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SMi presents its 4th conference and exhibition in the US series on...

Pre-Filled Syringes West Coast

JUNE 6 - 7 2016

Hyatt Regency Mission Bay, San Diego, USA

**Rethinking Your Device Design to Drive Patient's Safety,
Usability and Delivery Excellence**



HIGHLIGHTS FOR WEST COAST MARKET:

- How to **overcome regulatory hurdles** for drug delivery devices to ensure speedy approval
- **QbD application on combination products** for pre-filled syringes
- The **next generation of autoinjectors and pens** to support combination products
- Material selection: **Is COP the way forward?**
- **Compliance to GMPs** for combination products in PFS and how to manage quality assurance in a global environment

Chair in 2016:

- **Dr. Ed Israelski**, Former Director Human Factors, **Abbvie**; Co-Convener, **ISO/IEC Joint Working Group on Usability Standards for Medical Devices**

EXPERT SPEAKERS PANEL INCLUDES:

- **Jeffrey Givand**, Director – Device Development, **Merck, Sharp & Dohme Corp.**
- **Benir Ruano**, Vice President, Global Manufacturing & Technical Operations, **Xeris Pharmaceuticals, Inc.**
- **Shun Ogawa**, Research Manager, **Mitsubishi Gas Chemical Company, Inc.**
- **Toshiro Katayama**, Product Manager, **Zeon Chemicals L.P.**

PLUS AN INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOP

Wednesday June 8th 2016,
Hyatt Regency Mission Bay, San Diego, USA
08.00 - 12.00

HALF-DAY POST-CONFERENCE COMPLIMENTARY NETWORKING LUNCH AT BREWERY

Wednesday June 8th 2016,
Stone Brewing World Bistro & Gardens - Liberty Station
12.30 - 16.30
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Pre-Filled Syringes West Coast

Day One | Monday June 6th 2016

08.30 Registration and Coffee

09.00 Chairman's Opening Remarks

Dr. Ed Israelski, Former Director Human Factors, **Abbvie**;
Co-Convener, **ISO/IEC Joint Working Group on Usability Standards for Medical Devices**

REGULATORY UPDATES ON PRE-FILLED SYRINGES (PFS)

08.40 OPENING ADDRESS: Regulatory Hurdles and Challenges for Approval of Drug Delivery Devices

- Dealing with inconsistencies in regulatory expectations:
 - USA FDA – CDER (Drug Center) vs CDRH (Devices)
 - EU EMA – Notified body expectations
 - Simulated use versus actual use
 - Worst case use scenarios
 - Delay between usability testing and user training if applicable
 - Risk analysis expectations (quantitative vs. qualitative)
- Dr. Ed Israelski**, Former Director Human Factors, **Abbvie**;
Co-Convener, **ISO/IEC Joint Working Group on Usability Standards for Medical Devices**

09.20 Regulatory Updates – Navigating Global Expectations for Drug Delivery Systems

- Requirements for regulatory approval – with particular focus on US and EU expectations
- Verification testing vs. ICH M4Q delivery system suitability and compatibility
- Risk-based control strategies and stability/shelf-life considerations

Suzette Roan, Associate Director, Regulatory Affairs CMC Combination Products, **Biogen**

10.00 Extractables and Leachables (E&L): From Raw Materials to Plungers and Stoppers

- How to perform E&L test and present data to regulatory agencies?
- Understanding the forced degradation pathway and optimal tool for prediction
- Updates on recent cases of potential interaction of liquid drug with plunger/stopper

10.40 Morning Coffee & Networking Break

THE RISE OF COMPLEX BIOTHERAPEUTICS VS PFS

11.10 The Rise of Combination Drugs – Upcoming Challenges for PFS

- Escalating dosages (volume and viscosity considerations)
- The use of chamber system and implications for the device
- Drug-to-drug and drug-to-surface interaction studies

11.50 Application of Quality by Design (QbD) to Combination Product Development

- Connectivity between Quality Systems Regulations (21CFR820) and QbD (ICH Q8/Q9/Q10) principles
- QbD methodology as applied to combination product development
- Opportunities to improve assurance of quality and minimize post-launch product performance issues through QbD

Jeffrey Givand, Director – Device Development, **Merck, Sharp & Dohme Corp.**

12.30 Rethinking the Delivery Platforms – Can PFS Contribute Added Values?

- Adding competitive advantage to biosimilars with a self-injectable platform
- How changing the delivery route can revive the drug and win clinicians' and patients' hearts?
- Considerations and challenges when changing drug delivery route – compatibility and modifications required

13.10 Networking Lunch

14.10 Closed Loop Control for Repeatable Lubrication

- GMP in practice – maintaining a closed loop fill/finish manufacturing circuit to avoid contamination
- Container concerns – how a vacuum collection of spray and sealed machine design can assist with production and device assembly
- High speed inspection system for lubricant layer

14.50 Syringes for the Sterile Field: Nitrogen Dioxide Sterilization as a Solution

- The NO₂ sterilization process is designed to minimize impact on temperature - and pressure-sensitive drugs and biologics
- Discussing load configuration, biological indicator locations and process data
- Container-closure system integrity demonstration via sterility and NO₂ ingress testing
- Single batch release process for clinical trials

Senior Representative, Noxilizer

15.30 Aseptic Fill-Finish with the Emergence of Complex Drugs

- Advancements in aseptic filling process
- Real-time monitoring and accuracy
- Automated process to enhance accurate fill/finish and container-closure system
- Chambered system concerns and how to overcome such challenges

Session reserved for Genentech

16.10 Afternoon Tea & Networking Break

A HUMAN TOUCH FOR THE DEVICE

16.40 PLAJEX™ Polymer-Based PFS with a Tapered Needle for Use in Autoinjectors

- Application of PLAJEX™ polymer-based, silicone oil free, PFS in autoinjectors for sensitive, high viscous, therapeutics proteins
- Mitigating risks of:
 - Degradation of proteins due to extractables
 - High break loose and glide forces from viscous products
 - Aggregation of proteins due to silicone oil
 - Breakage from high forces in spring and pneumatic based injectors

Kevin Constable, Senior Director of Technology Development, **Terumo Medical Corporation**

17.20 Why Do We Do Formative Studies for Pre-Filled Syringes?

- The use of a pre-filled syringe, is it as straight forward as we think?
- Formative studies for generic products
- Case study: Formative studies impact on combination product projects

Lisa Nilsson, Human Factors Manager, **Teva Pharmaceuticals**

18.00 Chairman's Closing Remarks and Close of Day One

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08.30 Registration and Coffee

09.00 Chairman's Opening Remarks and Setting the Scene

TECHNOLOGICAL DEVELOPMENTS IN PFS

09.10 OPENING ADDRESS:

Market Trends for PFS

- Developing an integrated, automatic and user-controllable PFS
- Dual- or multi-chamber systems to allow liquid, lyophilized or powder-filled syringe
- Staked needles and IV connection for patient safety

09.50 Key Properties of COP Update

- Case study: Protein adsorption data – COP vs. glass
- Case study: Study on delamination with glass syringe vs. COP syringe
- Leachable data on COP syringe with various chemicals

Toshiro Katayama, Product Manager, **Zeon Chemicals L.P.**

10.30 The Next Generation of Autoinjectors and Pens to Support Combination Products

- Xeris combination product platform
- G-pen synthetic glucagon peptide formulation in PFS with autoinjector product for hyperglycemia
- Challenges with manufacturing a low volume, aseptically filled COP PFS
- Challenges with an international drug device supply chain
- Challenges with producing synthetic peptide in low humidity environments

Benir Ruano, Vice President, Global Manufacturing & Technical Operations, **Xeris Pharmaceuticals, Inc.**

11.10 Morning Coffee & Networking Break

11.40 Comprehensive Reporting with Operations and Maintenance to Ensure GMP Compliance

- How to analyse your syringes, vials, ampules or cartridges status with distribution and quality of the lubricant inside the container
- Method of root cause investigation for primary packaging failures in auto-injector devices
- Comparison of volumetric characterization techniques for siliconization of parenteral containers

Maria Toler, Senior Manager, Quality Assurance Technology & Innovation, **Pfizer***

12.20 Challenges of Pre-Filled Syringes Manufacturing

- Importance of plunger placement control in pre-filled syringes
- Qualification of automated pre-filled syringe assembly
- Design transfer and verification of pre-filled syringe combination products

Jennifer Vandiver, Senior Process Scientist, **Alkermes**

13.00 Networking Lunch

14.00 OXY-CAPTM Multilayer Plastic Pre-Filled Syringe with Glass-Like Gas Barrier

- Prevent oxidation of medicinal solution
- Low protein (medicinal solution) adsorption
- Low silicone prefillable syringe

Shun Ogawa, Research Manager, **Mitsubishi Gas Chemical Company, Inc.**

COMPETITIVENESS OF PFS AND PATIENT CONCERNS

14.40 Wearable Injector Technology

- Precision therapy with pre-programmed injection pattern
- Instant patch pump and convenience for use
- Customizable for therapeutic and regulatory requirements of target therapy

15.20 Afternoon Tea & Networking Break

15.50 Needle-Less Injection Device for Transdermal Delivery

- The non-invasive method: Delivering injectable liquid via precise fluid stream
- Compatible filling with multi-dose vials
- Cost-effectiveness – reducing sharp disposal costs and associated fees with needle-stick injury treatments

16.30 PANEL DISCUSSION: Patient Training and On-Boarding Program – The Last Step of the Journey



- The last leg of the journey – ensuring patients receive professional training for self-administrative injection device
- On boarding program to enhance usability and safety of the device
- Ongoing collaboration and feedback for device modification with clinicians and patients

Panel will be joined by speakers on the day

17.10 Chairman's Closing Remarks and Close of Day Two

*Subject to final confirmation

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HALF-DAY POST-CONFERENCE WORKSHOP
Wednesday June 8th 2016,
Hyatt Regency Mission Bay, San Diego, USA
08.00 - 12.00

Advanced Regulatory Compliance For Pre-Filled Syringes

Workshop leader to be announced shortly

What Is This Workshop About?

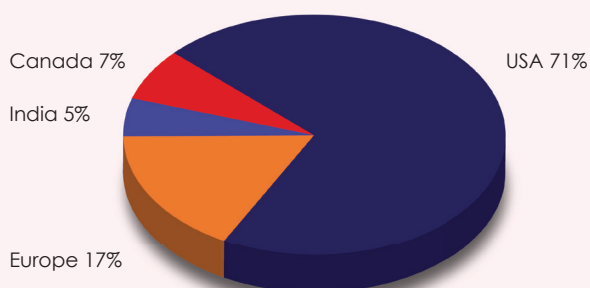
Regulatory compliance remains one of the top challenges in the pre-filled syringes industry. This workshop aims to provide an update to participants on the global landscape, capturing trends of pre-filled syringes and combination products, as well as CMC requirements.

Through practical case studies and interactive discussion, attendees will be able to gain a holistic picture of the industry and implement into everyday practice to ensure compliance.

Program:

- 08.00** **Registration & Welcome Coffee**
- 08.30** **Workshop Leader Introduction**
- 08.40** **Regulatory Updates on PFS**
 - Comparison between EMEA and US
 - Riding on the regulatory landscape and ensuring smooth approval for the device
- 09.45** **Morning Coffee**
- 10.15** **Challenges with Combination Products and CMC**
 - Practical case study on how to overcome challenges with combination products and CMCs
 - Incorporating human factor engineering into PFS design
- 11.30** **Q&A**
- 12.00** **Closing Remarks from Workshop Leader and End of Workshop**

Pre-Filled Syringes USA Series Attendees 2014-2015 by Location



HALF-DAY POST-CONFERENCE
Exclusive Networking Lunch at Brewery & Beer Tasting
Wednesday June 8th 2016
12.30 - 16.30

Stone Brewing World Bistro & Gardens – Liberty Station

This half-day networking lunch and brewery tour is a great networking opportunity amongst pre-filled syringes experts, and is exclusive to pharma and biotech companies only!

Limited availability – 40 places only to ensure an intimate networking environment.

Itinerary:

- 12.30** **Registration**
- 12.45** **Departure to Stone Brewing World Bistro & Gardens**
- 13.30** **Private Networking Lunch and Beer Flight Tasting at the Bocce Courtyard**
 - Guests will be able to sample the brewery's core 4 beers in an intimate networking environment.
- 16.30** **Departure to Hyatt Regency Mission Bay, San Diego**

About Stone Brewing World Bistro & Gardens - Liberty Station:

Stone Brewing World Bistro & Gardens – Liberty Station is located in San Diego's Point Loma community and encompasses more than 23,500 square feet of indoor and outdoor dining and bars, as well as a bocce ball court, outdoor cinema space and lush garden. Executive Chef Thomas Connolly offers an eclectic menu of world-inspired cuisine featuring local, organic fare. We proudly present 40 taps and more than 100 bottles of exceptional craft beers, including Stone year-round and special releases as well as craft and specialty beers from other breweries around the world.



www.stonelibertystation.com



Who Attended Our Pre-Filled Syringes Events?

Job Titles

- CEO
 - Chief Technology Officer
 - Associate Director
 - VP of Global Biologics Manufacturing
 - Chief Researcher
 - Director of Drug Delivery Device Development
 - Principal Scientist
 - Technical Expert – Packaging
- And many more!**

Organizations

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Pre-Filled Syringes West Coast

June 6th - 7th 2016

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