PharmaED RESOURCES, Inc.

2018 Pre-Filled Syringes Forum:

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

April 3–4, 2018, Racquet Club of Philadelphia, PA

Featuring Lessons Learned and Case Studies From Industry Experts:

Suraj Ramachandran
Director, Regulatory Affairs, Drug-Device Center of Excellence, ***Merck***

Mayumi Bowen
Senior Engineer, ***Genentech, Inc***

Rajiv Gupta
Device Program Leader, Associate Director (Medical Device), ***Shire***

Olga Laksina, PhD
Laboratory Director, Senior Scientist, ***rap.ID, Inc.***

Kashappa Goud Desai
Investigator, Biopharmaceutical Product Sciences, ***GlaxoSmithKline***

Alireza Jahangir
Sr. Manager, Combination Products & Emerging Technologies, PQM, ***The Janssen Pharmaceutical Companies of Johnson & Johnson***

With the Pre-Filled Syringes market expected to top $16 billion dollars by 2021, the industry is looking for next generation materials, technologies and production strategies to streamline commercialization and to adapt quickly to a changing regulatory environment. Pharma Ed Resources, an industry leader since 2004 in delivering market-driven research on PFS, is proud to announce its 2017 Pre-Filled Syringes Forum. Pharma Ed brings together top scientists, regulatory experts and innovators to share best practices and the latest research in this field, enabling you to maximize your organization's leverage in this dynamic and growing market.

Including Special Coverage On:

- **Critical Issues—Examining the Regulatory Environment for Pre-Filled Syringes & Combination Drug-Delivery Systems**
- **Quality and Regulatory Affairs Best Practices for External Partnerships in Combination Product Development**
- **Ophthalmic Injections: The Manufacturer, Regulator, Physician, and Patient Ecosystem**
- **Applying Quality-by-Design Principles to the Development of Pre-filled Syringes**
- **Filling of High-Concentration mAb Formulations into Pre-filled Syringes – Understanding Nozzle Clogging and Filling Accuracy**
- **Syringe Siliconization and its Role in Protein Aggregation**
- **Pre-filled syringes(PFS) and container closure integrity testing (CCIT)**
- **Challenges and Opportunities for Development of Stability Program for Combination Products**
- **Devices for Self-Injection: Advantages of the Platform Approach**
- **Challenges Associated with PFS Combination Product Development for Ophthalmic Applications**
- **Strategic and Technical Considerations for PFS and Auto injector Development for Biologics**

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Tuesday April 3, 2018

7:30 *Complimentary Breakfast*

8:00 *Welcome and opening remarks by Chairperson: Michael Eakins,* Principal Consultant, Eakins & Associates, Inc.

8:05

Critical Issues—Examining the Regulatory Environment for Pre-Filled Syringes & Combination Drug-Delivery Systems

Suraj Ramachandran, MS, RAC, Director, Regulatory Affairs, Drug-Device Center of Excellence, Merck

Over the past several years, combination products (which include pre-filled syringes) ,have become more of a household name both from an Industry and Health Authority perspective. It is only fitting that as the number of combination products available on the market continues to increase from previous years, so does the available guidance and scrutiny from regulators around the world. Legislation such as the 21st Century Cures Act, and the European Medical Device Regulation (MDR), has shed light on the direction that the regulation of combination products is heading. In this presentation, we will take a look at the evolving global regulatory landscape for combination products, best practices for regulatory filings, identification of regulatory opportunities and challenges, and future regulatory considerations for combination products as we move forward.

8:50

Quality and Regulatory Affairs Best Practices for External Partnerships in Combination Product Development

Jonathan Amaya-Hodges, Senior Manager, Regulatory Affairs CMC Combination Products and Medical Devices, Biogen

Combination products, particularly drug delivery systems, are becoming more prevalent with the increasing need for both product differentiation and ease of use for patients. These systems are often developed in partnerships between a biotechnology or pharmaceutical company and a device designer/manufacturer, and with the implementation of the combination product rule in the US (21CFR4), an effective working relationship between those parties becomes essential, particularly in Quality and Regulatory aspects. This presentation will highlight best practices in these areas including how companies can move beyond minimum compliance in order to establish and maintain an efficient, responsive, and mutually beneficial partnership for developing and supplying drug delivery combination products, including pre-filled syringes and auto-injectors.

9:30

Applying Quality-by-Design Principles to the Development of Pre-filled Syringes

Kashappa Goud Desai, PhD, Investigator, Biopharmaceutical Product Sciences, GlaxoSmithKline

Pre-filled syringes serve as both primary container closure and delivery device for drug products. The effect of pre-filled syringe components (e.g., plunger and needle), extractables/leachables (e.g., silicone oil and tungsten), shipping and storage conditions, and the potential interactions between these variables on drug product quality and stability, syringe functionality, and container closure integrity needs to be evaluated via a systematic approach. This can be accomplished using Quality-by-Design (QbD) principles. The QbD is a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management. This presentation summarizes the QbD principles/approaches applicable to the development of pre-filled syringes.

10:15 *Mid-Morning Coffee & Networking Break*

10:40

Ophthalmic Injections: The Manufacturer, Regulator, Physician, and Patient Ecosystem

Susan M. Dounce, PhD., Principal SME, Pre-filled Syringes, Crystal Zenith and Combination Products, West Pharmaceutical Services, Inc.

When it comes to ophthalmic injections, several distinct complex networks of interactions have evolved which reflect very different relationships between drug manufacturers, regulators, physicians and patients. These ecosystems present shared benefits to the different functional stakeholders but also have created new unmet needs in the primary packaging of biologic drugs for ocular injection. Here we will discuss an overview of the current and evolving ophthalmic injection market with a focus on anti-VEGF therapies for macular degeneration and related diseases. A case study will be presented to demonstrate the decision-making process of the physician and patient when selecting a treatment option. Strategies for addressing the current and future unmet needs around primary packaging will also be addressed.

11:20

Industrial Vacuum Liquid & Waste Water Conveyance Systems Within Cleanroom Syringe Washing Operations & other Applications

CASE STUDY

Philip Crincoli, LEAN / OSHA 40 Certified Industrial Segment Manager, and Clint Hawn, Vice President Operations, Aqseptence Group, Inc., Vacuum Technology Systems

An overview of how indoor & outdoor vacuum wastewater conveyance systems create value within industrial settings including FDA regulated properties

As Airvac evolved in the late 1960's, they quickly became known as the entity responsible for modernizing todays Vacuum Wastewater and Sewer Technology Systems. Today, Airvac® is considered the industry standard as both the U.S. EPA and the Water Environment Federation feature our patented system in their published technical manuals. In the 1970s, our company began applying their vacuum wastewater conveyance technologies in Cleanrooms and other industrial setting including FDA regu-

lated companies such as Merck, Avara, Bayer, Eli Lilly, Upjohn (Pfizer) and Roche.

Liquid collection systems in FDA & USDA environments require flexibility & reliability. With the capability to vertically lift liquids up to 21 feet & transport them horizontally over long distances, vacuum technology liquid conveyance systems provide unmatched layout flexibility particularly in Cleanroom settings. Some of the features and benefits of installing a vacuum powered wastewater conveyance systems include:

- Shorter construction duration as labor and project schedule is significantly shorter up to 60%
- Piping in the wall, ceiling, attics and other confined spaces is more easily installed
- Design and installation with piping flexibility (vertically and horizontally). Most obstacles can be simply bypassed. Piping can go up and around obstacles up to 20 foot vertically
- Small pipe diameter (typically 1 ¼"– 4") can literally be installed anywhere
- No blockages—liquid transport at 15–18 feet per second scours out piping regularly
- No dual containment piping is required as the system is leak proof operating in a vacuum. Vacuum pulls air inward and there is no external leakage/contamination. Pipe punctures don't leak liquid but rather suck more air into the system.
- Safe and reliable separation of different classifications of wastewaters for specified treatment including biological and chemical contamination.
- Infrequent maintenance can be performed outside the Cleanroom or Controlled Environmental area limiting downtime.
- Ease of future renovations and extensions. The system can be expanded or modified at a later date should circumstances change.
- A number of the original systems installed have been operating since the 1970s with minimal maintenance. The systems have proven to be reliable, safe and meet FDA requirements

Various case studies will be discussed with an emphasis on FDA Regulated solutions and applications particularly at Bayer, Eli Lilly, Avara, Pfizer, Roche and Merck West Point. The Merck West Point case study is of particular interest as it is part of a syringe washing operation in the production of different products including the Hep-C and Gardasil vaccines. Product changeover and sterilization techniques involve customized pre-treatment steps for wastewaters prior to conveyance to the onsite industrial wastewater treatment plant, while following all FDA regulations and protocols.

While vacuum wastewater collection systems may not be a perfect fit for every application; one must look past the initial material cost to judge the overall cost savings of a vacuum system. The savings during installation, including a significant decrease in construction project schedule and labor, reduced water usage and cost, and the reduced treatment cost, will continue to save money both in the short-and long-term. For a typical project budget of $100,000 or greater, the overall cost savings of a vacuum system over a gravity system is minimally 10% for any project, with the cost of materials within 20% by comparison, but the labor and project schedule (a larger portion of budget) costs are 60% less with our vacuum wastewater conveyance system.

12:05 *Complimentary Lunch & Networking Hour*

1:05 **Filling of High-Concentration mAb Formulations into Pre-filled Syringes – Understanding Nozzle Clogging and Filling Accuracy**

CASE STUDY

Yuh-Fun Maa, Senior Principal Engineer, Genentech

Syringe filling, especially the filling of high-concentration/viscosity monoclonal antibody formulations, is a complex process that has not been widely published in literature. The purpose of this presentation is to assess the tendency of high-concentration mAb formulation drying at the tip of the filling nozzle, to understand critical filling parameters that cause nozzle clogging; and to apply the learning to minimize formulation drying leading to fill nozzle clogging. A benchtop filling unit, comprising a peristaltic pump unit and a filling nozzle integrated with a linear actuator, was utilized; glass nozzles were employed to visualize liquid flow inside the nozzle with a high-speed camera. The desired outcome of process optimization is to establish a clean filling cycle (e.g. absence of splashes, bubbles, and foaming during filling and absence of dripping from the fill nozzle post-fill) and minimize the risk of nozzle clogging during nozzle idle time due to formulation drying at or near the nozzle tip. The key process variables are determined to be nozzle size, airflow around the nozzle tip, pump suck-back (SB)/reversing, fluid viscosity, and fluid/nozzle interactions (hydrophilic vs. hydrophobic). The SB and fluid/nozzle interactions particularly play a critical role in nozzle clogging. This study shows that an appropriate combination of optimal SB setting, nozzle size, airflow conditions, and the use of proper nozzle materials could effectively extend nozzle idle time in a large-scale filling facility and environment.

This talk also discusses fill weight accuracy/precision of filling high-concentration mAb formulations by peristaltic pump. Experimental results suggested that the 3% precision target is challenging for filling high-viscosity liquids due to run-to-run and day-to-day variability. More importantly, none of the system/pump parameters seemed to directly correlate with fill weight precision. Photograph analysis revealed liquid suck-back height variations during fill, which correlated well with fill weight variability. Suck-back height variation was attributed to two possible root causes: (1) inconsistent liquid stream separation point at the end of fill and (2) pressure-induced variations upon suck-back. Liquid stream break-up was influenced by liquid properties as well as liquid/nozzle interactions, and pressure variations might be associated with tubing and overall mechanism of the peristaltic pump. A custom nozzle-tip design

featuring a hydrophobic tip and a pressure-resistance barrier enabled consistent suck-back heights for each fill and approximately 90% of fill weight data within 3% precision for a high-concentration mAb formulation.

The outcomes of this study will benefit scientists and engineers who develop pre-filled syringe products by providing a better understanding of high-concentration formulation filling principles and challenges.

1:50

Syringe Siliconization and its Role in Protein Aggregation

Olga Laskina, PhD, Laboratory Director, Senior Scientist, rap.ID, Inc.

Silicone oils are applied to the inner surfaces of syringes to form lubricating films. However, protein based therapeutics can have strong interactions with the silicone oils used in prefilled syringes and lead to a formation of particles. It is important to keep the silicone thickness at minimum and maintain the silicone oil layer homogeneity to insure the quality of protein based formulations in prefilled syringes. Here, we monitored changes in silicone layer in prefilled syringe with a Layer Explorer (LE) instrument during storage and the subsequent formation of particles. We used a wet cell to enable characterization of particles using a Single particle Explorer (SPE) instrument. The SPE is an automated microscope combined with Raman spectroscopy that takes pictures, counts, and determines the chemical composition of particles.

2:35

A Framework For Extractable Leachables for Pre-filled Syringes

Dr. Andrew Hall, Study Director, Toxikon

Combination products containing drug and novel delivery systems have exploded over the past decade. Evaluating combination systems for extractables and leachables is new territory for many end-users. Establishing a framework between extractables and leachables is necessary to interpret, and assess the interaction between a drug product and its container. Leachables can generate new compounds from the interaction between drug solutions and the packaging material. This presentation will focus on providing a framework regarding extractable and leachable testing of pre filled syringes and the trials and tribulations associated with this testing with regard to analytical methodology.

3:15 ***Afternoon Networking Break***

3:40

Advances in Deterministic Parenteral Container Closure Integrity

Julian Stauffer, COO, PTI – Packaging Technologies & Inspection

This presentation outlines the challenges facing parenteral Container Closure Integrity (CCI) and recent developments in specific methods listed in USP 1207. The presentation will specifically explain the theory and application of the MicroCurrent HVLD, a next generation technology aimed at inspecting the integrity of a wide class of parenteral products and container formats. High voltage leak detection is included in USP 1207 as a deterministic test methodology. The presentation will cover practical implementations, and present hard data in the use of High Voltage Leak Detection for parenteral products.

The MicroCurrent HVLD technology uses unique voltage and current characteristics to inspect parenteral products with a wide range of product characteristics. Traditional HVLD has proven to be an effective solution for parenteral class products, with the MicroCurrent HVLD increasing the range of liquids that can be tested, and improving the overall safety of the high voltage solution. The nature of MicroCurrent HVLD allows for testing packages containing liquids with extremely low conductivity, such as sterile water (WFI). MicroCurrent HVLD reduces voltage exposure of the product to less than 5% when testing with comparable HVLD solutions, greatly reducing the voltage exposure to the product and environment.

The objective of the presentation is to provide attendees with an in-depth overview of deterministic parenteral CCI methods as well as provide statistical test result data on BFS, syringes and vials. The study will draw on some comparisons between the new MicroCurrent HVLD technology compared with conventional HVLD methods. Attendees will learn the different aspects of different High Voltage applications for both traditional and MicroCurrent technologies.

4:30

CASE STUDY

Analytical Challenges and State of the Art Solutions Related to Chemical Safety Assessment of Pre-Filled Syringes

Gyorgy Vas, PhD., Business-Technical Scientific Liaison, Intertek Pharmaceutical Services, (Contributing Authors: Louis Fleck, Jiun-Tang Huang)

Pre-Filled Syringes (PFS), are finished pharmaceutical products, what are packaged into the special delivery device, over a period of the intended shelf-life. Both the formulation and the route of delivery present relatively high risk for toxicological risk assessment. To have the safety risk assessment performed properly; chemical testing needs to be executed appropriately, based on high level analytical and quality standards.

PFS finished products are often formulated and delivered in a complex matrix, as well as the low-level impurities leaching out from the delivery system adding an extra layer of complexity of the testing.

To use complex and sophisticated analytical instrumentation been always required for providing reliable data for chemical safety assessment. New developments from the analytical instrument manufacturers re-shaped the testing industry. High performance extraction methods combined with various MS/MS and high resolution accurate mass (HRAM) detection, providing testing solutions

for low level analytes in highly complex matrices, such as PFS finished products.

This presentation will focus on few case studies where high performance complex instrumentation was used on a routine basis for safety evaluation of PFS products.

5:15 *End of day one*

Wednesday April 4, 2018

7:30 *Complimentary Breakfast*

8:00 *Welcome and opening remarks by Chairperson: Michael Eakins,* Principal Consultant, Eakins & Associates, Inc.

8:15 **Challenges and Opportunities for Development of Stability Program for Combination Products**

Alie Jahangir, PhD, Sr. Manager, Combination Products & EmergingTechnologies PQM, The Janssen Pharmaceutical Companies of Johnson & Johnson

Combination products are unique therapeutics that combine two or more regulated constituent parts (i.e. drugs, devices and/or biological products), leading to products that provide ease of use, safer and more effective. While the combination products have been developed and commercialized as a result of unprecedented collaboration between pharma and device industries to address patients' unmet therapeutic needs, they also have presented new regulatory, quality and development challenges. Unlike the stability program of pharmaceutical products, the combination product shelf life is not only determined by the effectiveness of a particular drug formulation, but also by device functionality as well as the sterile barrier system materials integrity during the product's entire supply chain from packaging to sterilization, transportation and storage. From a combination product perspective, while the individual shelf life data for each of the above-mentioned entities are critical, the complete stability testing plan should also include monitoring of the specific Stability Indicating Attributes/Parameters that demonstrate the interactions among these various constituent parts. Furthermore, in addition to following different international standards and guidelines (i.e. ICH, WHO, ASTM), governing the stability testing requirements for drugs, devices and/ or their packaging systems, the manufacturers should also be aware of differing expectations by two review centers within FDA (i.e. CDER and CDRH) for approval of a drug/ device combination product. Accordingly, by using case studies and industry best practices, this presentation will introduce a new end-to-end stability testing paradigm for different classes of combination products based on robust scientific, risk-based, holistic and proactive approach.

9:00 **Strategic and Technical Considerations for PFS and Auto injector Development for Biologics**

Rajiv Gupta, PhD, Device Program Leader, Medical Device, Shire

The pre-filled syringe and autoinjector presentations are injectable combination products that continue to be developed and commercialized for biologics. These product presentations provide patient-centric delivery options to patients in a home environment for self-administration and health care professionals in an office environment. The development of these drug-device combination products must be in accordance with regulations of the FDA and other regulatory authorities to support global launches.

This presentation discusses strategic considerations around device platform approaches and how to potentially bridge between devices. It also discusses the high-level process and feasibility/development activities that are typically conducted in a cross-functional team structure to enable the start of clinical trials and regulatory submissions. Key technical considerations during the design development process are also discussed.

9:45 **Multi-Faceted Approach to Container Closure Integrity**

Christopher J. Barnes, Technology Manager, Container Closure Integrity, Analytical Labs, West Pharmaceutical Services, Inc.

Pre-filled syringe and cartridge systems pose unique challenges regarding container closure integrity (CCI) analysis. With the advent of USP chapter <1207>, the industry is now better guided regarding applicable technology and proper method validation processes. Helium mass spectrometry (HeMS), frequency modulation spectroscopy (FMS), and high voltage leak detection (HVLD) are all advanced, deterministic techniques outlined in the chapter. This presentation will examine how these methods can be applied, individually, and in combination, to evaluate syringes and cartridges at temperatures from ambient to cryogenic (critical for biologic and cell therapies).

10:30 *Mid-Morning Networking Break*

11:00 **Devices for Self-Injection: Advantages of the Platform Approach**

CASE STUDY

Jakob Lange, Account Director, Ypsomed AG

- Overview of the market for self-injection devices
- Review of the different types of primary containers and devices
- Custom-made devices vs customized platform products
- Case study 1: Development of customized platform products
- Case study 2: Usability for platform products

11:45 *Complimentary Lunch*

12:45

Pre-filled syringes Novel approach & technology: increasing safety and performances in the delivery of demanding biodrugs

Howard Drake, Vice-President, Pharmaceutical System Division, Ompi of America, Stevanato Group

Today, biologics are fast becoming the driving force of the pharmaceutical industry. Because the primary route of administration for most biologics is still by injection, there is a demand for advanced drug-delivery systems that offer convenience and ease of administration. Pre-filled syringes have gained strong acceptance as delivery systems for injectable drugs, especially in the treatment of chronic conditions that require repeated administration of the medication. Nevertheless, it is well-known in the industry that Pre-filled syringes are not free of issues as they are complex systems where primary packaging components are challenged by large molecules such as MABS or sensitive drugs. This presentation will provide an overview of the latest Alba technology and the benefits for the Pharma to have a comprehensive solution under the same roof.

Items addressed are:

- Particles reductions
- Injections performances related to viscosity
- Delamination control
- DDS compatibility
- AI/Pen devices integration

Panel Discussion

1:15

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: Michael Eakins, Eakins & Associates

Panelists:

- Alie Jahangir, PhD, Sr. Manager, Combination Products & EmergingTechnologies PQM, The Janssen Pharmaceutical Companies of Johnson & Johnson

1:45

Important Features and Implementation of High Speed Automated Syringe Inspection Equipment

Johannes Roggemann, Sr. Engineer, Bosch

Inspection of a siliconized pre-filled syringe at speeds up to 600/min present both unique detection issues and complex mechanical handling challenges. This presentation will review solutions for both items with detail of the approach used for various detection items and illumination unique to syringes and the mechanical design needed to avoid breakage at high speeds. Adapting high resolution cameras, vision algorithms, Static Division sensors, and motion control using servo motors will be covered.

2:25

Afternoon Networking Break

2:50

CASE STUDY

Challenges Associated with PFS Combination Product Development for Ophthalmic Applications

Mayumi Bowen, Senior Engineer, Pharmaceutical Processing Technology Development, Genentech, Inc.

There are stringent Health Authority guidance and ISO requirements for ophthalmic applications to prevent infection by eliminating pathogenic micro-organisms, considering eye safety, which are challenges to development of ophthalmic PFS combination products. This presentation will address guidance & requirements pertaining to particulate, endotoxin, silicone oil leachates, and external surface sterilization for ocular applications. In addition, this presentation will discuss points to consider, strategies, and case studies regarding syringe and packaging material selection, sterilization method selection and sterilization process development and validation to meet the stringent guidance and requirements.

3:30

Close of Program

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Venue:	The Racquet Club of Philadelphia
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Hotel Room Block:	Club Quarters Hotel, Philadelphia
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