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SMi Presents the 3rd Annual Conference and Exhibition on...

Pre-Filled Syringes East Coast

25-26 APRIL 2016

Renaissance Woodbridge Hotel, Iselin, New Jersey, USA

Driving the Quality and Commercial Competitiveness of Patient-Centric Device Design

Image courtesy of Zeon Chemicals

KEY BENEFITS FOR 2016:

- How to eliminate **extractables and leachables (E&L)** – case study from **Merck**
- Hear from **Eli Lilly** on giving the PFS a human touch – incorporating **human factor engineering** into a patient-centric device
- Ensuring **commercial competitiveness** of PFS as a drug device
- Assessing trends of **combination products** and impacts on PFS
- Update on **latest technologies on COP and sterilization** to accelerate your PFS development

CHAIRS FOR 2016:

Stephen Barat,
Executive Director, Non-Clinical & Translational Sciences, Safety Assessment & Bioanalysis,
Allergan

Ravi S. Harapanhalli, Ph.D.,
Principal,
FDAPharma Consulting LLC

EXPERT SPEAKER PANEL INCLUDES:

- **Mathias Romacker,** Senior Director, Device Strategy, **Pfizer**
- **Dr. Paolo Mangiagalli,** Senior Director, Head PFS Platform, **Sanofi**
- **Ken Wong,** Deputy Director, MTech/ Process Technology – Extractables & Leachables, **Sanofi Pasteur**
- **Carsten Worsoe,** Principal Scientist, CMC Analytical Support, **Novo Nordisk A/S**
- **Dr. Shawn Davis,** Principal Engineer, Device Strategy, **Amgen**
- **Mohammed Umar,** Principal Technical Manager, Quality Engineering, **Genentech**
- **Jason Lipman,** Associate Director, Regulatory Affairs, Medical Devices & Combination Products, **Janssen R&D, LLC**

PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS

Wednesday April 27th 2016, Renaissance Woodbridge Hotel, Iselin, New Jersey, USA

The Pre-Filled Syringe as a System: Human Factors Considerations for PFS Development and Regulatory Submission

Workshop Leader:
Melanie Turieo, Associate Director, Medical Technology, **Cambridge Consultants**
8.30 – 12.30

Combination Rule and CMC Considerations for PFS and Autoinjectors

Workshop Leader:
Ravi S. Harapanhalli, Ph.D., Principal, **FDAPharma Consulting LLC**
13.30 – 17.30

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Pre-Filled Syringes East Coast

Day One | Monday April 25th 2016

08.30 **Registration & Coffee**

09.00 **Chairman's Opening Remarks**
Stephen Barat, Executive Director, Non-Clinical & Translational Sciences, Safety Assessment & Bioanalysis, **Allergan**

REGULATORY UPDATES ON PRE-FILLED SYRINGES (PFS)

09.10 **OPENING ADDRESS:**
The Top Priority for PFS – Addressing Regulatory Compliance and Clinical Needs
- US-FDA specific requirements vs. critical issues for regulatory approval in the EU
- What is required by the regulators for post-marketing?
- Concerns with combination products – challenges and solutions

Jason Lipman, Associate Director, Regulatory Affairs, Medical Devices & Combination Products, **Janssen R&D, LLC**

09.50 **Extractables and Leachables (E&L):**
The Value of the Simulated Study as a Prediction Tool for Actual Leachables in PFS
- Relationship between extractables, simulated leachables and leachables
- What is the optimal tool to predict leachables in a PFS?
- How to perform a simulated study for a PFS
- Case studies: Examples on simulated studies in PFS

Carsten Worsoe, Principal Scientist, CMC Analytical Support, **Novo Nordisk A/S**

PFS TECHNICAL AND PRODUCTION CHALLENGES FOR COMPLEX DRUGS

10.30 **PLAJEX™ Polymer-Based Pre-Filled Syringes (PFS) and its Value with a Novel Tapered Needle Design**
- Application of PLAJEX™ Polymer-based PFS without patch pumps for sensitive, viscous, therapeutic proteins
- Mitigating risks of:
  - high forces due to viscous products
  - aggregation due to silicone oil
  - leachables due to extractables from container materials
- An applied method of sterilization for a reduction in drug degradation due to radicals

Kevin Constable, Sr. Director of Technology Development, **Terumo Medical Corporation**

11.10 **Morning Coffee & Networking Break**

11.40 **Critical Steps for PFS Integration – From Early Stage to a Functional Delivery System**
- Translating integrated system approach into component requirements
- How to ensure effective PFS component control plans
- Open issues for PFS system and opportunities for knowledge sharing

Dr. Paolo Mangiagalli, Senior Director, Head PFS Platform, **Sanofi**

12.20 **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.**

13.00 **Networking Lunch sponsored by** West

14.00 **Development of Primary Container for Devices**
- Development of platform syringe configurations suitable for sensitive biologics
- How formulation development studies can enable successful device development
- Challenges with development of primary containers for devices

Roja Narwal, Scientist II, Formulation Sciences, **MedImmune**

14.40 **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

Evan Goulet, Ph.D., Director, Sterilization Operations, **Noxilizer**

15.20 **Thinking it From the Start – How to Compile a Strong E&L Case for the Regulatory Agency**
- Updates on E&L testing methods and how this will impact on your device design
- Clarity is key – what do the regulatory agencies expect?
- How to demonstrate evidence and incorporate this into your device development plan to ensure a smooth approval process?

Bobbijo Redler, Associate Principal Scientist, **Merck**

16.00 **Afternoon Tea & Networking Break**

A HUMAN TOUCH FOR THE DEVICE

16.30 **Achieving Patient-Centred Design through Human Factors**
- Understanding the multifaceted field of human factors and the process
- Why human factors evaluation methods are necessary to achieve optimized design
- Using user needs to drive human factors process and demonstrate traceability from requirements to validation outputs

Tiffnay McIntire, Human Factor Engineer, **Eli Lilly**

17.10 **Panel Discussion: The Future of Combination Product Review Process at FDA**
- The contributions of the Office of Combination Products to date
- Review of a recent report by the Office of Planning at FDA entitled 'Combination Product Review: Intercenter Consult Process Study, Oct 14, 2015'
- What is expected of combination product review process in the future

Moderated by:
Ravi Harapanhalli, Ph.D., Principal, **FDAPharma Consulting LLC**

17.50 **Chairman's Closing Remarks and Close of Day One**

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Pre-Filled Syringes East Coast

Day Two | Tuesday April 26th 2016

08.30 **Registration & Coffee**

09.00 **Chairman's Opening Remarks**
Ravi Harapanhalli, Ph.D., Principal, **FDAPharma Consulting LLC**

PRODUCTION AND MANUFACTURING DEVELOPMENTS FOR PFS

09.10 **OPENING ADDRESS:**
Current Market Developments and Global Market Trends for Advanced Injection Devices
- Continuous success of combination products
- Novel device technologies to enhance user experience and patient engagement
- How does device technology need to evolve to deliver future value to all stakeholders?

Mathias Romacker, Senior Director, Device Strategy, **Pfizer**

09.50 **Risk Based Statistical Sampling for Medical Device and Combination Product**
- How to apply statistical inputs for an informed decision – from product design to manufacturing
- Improve product quality and escape regulatory risk
- Technical challenges with more complex biologics products

Mohammed Umar, Principal Technical Manager, Quality Engineering, **Genentech**

10.30 **Emerging Trends in Pre-Filled Delivery: Next Generation Component Innovations and Risk Mitigation Strategies**
- Market trends in pre-filled delivery and self-injection
- New approaches to development and risk mitigation for components
- Next generation components; designed for enhanced quality and optimized performance to meet evolving prefilled delivery requirements

Royce Brockett, Senior Product Manager, PFS Platform, **West Pharmaceutical Services, Inc.**

11.10 **Morning Coffee & Networking Break**

11.40 **Challenges for PFS with More Complex Biologics Drugs**
- Escalating dosages (volume and viscosity considerations)
- PFS vs. autoinjector
- Viability and efficacy – can we reduce the dosage frequency effectively for patients' use?

Dr. Shawn Davis, Principal Engineer, Device Strategy, **Amgen**

12.20 **How Parenteral Combination Products Can Improve Drug Delivery: Insights into Patients' Intuitive Solutions, Design Risk Analysis and Robust Processes**
- Patients' intuitive solutions: safety devices
- Design solutions: Autoinjectors to reduce syringe breakage
- Process solutions: Robust added barrier to COP material for better drug protection

Isabelle Delcroix, Business Development Director, **Nemera**

13.00 **Networking Lunch sponsored by** West By your side for a healthier world

14.00 **OXY-CAPTTM Multilayer Plastic Pre-Filled Syringe with Glass-Like Gas Barrier**
- Introducing 'OXY-CAPTTM Multilayer Plastic Syringe' made of glass-like gas barrier polymer and COP
- Update on oxygen barrier study of OXY-CAPTTM syringe
- Key benefits and features of OXY-CAPTTM syringe comparing to COP monolayer and glass syringe

Kenichiro Usuda, Researcher, Advanced Business Development Division, **Mitsubishi Gas Chemical Company, Inc.**

14.40 **An E&L Qualification Case Study of New Label on Plastic PFS**
- Extractable studies on ink, label and adhesive
- Simulated in-use leachable study with labelled plastic PFS
- Leachable migration study from label into the plastic syringe

Ken Wong, Deputy Director, MTech/ Process Technology - Extractables and Leachables, **Sanofi Pasteur**

15.20 **Safety Assessment of Leachables for the Development of Pre-Filled Syringe and Parenteral Drug Products**
- An overview of leachables encountered in parenteral drug products – and need for safety assessment – will be presented
- Approaches to adequate safety evaluation related to the development of a pre-filled syringe combination drug products will be provided, illustrated with tangible examples
- Final PQRI best practice recommendations for leachable safety assessment for parenteral drug products will be covered

Stephen Barat, Executive Director, Non-Clinical and Translational Sciences, Safety Assessment & Bioanalysis, **Allergan**

16.00 **Afternoon Tea & Networking Break**

16.30 **New Technologies and Market Trends for Cartridge and Needle Components**
- Looking beyond – cartridge and needle as critical components for PFS, what are the trends?
- Designing a precise and effective device with safety in mind
- Assembly challenges and solutions
- Can we streamline a platform for a more customized syringe and lower manufacturing costs?

Speaker to be announced

17.10 **Panel Discussion: What Are the Latest Innovations in PFS?**
- How ergonometrics can help with a good design of PFS to increase value and compliance?
- Who and how? Always put your patients at heart
- The rise of e-apps and e-device for patient monitoring – how can this apply to PFS?

Moderated by:
Ravi Harapanhalli, Ph.D., Principal, **FDAPharma Consulting LLC**

17.50 **Chairman's Closing Remarks and Close of Day Two**

HALF-DAY POST-CONFERENCE WORKSHOP A

Wednesday April 27th 2016 | 8.30 – 12.30 | Renaissance Woodbridge Hotel, Iselin, New Jersey, USA

The Pre-Filled Syringe as a System: Human Factors Considerations for PFS Development and Regulatory Submission

Workshop Leader: **Melanie Turieo,** Associate Director, Medical Technology, **Cambridge Consultants**

Workshop Overview:
This half-day workshop will provide an overview of the Human Factors (HF) considerations for pre-filled syringes - not just as standalone delivery devices but in the context of the other elements that are considered part of the user interface of the devices, such as the instructional material, packaging, and training considerations. It will explore how to maximize efficiency and minimize HF-related regulatory surprises by addressing all of these elements in concert with one another.

Benefits of Attending:
- Understand how and why HF play a critical role in device success
- Design and develop your PFS in a timely manner with smooth regulatory approval by demonstrating HF considerations
- Incorporate use-related risk management early on to mitigate downstream risks
- Understand the considerations for designing and conducting an HF validation study

About Workshop Leader:
Melanie Turieo, Associate Director, Medical Technology, **Cambridge Consultants**

Melanie Turieo is an Associate Director in Cambridge Consultants' Global MedTech division, and Group Leader for Human Factors Engineering & Industrial Design. Melanie has 20 years' experience providing human factors expertise to the design and development of regulated and safety-critical items, including medical, military and consumer products. Her technical expertise has focused for the last 10 years on Human Factors Engineering in the design and development of medical products, and she has extensive experience designing and conducting user research for medical devices, especially drug delivery systems including injection and inhalation technology.

About the Organization:
Cambridge Consultants develops breakthrough products, creates IP, and provides business consultancy in technology-critical issues for clients worldwide. For more than 50 years, they have been helping clients turn business opportunities into commercial successes, from launching first-to-market products, entering new markets to expanding existing markets through new technologies. Their auto-injector, inhaler and injection device development programs extend from concept creation through to industrialisation, with a 'quality by design' approach and full compliance with international regulatory standards. **www.cambridgeconsultants.com**

Programme:

8.30 **Registration & Coffee**

9.00 **Workshop Leader's Opening and Introduction**
Melanie Turieo, Associate Director, Medical Technology, **Cambridge Consultants**

9.10 **Overview of Human Factors Engineering (HFE) for PFS**
- How HF applies to PFS
- What are the considerations and what are the regulators expecting?
- Planning ahead for your supporting rationale - how to address HF validation results in context
- Examples

10.30 **Morning Coffee & Networking Break**

11.00 **Creating a Consistent User Experience**
- Marrying safety, usability and commercial success
- User interface of the device - packaging, instructional materials, training and other 'peripherals'
- Realising efficiencies in the development process and accelerating validation readiness
- Case study

12.00 **Q&A**

12.30 **Closing Remarks from Workshop Leader and End of Workshop**

HALF-DAY POST-CONFERENCE WORKSHOP B

Wednesday April 27th 2016 | 13.30 – 17.30 | Renaissance Woodbridge Hotel, Iselin, New Jersey, USA

Combination Rule and CMC Considerations for PFS and Autoinjectors

Workshop Leaders: **Ravi S. Harapanhalli, Ph.D.,** Principal, **FDAPharma Consulting LLC**

Workshop Overview:
This hands-on workshop provides a didactic discussion on CMC regulatory considerations development of PFS, autoinjectors and related delivery devices. Over the past several years, the regulatory landscape of the combination products has shaped up and culminated into the combination rule 21 CFR Part 4, which has provided unique opportunities for traditional pharma/biopharma and device manufacturers to come together and forge into a regulatory framework that ensures compliance of individual constituents of a combination product. Functional testing of the delivery devices, ergonomics, usability, and human factors are some critical considerations during development and approval of these combination products.

The workshop will discuss the roles and responsibilities of the Office of Combination Products, streamlining 21 CFR Part 4 requirements for combination products, functionality testing of PFS/autoinjectors, usability/human factor considerations, and other critical issues. Several case studies will be presented to reinforce the discussion. The participants will leave the workshop with full understanding and appreciation for the CMC challenges and regulatory considerations of the development of PFS/autoinjectors.

Benefits of Attending:
Development and approval of combination products continue to be a challenge as drug and device developers need to overcome their silos and mindset and should see a common ground for these products. A recent report published by the Office of Planning at FDA entitled "Combination Product Review: Intercenter Consult Process Study, October 14, 2015" reveals that the review process for the combination products still needs major revamping. Streamlining of the combination rule continues to be a challenge. Many products are facing slowdown and multiple review cycles at FDA and other agencies.

This workshop is aimed at clarifying the confusion and providing a thorough discussion on CMC and regulatory considerations that should be proactively considered for a successful and right-first-time submission and approval of a regulatory application for PFS/autoinjectors and related combination products.

About the Workshop Leader and Organization:
The mission of **FDAPharma Consulting LLC** is to provide high quality technical and regulatory consultations to aid in medical product development and approval from health authorities.

Ravi S. Harapanhalli, Ph.D., Principal at FDAPharma Consulting, advises bio/pharmaceutical/device companies on regulatory strategies and Quality-by-Design approaches to medicinal product development and flexible regulatory approaches for drugs, biologics, and drug-device combination products. He also helps companies devise appropriate clinical and regulatory strategies such as 505(b)(2) versus 505(j), biosimilars, and biologics.

Until September of 2015, he was Vice President at PAREXEL International, and served as a Branch Chief in the Office of New Drug Quality Assessment, US FDA. During his tenure of over 7 years at PAREXEL, he worked with numerous clients in developing and getting approvals for their products. He brings his extensive FDA regulatory experience of over 11 years in this consulting strategies. He has wide experience in the CMC/biopharmaceutics review and inspection of a broad range of dosage forms and drug products including radiopharmaceuticals, parenterals, injectable suspensions, solid oral dosage forms, inhalation products, transdermal and topical systems, gels, and combination products including iontophoretic patches, pre-filled syringes and autoinjectors. He has over 25 years of extensive experience in the pharma/biopharma/combination product areas spanning 12 years at US FDA, 8 years in consulting, 11 years in R&D and Biomedical Research and has published over 30 peer-reviewed publications and holds a patent in tumor treatment from Harvard Medical School. He actively presents at national and international meetings on various aspects of medicinal product development.

Programme:

13.30 **Registration & Coffee**

14.00 **Workshop Leader's Opening Introduction**
Ravi S. Harapanhali, Ph.D., Principal, **FDAPharma Consulting LLC**

14.10 **Future Applications for PFS and Autoinjectors in Personalised Medicines**
- Personalised medicine and development landscape for PFS/autoinjectors
- Working of the Office of Combination Products

15.10 **Regulatory Considerations and Combination Rules**
- CMC considerations in the development of PFS/autoinjectors
- Regulatory issues and risk assessment
- Streamlining of 21CFR Part 4 for PFS/autoinjectors

16.00 **Afternoon Tea & Networking Break**

16.30 **Incorporating Human Factors into PFS and Autoinjectors**
- Usability and human factor considerations
- Case studies and discussion

17.30 **Closing Remarks from Workshop Leader and End of Workshop**

Pre-Filled Syringes East Coast

April 25th - 26th 2016

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Pre-Filled Syringes West Coast
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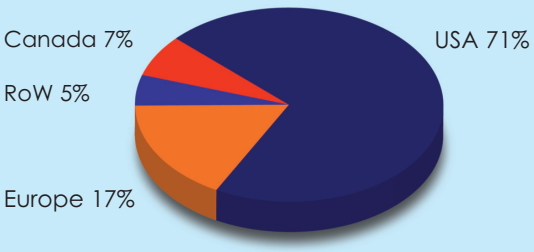

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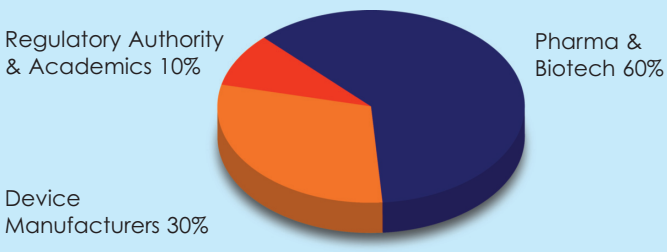

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Workshops: Wednesday 27th April 2016, Renaissance Woodbridge Hotel, Iselin, New Jersey, USA

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