Autoinjectors for both Novel and Biosimilar Products

Howard Drake, V-P/GM, Ompi of America

Prefilled syringes are industry's choice of platform for further innovating your product and adding value. With biological drug products being so complex, a huge amount of consideration needs to be taken regarding delivery method, design of primary packaging, device and analysis of product stability, safety and efficacy. A system approach is needed because of the interaction between the bio-drugs' unique features (i.e. viscosity), drug delivery devices, such as autoinjectors, and syringes' different geometries and elemental compositions. All these are critical aspects that need to be carefully evaluated in order to guarantee an effective, safe and painless injection to the patient. This presentation will highlight how to set critical parameters to fulfill these requirements.

2:15

A Complete E&L Qualification Case Study of New Label on Plastic PFS

CASE STUDY

Tina Tubbs, Deputy Director, Sanofi Pasteur

This presentation will cover an E&L qualification case study of new label on plastic PFS. The presentation will encompass the following studies: 1) Extractable studies of ink, label and adhesive; 2) Simulated in-use leachable study with labeled plastic PFS; and 3) Leachable migration study from label into the plastic syringe.

2:55

The Evolution of Fluoropolymer Coatings for Parenteral Packaging

Susan M. Dounce, Ph.D., Senior Manager, Injection Systems, Datwyler Sealing Solutions

In the conservative, data-driven industry of parenteral packaging, market trends indicate a growing demand for fluoropolymer-coated elastomeric closures, primarily to mitigate risks related to drug stability and compatibility. Traditionally, the design of coated closures has focused only on barrier properties. However, reducing rubber leachables, while critical, is no longer the sole driver for coated closure development, and it is no longer enough to meet the needs of biologic and ophthalmic drug packaging. Particularly, silicone oil, and its direct and indirect contributions to particle levels, has become both a significant nuisance and a legitimate concern. This talk will discuss the role of silicone oil in syringe performance and opportunities to reduce subvisible particle levels while maintaining functionality.

3:35

Polymer Prefillable Syringes in Combination with Syringe Pumps – A Potential Solution to Improve Medication Safety in Hospital Care Environment

Anil Kumar Busimi, Head of Global Product Management Syringe Business, Schott Pharmaceutical Packaging

Numerous studies have reported that errors occur during the preparation and/or administration of IV drugs hospital care environments. The problems could include wrong dosage due to mistakes in the manual dose calculation or in the preparation; low percentage of adequate labelling. These might lead to patient safety risk and consequently to the need of longer intensive care thus cost increase for hospitals. Health Care Authorities measures have increased requirements to mitigate these risks. However, to reduce costs and risks, hospitals started outsourcing drug admixture to specialized companies. However these companies' uses single use Polypropylene syringes in a semi-automatic filling process and can only guarantee the drug stability for a short period of time.

Polymer prefillable syringes (PFS) made out of high-tech polymers like Cyclo-Olefin Copolymer (COC) could

help reduce such potentially harmful errors increasing medication safety requirements, and increasing drug availability in Hospital Care environment. COC PFS in combination with syringe pumps allow controlled and very precise delivery of high potency drugs with short biological half life as e.g. some hypnotic - and inotropic drugs in Hospital Care environment.

Schott will share its experience and thoughts how the large volume PFS (10 mL, 20 mL and 50 mL formats) in combination with syringe pumps could improve medication safety and also help reduce the total cost of drug administration in hospitals. The following points will be discussed in the presentation.

- Challenges in the current practices for infusion therapy
- Design requirements for COC prefillable syringe to be used in combination with syringe pumps
- Potential challenges in such a project and how to overcome that?

We believe this could become the solution of choice for drugs with a narrow therapeutic window and administered with syringe pumps. The results may have broader application in future development projects for safer drug delivery systems.

4:05 *Close of Program*

Pharma Ed's 8th Annual Pre-Filled Syringes Forum is Sponsored By:

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