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SMi Group Proudly Presents the 9th Annual Conference...

Pre-Filled Syringes East Coast

Device Innovations, Connected Delivery and Regulatory Guidance for Advanced Parenteral Systems

Sheraton Boston Hotel, Boston, USA

CONFERENCE: 25TH - 26TH
WORKSHOPS: 27TH
APRIL 2022

HIGHLIGHTS FOR 2022:

- **Delve** into the latest developments in innovative technologies for device design accelerating the path to self-administration
- **Assess** the evolving regulatory landscape for pre-filled syringes and discuss approaches to work with regulators and industry leaders as guidance is updated
- **Engage i**n panel discussions with industry leaders to navigate the major industry developments of the past year and assess approaches to accelerate next generation device development
- **Explore** advancing approaches to subcutaneous delivery of complex molecules including case studies of COVID-19 vaccine delivery

CHAIR FOR 2022:

Gretchen Vandal, Sr. Director, Head of Global Regulatory Affairs – Devices and Combination Products, **Takeda**

GUEST FDA SPEAKER:

- **John Barr Weiner,** Associate Director for Policy and Product Classification Office, **Office of Combination Products, FDA**

Featured 2022 Speakers Include:

- **Joyce Zhao,** Associate Director, Combination Product, **Takeda**
- **Suzette Roan,** Associate VP and Head of Global Device Regulatory Affairs, **Sanofi US**
- **Christine Lynn Lanning,** Distinguished Scientist, Device Area Leader, **Merck**
- **Heather L. Guerin,** Associate Director, Regulatory Affairs – CMC, **Janssen**
- **Tieming Ruan,** Senior Director of Device Development, **Alexion Pharmaceuticals**
- **John Schalago,** Executive Director, Senior Global Program Director Regulatory Affairs, **Novartis**
- **Gretchen Piwinski,** Manager, Combination Product Laboratories, **Regeneron**
- **Michael Song,** Associate Director, **Takeda**
- **Deep S Bhattacharya,** Senior Scientist, Drug Product Development and Design, **Pfizer**

PLUS TWO INTERACTIVE POST CONFERENCE WORKSHOPS
WEDNESDAY 27TH APRIL 2022, SHERATON BOSTON HOTEL, BOSTON, USA

A: EU MDR 2017/745 Article 117 Requirements

Workshop Leader: **Theresa Jeary,** Technical Specialist & Scheme Manager, **BSI**

08.30 - 12.30

B: Developing User-Centric Next Generation Combination Products

Workshop Leaders: **Marty Coyne,** Principal & Co-Founder, **Matchstick**
Chris Franzese, Principal & Clinical Leader, **Matchstick**

13.00 - 17.00

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Pre-Filled Syringes East Coast Conference

DAY ONE | MONDAY 25TH APRIL 2022

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Dear Colleagues,

It is with great pleasure and delight that we welcome you to SMi's highly anticipated Pre-Filled Syringes East Coast conference taking place on the 25th - 26th April 2022 in Boston.

Now in its 9th year, the Pre-Filled Syringes East Coast conference will bring together international industry experts in the field. This 2-day packed agenda will offer insights into innovations and advances in device design technologies, strategies for streamlined device development and risk management approaches for combination products. Furthermore, regulatory leaders from the FDA, notified bodies and industry will provide expert insights into navigating landscape for the future of device development, and industry thought leaders will provide updates on the evolving digital landscape.

Following the main event, 2 post-conference interactive workshops will be held on Wednesday 27th April 2022. There will be the opportunity to discuss 'EU MDR 2017/745 Article 117 Requirements' with notified body BSI and a deep dive into 'Developing User-Centric Next Generation Combination Products' with Matchstick.

As chair of this conference, we look forward to personally welcoming you to this must-attend event in Boston this April.

Yours sincerely,

Gretchen Vandal,
Sr. Director, Head of Global Regulatory Affairs – Devices and Combination Products, **Takeda**

08.00 **Registration & Coffee**

09.00 **Chairs' Opening Remarks**
Gretchen Vandal, Sr. Director, Head of Global Regulatory Affairs – Devices and Combination Products, **Takeda**

FURTHERING INNOVATIONS AND NEW TECHNOLOGIES IN DEVICE DESIGN

09.10 OPENING ADDRESS
Approaches and considerations to building an efficient and de-risk combination product development program
- Cross functional interconnection and ways to ensure program success
- EU MDR GSPR and leveraging from program success
- Understanding essential performance requirement
- How an effective control strategy can help ensure program success
- Design control and risk reduction activities

Michael Song, Associate Director, **Takeda**

09.50 **Lessons learned: on-body delivery system design and development**
- Learning from user experiences in early development of delivery systems
- Current regulatory guidance for wearable devices and understanding international requirements
- Case Study: designing patient-centric on-body delivery systems
- How have we seen device design evolving in recent years and a future forecast

Amber Witteman, Founding Director, Ebenroth B.V.- **EpiWatch**

10.30 **Morning Coffee Sponsored by Zeon**

11.00 **Improvement of complaint intake process for combination products: a patient centric approach**
- Overview of complaint intake process and current limitations for complaint analysis
- Harmonization, accuracy, and time reduction for complaint analysis

Amir Fakhari, Senior Engineer, Combination Products, Global Technical Operations, **AstraZeneca**

STRATEGIES FOR STREAMLINED AND NEXT-GENERATION PARENTERAL DELIVERY DEVICES

11.40 **A Glass Alternative: ZEONEX® and ZEONOR® Cyclo Olefin Polymer (COP) for Pre-Filled syringes**
- Key Benefits of COP for Medical Devices
- Case Study on Delamination: COP Syringe vs Glass Syringe
- Case Study on Protein Adsorption/Aggregation and its effect on Immunogenicity

Larry Atupem, Strategic Business Development Manager, **Zeon Specialty Materials**

12.20 **Networking Lunch**

13.20 PANEL DISCUSSION
Learnings from the past year to accelerate next generation device development
- Assessing regulatory developments for combination products over the past year
- Emerging device design innovations for parenteral delivery
- Assessing the landscape of connected technology applications, how can we ensure smart features are aiding he user?
- Encouraging flexibility and collaborations throughout the combination product development process across all teams

Panel Moderator:
Gretchen Vandal, Sr. Director, Head of Global Regulatory Affairs – Devices and Combination Products, **Takeda**
Panelists:
Christine Lynn Lanning, Distinguished Scientist, Device Area Leader, **Merck**
Gretchen Piwinski, Manager, Combination Product Laboratories, **Regeneron**
Amir Fakhari, Senior Engineer, Combination Products, Global Technical Operations, **AstraZeneca**
John Schalago, Executive Director, Senior Global Program Director Regulatory Affairs, **Novartis**

14.00 **Considerations for Designing Test Method Validation Studies**
- Identification of critical variables affecting test output
- Establishing test limits and acceptance criteria
- Understanding the manufacturing process for sample parts
- Special considerations for destructive testing

Gretchen Piwinski, Manager, Combination Product Laboratories, **Regeneron**

14.40 **Afternoon Tea Sponsored by Zeon**

CONTROL STRATEGIES AND RISK MANAGEMENT FOR COMBINATION PRODUCTS

15.10 **Leveraging supplier information for pre-filled syringe development**
- Biocompatibility basics in drug delivery device development
- Engaging in supplier information in drug delivery development
- Assessing ISO 10993 and the phased approach
- Understanding materials safety concerns and know the critical questions to ask suppliers

Christine Lynn Lanning, Distinguished Scientist, Device Area Leader, **Merck**

15.50 **Combination Product Essential Performance Requirement Identification and Control Strategy Development**
- Challenges to define and identify essential performance requirement (EPR) during the development of a combination product
- EPR to be developed in accordance with the risk profile of the entire combination product as well as the intended function of the device constituent part
- A control strategy is developed based on essential performance requirements of the combination product. Traceability matrix should demonstrate all the essential performance requirements have been adequately verified and validated

Joyce Zhao, Associate Director, Combination Product, **Takeda**

16.30 CASE STUDY INSIGHT
EPR and Control Strategy of Prefilled Syringe
- Discuss the latest EPR feedback of a Prefilled Syringe
- Discuss the control strategy practice of a prefilled syringe
- Discuss a case study of prefilled syringe control strategy

Tieming Ruan, Senior Director of Device Development, **Alexion Pharmaceuticals**

17.10 **Chairs' Closing Remarks and Close of Day One**

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08.30 Registration & Coffee

09.00 Chairs Opening Remarks
Gretchen Vandal, Sr. Director, Head of Global Regulatory Affairs – Devices and Combination Products, **Takeda**

EVOLVING REGULATORY ENVIRONMENT FOR THE FUTURE OF DEVICE DEVELOPMENT

OPENING ADDRESS

09.10 **An update on FDA regulatory guidance from the office of combination products**
- Summary of recently issued premarket and postmarket policies for combination products, and status of pending policy projects, including on such topics as:
  - Essential performance requirements
  - Human factors studies and related clinical study considerations
  - Principles of premarket pathways for combination products
  - Post market safety reporting
  - Facility inspections
- Looking to the future, how can we expect the regulatory landscape to evolve for combination products, and opportunities to promote cross-jurisdiction collaboration and convergence

John Barr Weiner, Associate Director for Policy and Product Classification Office, **Office of Combination Products, FDA**

09.50 **Combination Product Verification and Validation: Leveraging Data for Regulatory Submissions**
- Discussion of how verification and validation data can be bridged from one product to another, review of FDA Guidance
- Examples of successful human factors validation data leveraging
- Review of current thinking on Essential Performance Requirements for combination products submitted to FDA

Heather L. Guerin, Associate Director, Regulatory Affairs – CMC, **Janssen**

10.30 Morning Coffee Sponsored by Zeon

11.00 **Regulatory Considerations for Combination Product Lifecycle Management**
- An overview of the current regulatory requirements for change management
- Best practices for assessing device changes and use of ISO 20069, Guidance for assessment and evaluation of changes to drug delivery systems
- Considerations for defining reporting categories for device changes
- Submission considerations and utilization of regulatory tools, including ICH Q12, Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

Suzette Roan, Associate VP and Head of Global Device Regulatory Affairs, **Sanofi US**

11.40 **EU MDR Article 117: Notified Body update on the quality of submissions and lessons learnt**
- Recap of requirements and products impacted
- Update on NB experience of process and submissions
- Common gaps in applications
- Available Guidance

Theresa Jeary, Technical Specialist & Scheme Manager, **BSI**

12.20 Networking Lunch

APPROACHES TO DELIVERY OF COMPLEX MOLECULES

13.20 **Cold Temperature Performance of Glass and Polymer PFS**
- Current Covid-19 mRNA vaccines on the market are available in vials, which is great for vaccine time-to-market, but because of the drug preparation time and the potential risk for medical errors, vaccine manufacturers are looking for a second generation drug presentation in the form of a PFS
- Because of the demanding requirements for the vaccine stability and the low temperature supply chain, multiple aspects of the PFS need to be considered
- In this presentation we want to share our experience and data on syringe functionality and CCI to help accelerate mRNA manufacturers in their life cycle quest from vials into PFS.

Daniele Tartini, Business Development Manager for Glass Syringes, **SCHOTT North America, Inc.**

14.00 **Assessment of structural integrity of biologics through simulated sub-cutaneous environment using the SCISSOR**
- Structural assessment of simulated in vitro conditions of biologics using the SCISSOR
- Understanding of destabilizing mechanisms of biologics in the sub-cutaneous environment
- Deeper dive into peptide hotspots to identify potential sites for destabilization and re-iterative formulation development

Deep S Bhattacharya, Senior Scientist, Drug Product Development and Design, **Pfizer**

14.40 Afternoon Tea Sponsored by Zeon

ADOPTING CONNECTIVITY IN COMBINATION PRODUCT DEVICE DEVELOPMENT

15.10 **Connected device considerations and the evolving digital landscape**
- An update on the evolving digital health landscape and how it has developed for combination products in recent years
- An insight into regulations for connected devices and recent updates
- Ensuring patient usability and human factors is kept at the forefront when adding connected features
- A future outlook for digital health: forecasting the potential of connected delivery devices

Gretchen Vandal, Sr. Director, Head of Global Regulatory Affairs – Devices and Combination Products, **Takeda**

15.50 **Product lifecycle development from pre-filled syringes to digital ecosystem**
- Smart Device and connected health platforms – regulatory considerations and industry outlooks
- Combination product lifecycle management and post market safety reporting for connected combination products
- Software as a Medical Device and connected device regulatory submission case studies

John Schalago, Executive Director, Senior Global Program Director Regulatory Affairs, **Novartis**

16.30 **Technology and design considerations in developing easy-to-adopt user centric digital health products**
- Creating easy to adopt user centric products through smart utilization of sensor and technology fundamentals.
- Software update considerations and minimize life cycle management complexity
- Understand societal and behaviour imprints to develop solutions with easier adoption and simple learning curve for patient.
- User centric design considerations in product design beyond the patient

Jason Song, Chief Technology Officer, **SureMed Technologies**

17.10 Chairs' Closing Remarks and Close of Day Two

UPCOMING EVENTS IN SMI'S DRUG DELIVERY DEVICES SERIES:

Pre-Filled Syringes and Injectable Drug Devices Focus Day: Sustainability for Drug Delivery Devices
11th – 13th January 2022, London, UK
www.pre-filled-syringes.com

Injectable Drug Delivery
11th – 12th May 2022, London, UK
www.injectable-drug-delivery.com

Transdermal and Microneedle Delivery
24th – 25th January 2022, London, UK
www.transdermal-microneedle-delivery.co.uk

Pre-Filled Syringes West Coast
13th – 14th June 2022, San Diego, CA, USA
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Pre-Filled Syringes East Coast Conference

Wednesday 27th April 2022, Sheraton Boston Hotel, Boston, USA

POST CONFERENCE WORKSHOP A
08.30 - 12.30

Workshop Leader:
Theresa Jeary, Technical Specialist & Scheme Manager, **BSI**

EU MDR 2017/745 Article 117 Requirements

Overview of the workshop:
The workshop is aimed to provide an introduction to the key elements of the Medical Device Regulation that Companies affected by article 117 need to consider.

Why you should attend:
- Be able to determine if Article 117 is applicable to your products
- Understand and be able to interpret the requirements of Article 117
- Understand the impacts on your marketing authorization application or post-market variation
- Gain an appreciation and understanding of the MDR Annex I, General Safety & Performance Requirements
- Understand requirements to facilitate the documentation preparation needed to obtain a NB Opinion

About the workshop leader:

Theresa Jeary has over 30 years' experience working in both the Pharmaceutical and Medical Device industries and has worked in a variety of roles across the full development cycle. She holds a master's degree in Pharmaceutical Science from the Royal College of Surgeons, Ireland and is eligible to be a Pharmaceutical Qualified Person.

Additionally, Theresa has over 12 years Notified Body experience, at BSI as a technical expert and LRQA as the Head of Notified Body. Before re-joining BSI as a technical specialist in the Medicinal and Biologics team, Theresa worked as a consultant to the Medtech sector.

About the organisation
BSI is the business improvement company that enables organizations to turn standards of best practice into habits of excellence. For over a century, BSI has championed what good looks like and driven best practice in organizations around the world. Working with 84,000 clients across 193 countries, it is a truly international business with skills and experience across a number of sectors including healthcare. Through its expertise in Standards Development and Knowledge Solutions, Assurance, Regulatory Services and Consulting Services, BSI improves business performance to help clients grow sustainably, manage risk and ultimately be more resilient and trusted.

Programme

08.30 **Registration and Coffee**

09.00 **Opening Remarks**

09.10 **Session 1**
- Introduction to Article 117 Requirements
- How to identify products impacted by A117
- When is a NB Opinion Required?

09.50 **Session 2**
- Introduction to the MDR and key concepts on how devices are regulated
- Notified Bodies – Role in the process & the NB Opinion Report
- Medical Device Classification – how is this done

10.30 **Morning Coffee**

11.00 **Session 3**
- MDR Annex I – General Safety & Performance Requirements
- Impact of A117 on Product Documentation Requirements
- NB process for reviews

11.40 **Session 4**
- NB Expectations for technical documentation
- Common omissions
- Management of changes

12.20 **Closing Remarks**

12.30 **Closing Remarks and end of workshop**

POST CONFERENCE WORKSHOP B
13.00 - 17.00

Workshop Leaders:
Marty Coyne, Principal & Co-Founder, **Matchstick**
Chris Franzese, Principal & Clinical Leader, **Matchstick**

Developing User-Centric Next Generation Combination Products

Overview of the workshop:
This interactive workshop will explore approaches for developing innovative drug delivery device combination products offering tools for optimal device development with the user in mind. Workshop leaders will provide insights into effectives strategies for concept generation, product testing and validation for the future of device design.

Why you should attend:
- Discover innovative concept generation approaches for device development
- Understand how to utilise user feedback and experiences in early stages of development
- Walk through unique examples assessing effective testing to ensure an optimal product
- Engage in interactive discussions to assess opportunities for enhanced devices ensuring the patient is kept at the forefront

About the workshop leaders:

Marty Coyne: Engineer and business leader with experience inventing, launching, and marketing medical and drug delivery devices. Leads overall company and innovation programs. 11 patents and numerous patents pending. BE Mechanical Engineering Stevens Institute of Technology, MBA Columbia University.

Chris Franzese: Clinical trial researcher with 19 peer-reviewed papers. Leads clinical team, ensuring that deep understanding of clinical perspective is reflected and embedded in our work. Responsible for all secondary research projects. BS Biology Loyola University, PharmD and MHS Health Informatics from Fairleigh Dickinson University. PGY1 Residency, Atlantic Health System.

About the organisation
Matchstick is a specialty consultancy focused on pre-concept and concept stage development of combination products and specialty pharmaceuticals including devices, patient support and engagement programs, training, and lifecycle strategies. Matchstick helps global pharmaceutical firms understand unmet patient and healthcare provider needs, invent useful and relevant product and service solutions that work in a regulated environment, and deliver compelling business cases to drive programs forward within client organizations. Matchstick is well-known in the combination product space as a model of small-company culture, creativity, and corporate polish. Delivering a high touch, deeply personal experience, Matchstick is sought after by pharmaceutical clients to crack problems that defy easy elevator speeches and cookie-cutter approaches.

Programme

13.00 **Registration and Coffee**

13.30 **Opening Remarks**

13.40 **Session 1 - Understanding user needs to guide device design**
- The landscape of patients using self-administered injectable delivery devices on a regular basis
- How have we seen device design develop in recent years for self-administration
- Working with users to understand current therapies and develop deep understandings of users, practices, needs and challenges
- Using patient requirements and experiences to guide device development

14.20 **Session 2 - Effective testing for an enhanced product**
- Assessing preference and acceptance rates of a device in early stages of development
- Evaluating the value of device features and functionality to aid the user
- Refining smart features to ensure ease-of-use
- Performing appropriate usability testing to assess device concepts, instructions and training materials

15.00 **Afternoon Tea**

15.30 **Session 3 - Thinking outside the box – concept generation**
- Based on a case study example, attendees will take this time to review approaches for new product concept generation for an injectable drug delivery device

16.10 **Session 4 - Case Study Discussions and Takeaways**
- Combining patient feedback with new technologies – insights into the future of design
- Guidance in working across teams for optimal combination product development
- Attendees will have the chance to discuss and assess opportunities for next generation devices ensuring the patient is kept at the forefront while implementing innovative technologies for an optimal combination product.

16.50 **Closing Remarks**

17.00 **End of Workshop**

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Pre-Filled Syringes East Coast **Past Attendee Breakdown**

"The conference was a great learning opportunity and also a great way to connect with other professionals in spite of COVID-19."

"I enjoyed the conference very much, especially the variety of topics that were covered."

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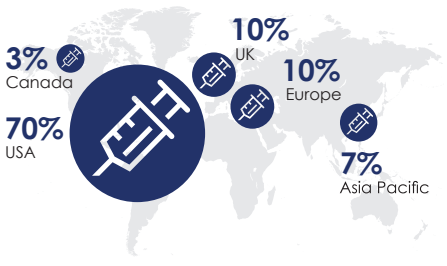

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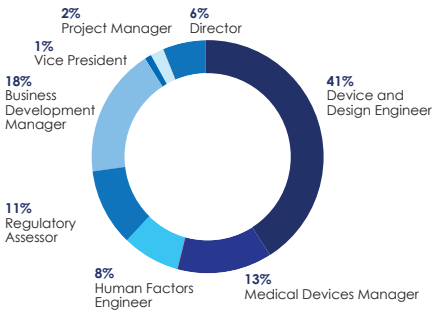

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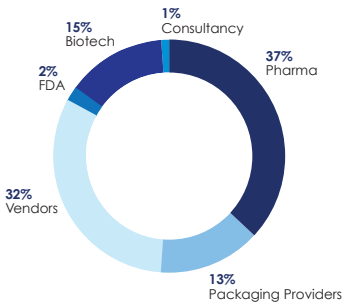

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