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SMi proudly present their 4th annual conference and exhibition...

Pre-Filled Syringes East Coast

The Colonnade, Boston, MA, USA

26TH - 27TH APRIL 2017

Opportunities and innovations in pre-filled technology developments

Cover image by Nemera

HIGHLIGHTS IN 2017:

- Analyse and forecast market trends for prefills with **Pfizer**
- Explore safety assessments, leachables and the PQRI with **Allergan**
- **AstraZeneca** give key guidance on successful change controls for **design changes** and **device changes**
- Highlight the innovative solutions that **wearable devices** provide in overcoming the challenges presented by biologic drugs with **Amgen**
- Navigate **Human Factors regulations** with **AbbVie**

CHAIRS:

Dhairya Mehta, Associate Director, **Shire**

Michael Selzer, Manager Combination Products Engineering, **Regeneron**

FEATURED SPEAKERS:

- **Li-Chun Tsou,** Global Device Technical Director, **AstraZeneca**
- **Ronald Iacocca,** Research Fellow, Delivery and Device R & D, **Eli Lilly**
- **Edmond Israelski,** Director Human Factors, **AbbVie**
- **Antony Trupiano,** Head of Combination Product Development, **Shire**
- **Sudeshna Dutta Ray,** Senior Engineer Advanced Device Technology, **Amgen**
- **Stephen Barat,** Executive Director, Non-Clinical and Translational Sciences - Safety Assessment and Bioanalysis, **Allergan**
- **Tiffnay McIntire,** Human Factors Engineer, **Eli Lilly**
- **Hemal Mehta,** Manager, Global CMC-RA, Medical Devices and Combination Products, **Janssen R&D**
- **Phillip Green,** Executive Director, **Merck**
- **Kiran Singh,** Associate Director, **Sandoz**
- **Mike Price,** Senior Engineer, **Biogen**

PLUS TWO INTERACTIVE HALF-DAY PRE-CONFERENCE WORKSHOPS
Tuesday 25th April 2017, The Colonnade, Boston, MA, USA

WORKSHOP A
Successful incorporation of Human Factors in prefilled devices

08.30 – 12.30
Leader: **Melanie Turieo,** Director, Human Factors & Industrial Design, **Cambridge Consultants**

WORKSHOP B
Navigating the Silicone layer; a training program, to measure and understand siliconisation of syringes, cartridges and vials

13.30 – 17.30
Leaders: **Oliver Valet,** Vice President, **rap.ID**
Olga Laskina, Application Scientist, **rap.ID**

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Pre-Filled Syringes East Coast

Day One | Wednesday 26th April 2017

08.30 **Registration & Coffee**

09.00 **Chairman's Opening Remarks**

Dhairya Mehta,
Associate Director,
Shire

Michael Selzer,
Manager, Combination Products Engineering,
Regeneron

REGULATORY UPDATES AND STRATEGY

OPENING ADDRESS:

09.10 **Safety evaluation of leachables from pre-filled syringe drug products**

- Background on leachable safety assessment – why and how
- Application of safety evaluation of leachables for pre-filled syringe drug products
- Utilisation of PQRI PDP best practice recommendations for small volume parenterals and how these are applied to pre-filled syringes to support biological safety

Stephen Barat, Executive Director, Non-Clinical and Translational Sciences, **Allergan**

09.50 **Successful change control for patient centric drug delivery devices design and combination products post commercialisation market strategy**

- When to initiate a design change or device change?
- Which changes may require post regulatory submission? All changes should be assessed as design changes, however not all device changes need to follow the full design control process
- Implementing a change – changes to correct an existing problem may have unforeseen side effects on the device

Li-Chun Tsou, Global Device Technical Director, **AstraZeneca**

10.30 **Morning Coffee & Networking break sponsored by** TERUMO PHARMACEUTICAL SOLUTIONS

BIOLOGICS – CHALLENGES AND OPPORTUNITIES

11.00 **The role of wearable devices in overcoming the challenges of delivering large-molecule and high-volume biologics**

- Latest developments - a new class of wearable on-body drug delivery devices capable of delivering higher volumes and viscosities with minimal discomfort
- The revolutionary impact of advancements with wearable injectors on biological therapy treatments
- Product uptake and acceptability – patient's view

Sudeshna Dutta Ray, Senior Engineer – Advanced Device Technology, **Amgen**

11.40 **Tailoring the autoinjection with SAFELIA**

- For a better patient experience and for optimised drug delivery, including high volumes and high viscosities formulation
- Safelia injection course can be adjusted to fit 'difficult' formulations delivery, reconstitution, dual injections for subcutaneous or intra-muscular injections

Isabelle Delcroix, Business Development Manager, **Nemera**

12.20 **Networking Lunch Sponsored by** West

GOOD MANUFACTURING PRACTICE PART 1: DESIGN CONSIDERATIONS FOR COMBINATION PRODUCTS

13.30 **Combination products: Clinical and quality considerations applicable to bridging principles**

- Bridging design verification and validation for pre-filled syringe supplier changes
- Clinical bridging between Pre-filled syringes and injectors in and after Phase 3 trials – PK comparability risks
- Bridging legacy product design history files to meet 21 CFR part 4 requirements

Hemal Mehta, Manager, Global CMC-RA, Medical Devices and Combination Products, **Janssen R&D**

14.10 **A comparison of the stability of protein solutions in prefillable syringes made of glass or plastic under quiescent conditions and when subjected to mild agitation**

- Protein stability during long-term storage in glass vs plastic prefillable syringe systems
- The effect of autoclave vs E-beam sterilization of COP prefillable syringes on protein degradation
- Protein aggregation in prefillable syringes made of glass or plastic subjected to agitation stress
- The importance of performing a stability study in primary container systems made of glass vs plastic to determine the optimal packaging material

Lloyd Waxman, Lead Research Scientist,
West Pharmaceutical Services

14.50 **PLAJEX™ with Safe 'n' Sound®: Safe delivery of biotherapeutics**
William Dierick, Director Technology Development, **Terumo Pharmaceutical Solutions**
Adrien Tisserand, Global Category Manager – Parenteral & CMO, **Nemera**

15.30 **Afternoon Tea & Networking break sponsored by** TERUMO PHARMACEUTICAL SOLUTIONS

16.00 **Pre-filled syringe selection and the impact to life cycle management of drug products**

- Early decisions /stages of drug and device development - how do these systems work in parallel?
- Primary container selection and impact to life cycle management of combination products
- Moving towards auto injectors and pen devices

Antony Trupiano, Head of Combination Product Development, **Shire**

16.40 **Panel Discussion: Combination products – challenges and opportunities**

- On the road to patient-centric drug delivery - understanding the patient's interaction with the delivery system to be able to incorporate features which promote adherence to treatments
- Identifying the good manufacturing regulations that apply to combination products
- Technical challenges for developing and manufacturing combination products
- Regulatory hurdles in obtaining approval for pre-filled syringes and pens in human factors studies

Moderated by: Michael Selzer, Manager, Combination Products Engineering, **Regeneron**
Isabelle Delcroix, Business Development Manager, **Nemera**
Mike Price, Senior Engineer, **Biogen**

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

Letter from our Chair

Dear participants,

Pre-filled syringes have undoubtedly been one of the greatest platforms to modern medicine. Giving patients the power to handle and control their conditions and treatments has revolutionised many lives.

Though market success is determined by numerous factors; pharmaceutical work with syringes and drug delivery devices is inherently underpinned by patient centricity, and therefore bears huge responsibility to provide safe, useable and effective products. Being such a complex industry, this comes coupled with intricate challenges, opportunities and competition between pharmaceutical and device developing companies. Where there is competition, there is innovation, and we should take this opportunity to learn, develop and improve our best practise and strategy for pre-filled syringes.

Dhairya Mehta,
Associate Director
Shire

Upcoming events for the diary

- **Pre-Filled Syringes Europe**
  Copthorne Tara Hotel, London UK
  18th-19th January 2017
- **Pre-Filled Syringes West Coast**
  Hyatt Regency Mission Bay, San Diego CA
  5th - 6th June 2017

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08.30 **Registration & Coffee**

09.00 **Chairman's Opening Remarks**

Dhairya Mehta,
Associate Director,
Shire

Michael Selzer,
Manager, Combination Products Engineering,
Regeneron

GIVING YOUR DEVICE A HUMAN TOUCH

09.10 **Navigating regulations surrounding Human factors**

- Current regulatory climate, international and domestic
- Updates from the IEC/ISO – what does this mean for assessing and approving devices globally
- Other Human Factors standards – MHRA and AAMI – What is their impact

Edmond Israelski, Director of Human Factors, **AbbVie**

09.50 **The new paradigm of digital health and connectivity – From strategy to execution with compliance**

- Data collecting from patient behaviour and smart devices
- Exploring the connected drug delivery ecosystem; opportunities for feedback and monitoring
- Moving forward with smart devices

Dhairya Mehta, Associate Director, **Shire**

10.30 **Morning Coffee & Networking break sponsored by** TERUMO PHARMACEUTICAL SOLUTIONS

11.00 **Patient centric designs for pre-filled syringes**

- Understanding Human factors evaluation methods in order to achieve optimal design
- Empowering and involving patients – the role of patient-centered models in drug delivery
- New materials and modifications to existing materials – their impact on quality and reliability

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

GOOD MANUFACTURING PRACTICE OF PRE-FILLED SYRINGES – PART 2

11.40 **'The use of Cyclo Olefin Polymers (COP) for syringe, vial and cartridge applications in the pharma industry**

- 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 in COP syringes with various chemicals
- Protein adsorption/aggregation study data with actual protein drugs to COP vs. glass
- Delamination study data on glass syringe

Toshiro Katayama, Senior Product Manager, **Zeon**

12.20 **Networking Lunch sponsored by** West

13.30 **Application of computer modelling in pharmaceutical packaging**

- Empirical performance testing can be difficult to perform, and it can be difficult to determine the root cause of the lack of detail that can be present with empirical methods
- Modeling to minimize testing and provide greater insight for prefilled syringes
- Demonstrating how computer modelling provides greater insight into mechanical designs and material selection for primary container closure systems and the combination products that employ them
- Case study examples of the application of computer modelling in pharmaceutical packaging

Ronald Iacocca, Research Fellow, Delivery and Device R & D, **Eli Lilly**

14.10 **OXYCAPT Multila**yer Plastic Vial & Syringe with glass-like gas barrier for oxygen sens**itive biologics**

- Debating advantages of plastic syringes versus glass syringes
- How to overcome disadvantages of existing plastic syringes
- Latest studies for extractables from plastic and glass
- Minimising oxygenation and external changes through materials and development strategies

Kenchiro Usada, Researcher, **Mitsubishi Gas Chemical Company**

14.50 **Criteria for pre-filled syringes CMO selection**

- CMOs are a critical component of the drug product development and commercial manufacturing supply chain for many bio/pharmaceutical companies.
- The CMO must provide the specific manufacturing technologies, quality systems and regulatory support required to meet the drug product's critical quality attributes and business goals.
- Identifying and selecting the best CMO is essential to the success of any drug product program

Kiran Singh, Associate Director, **Sandoz**

Gary Mills, Associate Director Drug Development, **Tesaro**

15.30 **Afternoon Tea & Networking break sponsored by** TERUMO PHARMACEUTICAL SOLUTIONS

PATIENT CONCERNS FOR THE DEVELOPMENT OF PRE-FILLED SYRINGES

16.00 **Challenges of Drug Delivery for Pediatric Patients: A Case Study**

- How are pediatric patients different from adults?
- Should you focus on the device or the formulation?
- Pros and cons of developing solutions internally vs. outsourcing with development partners
- Commercial implications of pediatric devices

Steve Bowman, Leader, Device Center of Excellence, **Shire**

16.40 **Panel Discussion: The future of parenteral drug delivery**

- Addressing the need and challenges of high volume injectables:
  - Commercial opportunity and challenges
  - User considerations
  - Technologies: Wearable injectors Hand held autoinjectors & syringes etc
- Connectivity and connected devices:
  - Are they the future of parenteral drug delivery?

Moderated by: Phillip Green, Executive Director, Biologic Device Strategy, **Merck**
David Chen, Principal Scientist, Novel Drug Delivery Technologies, **Pfizer**
Sudeshna Dutta Ray, Senior Engineer – Advanced Device Technology, **Amgen**

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

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Half-Day Pre-Conference Workshop A

Tuesday 25th April 2017, The Colonnade, Boston, MA, USA

Melanie Turieo,
Director, Human Factors & Industrial Design,
Cambridge Consultants

Successful incorporation of Human Factors in prefilled devices

Workshop Overview:
This workshop will provide guidance and advice on how to successfully incorporate Human Factors into prefilled devices. Improve your understanding of Human Factors for pre-filled syringes in the context of the whole user interface; including instructional material, training and packaging. Learn to succeed in the application of Human Factors in pre-filled devices to enable delivery of high quality, market leading devices.

Reasons to attend:
- How to successfully incorporate Human Factors into device development
- Considerations for design and evaluation
- Navigating regulations and seeking approval
- Ensuring success; case study examples
- How to balance safety, usability and commercial success

About the Workshop Leader:
Melanie Turieo is a Director in Cambridge Consultants' Global MedTech division, and head of Human Centered 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 organisation:
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

08.30 **Registration & Coffee**

09.00 **Workshop leader's opening remarks and introduction**

09.10 **Incorporating Human Factors into prefilled device development**
- What to consider when making your device Human
- Design Intent
- Tests and evaluations
- Seeking regulatory approval – what to provide to gain regulatory approval

09.40 **Case study examples - common pitfalls vs success stories**

10.10 **Discussion**

10.30 **Coffee**

11.00 **The bigger picture; Human Factors as an ecosystem consideration**
- Human Factors is not a stand-alone consideration
- Balancing safety, usability and commercial success

12.00 **Discussion**

12.30 **Workshop leader's comments and close of the workshop**

Half-Day Pre-Conference Workshop B

Tuesday 25th April 2017, The Colonnade, Boston, MA, USA

Oliver Valet,
Vice President, **rap.ID**
Olga Laskina,
Application Scientist, **rap.ID**

Navigating the silicone layer; a training program to measure and understand siliconisation of syringes, cartridges and vials

Workshop Overview:
This half day training program will teach you to put quality at the heart of your product specification and provide you with the key learning points and information needed for you to control and validate the quality parameters in a pre-filled syringe. Increasing focus on patient satisfaction, coupled with increasingly excellent homogenous silicone layers demanded by auto-injector applications and protein based formulation mean it is essential to understand and control the silicone layer in prefilled syringes.

Reasons to attend:
- Understand control of the silicone layer; application, characteristics and measurements
- Validating your product; adding value and credibility to your control and quality parameters
- Practical breakout session; test and discuss your own samples and devices

About the Workshop Leaders:
Dr Oliver Valet is the co-founder of rap.ID Inc. rap.ID's technology has combined particle isolation, imaging analysis and spectroscopic technologies, creating investigative tools for particle identification and characterization. Dr. Valet has extensive experience in foreign particulate matter testing and Root Cause Investigation. He has also worked on the development of accurate and reproducible technologies for characterizing silicone oil layer thicknesses and its distribution in parenteral packaging materials.

Dr. Olga Laskina is an Application Scientist at rap.ID Inc, specializing in developing new approaches and methodologies for analysis of active ingredients and foreign particulates in pharmaceutical products. Prior to joining rap.ID Inc., Olga did PhD research studies of chemical and physical properties of micro particles using IR and Raman spectroscopies. Olga is involved with supplier evaluation and stability studies for prefilled syringes. She has extensive experience in protein agglomeration caused by presence of silicone or tungsten and by polysorbate degradation.

13.30 **Registration & Coffee**

14.00 **Workshop leaders' opening remarks and introduction**

14.10 **Application of silicone oil and the siliconization process**
- Different methods of silicone application; spray on and baked on
- Results from static and dynamic siliconization processes
- Impact of parameters on baked silicone oil

14.40 **Silicone layer characteristics**
- From 'dust test', gravimetric extraction and force displacement measurements to image analysis an bubble counting
- Advantages and limitations of different techniques
- What do the measurement results mean?

15.10 **Discussion**

15.30 **Coffee**

16.00 **Layer explorer technology and results**
- Technology, traceability and reproduceability
- Comparison with other siliconization measurements
- Resolution and accuracy of the measurement
- Measurement results and limitations

16.30 **Case studies and investigation strategy**
- Examples of silicone thickness and distribution and stability measurement in pre-filled syringes and baked-on cartridges
- Product stability studies
- Control suppliers quality

17.00 **Protein particle investigations**
- Raman spectroscopy and image analysis of particles
- Relationship between inhomogeneous silicone oil distribution and protein aggregation
- Breakout session; How can I measure the relationship between silicone oil and protein aggregation in my product?

17.30 **Workshop leader's comments and close of Workshop**

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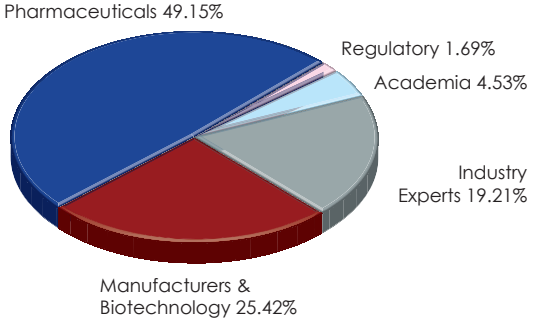

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Valid From ☐☐/☐☐ Expiry Date ☐☐/☐☐
CVV Number ☐☐☐☐ 3 digit security on reverse of card, 4 digits for AMEX card

Cardholder's Name:
Signature: **Date:**

I agree to be bound by SMi's Terms and Conditions of Booking.

Card Billing Address (If different from above):

VAT

VAT at 20% is charged on document portal and literature distribution for all UK customers and for those EU Customers not supplying a registration number for their own country here.

If you have any further queries please call the Events Team on tel +44 (0) 870 9090 711 or you can email events@smi-online.co.uk