Dear participants,

As chairs of the 11th annual Pre-Filled & Injectable Drug Devices Europe conference, we cordially invite you to attend this anticipated event taking place on the 16th-17th of January 2019 in London.

The 11th annual Pre-Filled Syringes & Injectable Devices Europe conference will bring together expertise from individuals in multiple disciplines in the field of Pre-Filled Syringes and Injectable Drug Devices. The 2-day, packed agenda will offer a series of presentations, through which you will gain insight into current industry trends, innovations in injectable drug delivery and considerations for combination product development.

More and more injectable drugs are administered using devices like pre-filled syringes, auto-injectors, and pen-injectors. Patient-centricity is driving the future of injectable drug delivery market whether it’s through more self-administration, connectivity, or even wearables devices. The development and commercialisation of these injective devices pose many challenges to pharma and biotech companies at every stage of the life cycle from product development to life cycle management. Understanding these challenges and the strategies needed to overcome them reduces the risk of safety and performance for improved patient outcomes while driving efficiencies across the organisation.

Delegates stand to gain many valuable insights from this event, such as:
• New technologies and innovations for platform systems of injectable delivery devices
• Strategies for defining the design space of a platform system
• Defining the regulatory requirements and compliance activities across the product life cycle
• The impact of the digitalisation of devices

Prior to the main event, two pre-conference, half-day workshops will be held on Tuesday 15th January 2019. There will be the opportunity to discuss ‘Connected Devices and Digital Health: How to Navigate the U.S. FDA Usability Engineering Requirements’; and to delve into the concept of ‘Body Worn Injectors: Shaping the future of parenteral drug delivery’.

As the chairs of this event, we look forward to personally welcoming you to this must-attend event in London this January.

James Mellman, Strategy and Innovation Global Product Manager, SCHOTT Schweiz AG

Anil Busimi, Device Manager, Novartis

10.30 Morning Coffee

11.00 Preferred Properties of Pre-Filled Syringes for Biopharmaceuticals
• Physico-chemical characterisation of biopharmaceuticals
• Degradation and stabilisation of biopharmaceuticals
• Relation to typical container systems

Reinhard Scheller, Commercial Manager Cyclo Olefin Polymers - COP Europe, Zeon Europe GmbH

11.40 Development of a Combination Product Control Strategy
• Steps towards the development of a combination product control strategy
• The essential performances requirements
• The critical process parameters for generation on the control strategy
• Case studies following this approach

Matthieu Rigolet, Senior PFS Engineer, Roche

12.20 Networking Lunch

13.20 Computational Model supporting design verification data to estimate occurrence levels of critical quality attributes
• Computational Model for automated injection device
• Simulation in context of design verification and estimation of occurrence rate for post market
• Combining models with physical testing to reduce test effort, sample sizes and failure risk

Michael Becker, Design Engineer, Boehringer Ingelheim

14.00 Application of Quantitative 1H-NMR Spectroscopy for the determination of silicone oil and degradation products hereof
• Non-destructive detection of silicone oil and its degradation products
• Linear quantitative method working in aqueous as well as organic solvents
• Simple to validate according to ICH principles
• Stability indicating method
• Orthogonal method to e.g. MFI and ICP

Joan Malmström, Principal Scientist, Novo Nordisk A/S

14.40 High throughput testing of injectable devices with a fully automated testing system using special sampling plans
• 24/7 measurements of injectable devices using a fully automated testing machine
• Measuring up to 600 devices within 24 h fully automated and GxP compliant
• Fully automated testing of different devices in parallel
• Special sampling plan based on ISO3951-2 with reduced, batch independent sample size

Alexander Zuer, Device Testing Manager, Novartis

15.20 Afternoon Tea

15.50 Regulatory updates in the Pre-Filled Syringes and Injectable Drug Devices market
• Safety legislation and revisions to current guidelines
• Change in device regulations and what that means for the pharmaceutical side of the industry
• The added layer of safety assurance through physical, pre-administrative checks. How this not only meets regulatory requirements, but assures patient safety as well
• Human factors engineering – regulatory challenges
• Control strategy for combination products

Vikas Jaitely, Senior Manager Pharmaceutical Sciences & CMC Regulatory Intelligence, Merck Group

16.30 Regulatory expectations on emerging technologies
• Updates on combination product regulation and the view of auto-injectors and pre-filled syringes within that scope
• The difference between injectors and pre-filled syringes – the line between a drug product and a device
• Where new technologies fall within the regulatory scope of device development
• New medical device directives

Suraj Ramachandran, Director, MSD

17.10 Chairman’s Closing Remarks and Close of Day One
Pre-Filled Syringes & Injectable Drug Devices
DAY TWO | THURSDAY 17TH JANUARY 2018

08.30 Registration & Coffee

09.00 Chairman’s Opening Remarks
James Mellman, Device Manager, Novartis
Anil Busimi, Strategy and Innovation Global Product Manager, SCHOTT Schweiz AG

09.10 Opportunities and challenges of implementation of platform component for biologic injectable delivery
• Why do we need a platform? A standardised approach
• Where does the platform start and stop in the development process? And are all the area impacted?
• What are the challenges for the projects? The team and the documentation?
Elise Legendre, Head of Late stage PFS Development, Sanofi

09.50 Pre-clinical development of a drug product for injection
• Recognition of molecule and formulation needs to support product development
• Considerations necessary for early development injectable program vs. bridging to existing program from another route
• Drug/Device considerations and the need for leachable evaluations and qualifications
Stephen Barat, Head of Pre-Clinical and Early Clinical Development, SCYNEXIS Inc

10.30 Morning Coffee

11.00 SESSION RESERVED FOR NEMERA
Nemera

11.40 Harnessing the Digital Exhaust: Incorporating wellness into the Pharma Model and how Drug Delivery will be a key enabler
• The industry is undergoing a pivotal transformation as traditional drugs are supplanted by next generation product systems where, in some cases, the drug is only a component of the overall product offering
• This situation has created a compelling entry point for non-traditional competitors and start-ups to access this market and potentially redefine the value model associated with drug pricing
• A dynamic patient interface which leads to extraordinary patient engagement
• A review of the current and future state along with perspective and case studies will be provided in order to help shed light on the areas of needed focus and corresponding opportunity
Justin Wright, Global Head of Innovation, Novartis

12.20 Innovative glass pre-filled syringe (PFS) solutions for biotech drugs
• The R&D pipeline of global pharma industry is full with biotech-based drugs making personalized medicine a reality
• Most of these drugs are target specific and highly sensitive demanding special attention to all the steps along the development process and value chain
• Biotech drugs are complex molecules and may interact with the components of the PFS (needle, glue, silicone, elastomer etc.) leading to stability issues, impact efficacy of the drug and worst cases immunogenic response in patients

13.00 Networking Lunch

14.00 The best plastic syringe for biologics
• OXYCAPT Multilayer Plastic Syringe having Glass-like Oxygen Barrier
• Excellent Oxygen Barrier Contributes to Stability of Biologics
• Latest Protein Aggregation Study
• Latest Container Closure Integrity Study
Shota Arakawa, Researcher, Mitsubishi Gas Chemical

14.40 Dosing accuracy-and precision of intravitreal injection with 0.5 mL syringe in comparison to 1 mL long syringe
• Regulatory requirements on dosing accuracy
• Significant test parameters
• Test results and statistical analyses
• Optimization and verification of dose mark position for 0.5 mL syringe
Markus Hemminger, Senior Device Engineer, Roche

15.20 PANEL: Glass vs Polymers for primary packaging for injectable drug devices
• The regulatory perspective surrounding primary packaging
• Technical standards
• Component integration
James Mellman, Device Manager, Novartis
Suraj Ramachandran, Director, MSD
Anil Busimi, Strategy and Innovation Global Product Manager, SCHOTT

16.00 Afternoon Tea

16.30 Change is Inevitable- Post Market considerations for combination products
• Overview of regulatory expectations for post marketed products
• Leveraging design controls in order to manage changes and mitigate risks
• Considerations and best practices
• Challenges and Opportunities
Maggie Reiff, Associate Device Engineer, Pfizer

17.10 Risk Management for injectables drug devices throughout the lifecycle
• Integrated Risk Management model for Drug-Device Combination Products
• Hazard analysis: Key role to lead the risk management process
• Risk Analysis and Control
• Importance of the post-marketing phase to revise the Risk Management File
Davide Mercedante, Sr Associate Quality Drug Devices, Biogen

17.50 Chairman’s Closing Remarks and Close of Day Two

Connected Devices and Digital Health:
How to Navigate the U.S. FDA Usability Engineering Requirements

Workshop Overview:
Shannon has conducted numerous workshops on human factors and usability testing throughout the world, from Stockholm to Shanghai. This workshop will discuss the U.S. FDA Human Factors Engineering Process in the context of digital health and connected devices, as well as unique U.S. FDA regulatory hurdles related to this domain.

The workshop will include case studies related to emergent digital health innovations currently coming out of Silicon Valley, software apps connected to drug delivery platforms, and new applications for medical software.

Why You Should Attend:
• Review applications for connected devices
• Discuss the unique U.S. FDA regulatory requirements related to phone applications and connected devices
• Discover common software and device development pitfalls related to connected devices and digital health
• Walk through the unique considerations for your human factors strategy and the details of usability testing for Apps and connected devices.

Workshop Leader Biography:
Shannon Clark is the Founder and CEO of UserWise, a consultancy that helps medical product manufacturers and start-ups to design safe and easy-to-use medical devices, ranging from surgical robots to home-use injection platforms. Before founding UserWise in 2015, Shannon was a Human Factors Engineer at Intuitive Surgical and Abbott Laboratories/AbbVie. She graduated from UCLA with a B.S. in Mechanical Engineering and a technical breadth in Technology Management. In addition, she is a U.S. Certified Professional Industrial Engineer, holds two patents, and has written and published three books.

Organisation Synopsis:
UserWise is a team of Human Factors Engineers dedicated to designing best-in-class medical products, packaging, and labelling. With experience ranging from home-use injectables and diagnostics to robotic surgery platforms, our consultants successfully navigate medical device and combination product regulations via usability testing, use-related risk analysis, and compliance documentation. www.userwiseconsulting.com

Body Worn Injectors: Shaping the future of parenteral drug delivery

Workshop Overview:
Body worn injectors will become a key choice for injectable drug delivery and reshape healthcare by disrupting therapy administration and patient management in and out of hospitals. In this workshop, we will explore the factors that will drive the transformation of the parenteral drug delivery device landscape and explore the key technologies and healthcare innovations necessary to materialise this future.

Why You Should Attend:
• Learn what will drive increased adoption of body worn injectors
• Explore the innovations that will catalyse the transformation of body worn injectors to a primary choice for parenteral drug delivery

Workshop Leader Biography:
James Blakemore is a Senior Consultant in the Medical Technology division at Cambridge Consultants. He specialises in market strategy and transaction support within the pharmaceutical and drug delivery device markets. He manages drug delivery device development projects bringing together commercial insight and technical expertise. Prior to working in the healthcare consulting industry, Dr Blakemore worked in a number of business development and licensing roles for specialty pharmaceutical and biotechnology companies, working towards the identification, validation and commercialisation of broad new therapies. He holds a PhD in Molecular Biology from King’s College, University of London, UK.

Sergio Malorni is a Senior Consultant in the Medical Technology division at Cambridge Consultants. He specialises in leading multidisciplinary development programmes for drug delivery devices - from early-stage product research and strategy, concept definition, design and engineering to product launch. His 28-year experience spans across the development of a variety of mechanical and electromechanical devices including body-worn injectors, pre-filled syringes, pen injectors, dry powder nasal inhalers, sub-lingual sprays, and patient-controlled analgesia pumps. Sergio balances technical, human sciences and market requirements to create technically novel, patient centric and commercially successful devices. With 20+ years of consultancy experience including work in surgical, diagnostic and aerospace sectors, he is named as inventor on several medical device patents and application and holds a Mechanical Engineering degree from McGill University, Montreal, Canada.

Organisation Synopsis:
Cambridge Consultants is a world-class supplier of innovative product development engineering and technology consulting. For more than 55 years, we have been helping clients turn business opportunities into commercial successes, whether they are launching first-to-market products, entering new markets or expanding existing markets through new technologies. By combining scientific understanding with patient and healthcare insight, we have created award-winning drug delivery devices for the treatment of conditions ranging from cancer and autoimmune diseases to diabetes and asthma.

Programme
08.30 Registration and Coffee
09.00 Opening Remarks and Introductions
09.10 Session 1:
Connected Devices and Digital Health - Current and Future Applications
09.50 Session 2:
Overview of Applicable U.S. FDA Usability Engineering Requirements & Regulatory Requirements for Connected Devices and Digital Health
10.30 Morning Coffee
11.00 Session 3:
Review Unique Usability Engineering Considerations Related to Connected Devices
11.40 Session 4: Q&A
12.30 Closing Remarks and End of Workshop

Programme
13.30 Registration & Coffee
14.00 Opening Remarks and Introductions
14.10 Current Developments in the Body Worn Injector (BWI) Device Landscape
14.50 Holistic Review of Stakeholder Needs to Drive BWI Innovations
15.30 Afternoon Tea
16.00 Understanding Future and Unmet Needs to Drive BWI Innovations
17.00 Potential New BWI Technologies
17.30 Closing Remarks and End of Workshop