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Pre-Filled Syringes Europe

Excelling in Quality – from Device Design to Manufacturing

WORKSHOPS: 17TH
CONFERENCE: 18TH - 19TH
JAN 2017

Copthorne Tara Hotel London Kensington, London, UK

Key topics for 2017:

- Regulatory challenges at the interface of medicines and medical devices
- New technologies for pre-filled syringes – streamlining innovation
- Combination products – challenges and opportunities
- Recent guidelines on Human Factors Engineering
- The future of parenteral drug delivery - moving from drug delivery devices to therapy management ecosystems

CHAIRMAN:

Alphons Fakler, Group Head Risk Management, **Novartis Pharma**

FEATURED SPEAKERS:

- **Vikas Jaitely,** Deputy Manager and Senior Pharmaceutical Assessor Licensing Division, **Medicines and Healthcare Products Regulatory Agency (MHRA)**
- **Alexander Jung,** Senior Manager Technology and Innovation, Drug Delivery & Devices, **Boehringer Ingelheim**
- **Christian Dechant,** Primary Packaging Director, **Boehringer Ingelheim**
- **Serkan Oray,** Senior Director, Device & Technology, **UCB**
- **Paolo Mangiagalli,** Senior Director - PFS Platform, **Sanofi**
- **David Blakey,** Device Development Manager, **GSK**
- **Sachin Dubey,** Head of Formulation, **Glenmark Pharmaceuticals**
- **Andreas Kerschbaumer,** Facilitator Compounding, Filling & Inspection, **Sandoz**
- **Ed Cahill,** Senior Director, Technical and Scientific Affairs - Sterile Products, **Teva**
- **Nick Stones,** Fellow, Human Factors Engineering, **Novartis Pharma**
- **David Ottolangui,** Device Technology Director, **GSK**
- **Vincent Cazanave,** Pre-Fillable Syringe Engineering - Device Development, **F. Hoffmann-La Roche**
- **Markus Hemminger,** Senior Engineer Pre-Filled Syringes, **F. Hoffmann-La Roche**

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PLUS TWO INTERACTIVE HALF-DAY PRE-CONFERENCE WORKSHOPS
Tuesday 17th January 2017, Copthorne Tara Hotel London Kensington, London, UK

WORKSHOP A | 08.30 – 12.30

The future of parenteral drug delivery - moving from drug delivery devices to therapy management ecosystems

Workshop leader:
Vaishali Kamat, Head of Digital Health, **Cambridge Consultants**

WORKSHOP B | 13.30 – 18.15

Regulatory challenges at the interface of medicines and medical devices

Workshop leader:
Janine Jamieson, Regulatory Consultant, **ex-MHRA assessor**

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Pre-Filled Syringes Europe

Day One | Wednesday 18th January 2017

08.30 **Registration & Coffee**

09.00 **Chairman's Opening Remarks**
Alphons Fakler, Group Head Risk Management, **Novartis Pharma**

REGULATORY UPDATES AND TECHNOLOGICAL DEVELOPMENTS

09.10 **OPENING ADDRESS:**
Regulatory aspects of pre-filled syringes - latest updates from MHRA
- Pre-filled syringes regulated as a medicinal products or a medical device in the EU (combination products – definitions and examples)
- Regulatory pathways and data expected in the registration dossier
- Usability studies – human factor engineering – clarity on what's expected?

Vikas Jaitely, Deputy Manager and Senior Pharmaceutical Assessor Licensing Division, **Medicines and Healthcare Products Regulatory Agency (MHRA)**

09.50 **New technologies for pre-filled syringes - streamlining innovation**
- Product development as a way to differentiate from competitors
- Empowering and involving patients – the role of patient-centered model in drug delivery
- New materials and modifications to existing materials – their impact on quality and reliability
- Other innovative options including new devices, new safety and new connectivity features
- Which options can be implemented in the quickest way and which require more long-term planning and investment in resources

Alexander Jung, Senior Manager Technology and Innovation, Drug Delivery & Devices, **Boehringer Ingelheim**
Christian Dechant, Primary Packaging Director, **Boehringer Ingelheim**

10.30 **Components and systems selection strategies for pre-filled syringes, risk mitigation, performance and quality**
- Current trends and new technologies in the market of pre-filled syringes and self administration systems
- Challenges for companies developing products in PFS
- Key critical product requirements
- Components and systems designed specifically for optimised performance as well as to address demanding drug components (sensitivity, viscosity, volume)

Christa Jansen-Otten, Director Global Product Management Prefilled Systems and Delivery, **West Pharmaceutical Services**

11.10 **Morning Coffee & Networking Break**

11.40 **Device design implications of increasing dose volume on injection time and patient factors**
- Beyond the first self-administered parenteral bolus dose
- Causes of infusion pain and how to mitigate it
- Patient factors that may influence adherence
- Device design options for this emerging dose form

David Blakey, Device Development Manager, **GSK**

THE RISE OF COMPLEX BIOTHERAPEUTICS VS PFS

12.20 **Combination products: a need for flexible and customisable drug delivery devices**
- Challenges within drug life cycle management
- Drug and patient problems
- Case study, the collaboration of a device manufacturer and a pharma

Adrien Tisserand, Category Manager – Parenteral, **Nemera**

13.00 **Networking Lunch**

14.10 **Engineering of delivery system integration for biologics and primary containers**
- How to integrate the various platforms: From PFS to pens to autoinjectors
- Translating integrated system approach into component requirements
- Opportunities for knowledge sharing

Paolo Mangiagalli, Senior Director- PFS Platform, **Sanofi**

GOOD MANUFACTURING PRACTICE OF PFS – PART 1

14.50 **Introduction of an innovative and groundbreaking in-line X-ray inspection technology in a pre-fillable syringe manufacturing line**
- Limits of current needle shield assembly inspection systems
- X-ray inspection technology presentation
- Features and benefits of the concerning X-ray inspection unit to address increasing regulatory requirements for container closure integrity assurance and for drug delivery systems safety

Matteo Falgari, Sales Manager PFS, **Nipro PharmaPackaging**

15.30 **Afternoon Tea & Networking Break**

16.00 **Ocular injection - PFS development**
- Ocular drug delivery - inherent physiology and natural barriers
- Drug product administration
- Specific requirements and challenges (e.g. sterility of PFS outer surface, particle specification, dosing accuracy)

Markus Hemminger, Senior Engineer Pre-Filled Syringes, **F. Hoffmann-La Roche**

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
- What good manufacturing practice regulations apply to combination products?
- Technical challenges for developing and manufacturing combination products

Moderated by:
Alphons Fakler, Group Head Risk Management, **Novartis Pharma**

Speakers:
Serkan Oray, Senior Director, Device & Technology, **UCB**

David Ottolangui, Device Technology Director, **GSK**
Ed Cahill, Senior Director, Technical and Scientific Affairs – Sterile Products, **Teva**

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

Dear participants,

Parenteral drug delivery systems face increasingly numerous and diverse challenges. The success of our products and services is decided by several key factors; managing the growing complexity of our development activities, meeting different requirements, and handling the expectations of increasing numbers of stakeholders. In addition to that, new products often address more and more specific patient groups and require more innovative approaches to manufacturing and supply chain.

Our industry goal must always be to improve patient quality of life, and to provide new and safe treatments. This of course relies on several things; for example understanding the science behind everything we do, developing platform solutions instead of stand-alone solutions, and applying integrated systems engineering approaches instead of sequential and discrete work streams to reduce or eliminate patient risk by patient centric device designs.

In a highly competitive industry like ours, where intellectual property and innovation disclosure is handled restrictively, let us appreciate the unique opportunity offered by this event to share best practice and network with other experts in the field.

Alphons Fakler,
Group Head Risk Management,
Novartis Pharma

Book the dates in your diary for the upcoming events!

- Pre-Filled Syringes East Coast
  The Colonnade Hotel, Boston, MA
  26th - 27th April 2017
- Pre-Filled Syringes West Coast
  Hyatt Regency Mission Bay, San Diego, CA
  5th - 6th June 2017

Register online at www.pre-filled-syringes.com

08.30 **Registration & Coffee**

09.00 **Chairman's Opening Remarks and Setting the Scene**
Alphons Fakler, Group Head Risk Management, **Novartis Pharma**

THE WINNING DESIGNER – GIVING YOUR DEVICE A HUMAN TOUCH

09.10 **OPENING ADDRESS:**
Regulatory updates – recent guidelines on human factors engineering
- Overview of new and revised HFE Guidelines
- What does this mean for device developers?
- Impacts on different devices – PFS vs autoinjectors

Nick Stones, Fellow, Human Factors Engineering, **Novartis Pharma**

09.50 **Formulation and drug delivery challenges for mid-sized companies**
- Tailoring your formulation for pre-filled syringes or injectable delivery
- What are the considerations and parameters
- Flexibility for customising your formulation and device for a mid-sized company for competitive advantage?

Sachin Dubey, Head of Formulation, **Glenmark Pharmaceuticals**

10.30 **An insight into patient preferences for injection devices**
- What do patients want in their injection devices? What features are important to them and why?
- In this talk, Richard will present the results of a recent research study that MDU have carried out into the preferences for injection devices among 136 patients across a range of disease areas.

The results provide insight into questions such as:
- Why do some patients prefer to see the needle but others don't?
- Why do some patients want large devices but others want small ones?
- How important is the colour of the device?
- Do patients want devices that make sounds, or do they want silent devices?

Richard Featherstone, Managing Director, **Medical Device Usability**

11.10 **Morning Coffee & Networking Break**

GOOD MANUFACTURING PRACTICE OF PFS – PART 2

11.40 **An update on Polymer-based pre-fillable syringes addressing the challenges of therapeutic proteins**
- The impact of rapid growth and broad application of therapeutic proteins for the treatment of severe diseases - the need for high concentrated protein formulations
- Protein drug product formulations – the propensity to aggregate poses technical challenges with respect to manufacturing, stability (concentration-dependent protein degradation) and delivery
- An update on the assessment on Terumo's development of a COP Pre-fillable Syringe system and the options to mitigate potential interactions, including:
- A COP pre-fillable syringe system specifically designed to mitigate risk of protein degradation
- Protein aggregation from effects of the method of sterilisation of polymer pre-fillable syringes
- Sub-visible particles (micro- and nano-particles) from silicone oil compared to a silicone oil-free PFS system

William Dierick, Director Technology Development, **Terumo Pharmaceutical Solutions**

12.20 **Siliconisation - influence on functionality**
- Understanding the impact of the pre-filled storage and type of drug filling as well as testing method
- Silicone thickness and distribution overtime on empty and filled syringes
- Break Loose force and Injection force: Impact of the Ageing, the content and the test method

Vincent Cazanave, Pre-Fillable Syringe Engineering – Device Development, **F. Hoffmann-La Roche**

13.00 **Networking Lunch**

14.10 **OXYCAPT multilayer plastic syringes having excellent oxygen and water vapor barrier**
- Debating advantages of plastic syringes versus glass syringes
- How to overcome disadvantages of existing plastic syringes
- Latest studies for extractables from plastic and glass

Kenichiro Usuda, Researcher, **Mitsubishi Gas Chemical Company**

14.50 **From filling to packaging**
- Aseptic filling (incl. 100% inline weight control)
- Fully automatic inspection
- Assembly and packaging

Andreas Kerschbaumer, Facilitator Compounding, Filling & Inspection, **Sandoz**

15.30 **Afternoon Tea & Networking Break**

COMPETITIVENESS OF PFS AND PATIENT CONCERNS

16.00 **Panel Discussion: The future of parenteral drug delivery - moving from drug delivery devices to therapy management ecosystems**
- Wearable injector technology – opportunities and challenges
- Switching to needle-free delivery system – comparing pens and pumps
- Safety at the forefront – auto-disabling disposable syringe with portable injector

Moderated by:
Alphons Fakler, Group Head Risk Management, **Novartis Pharma**

Speakers:
Ignace Wallaert, Principal Scientist Packaging Development, **Janssen Pharmaceutica**

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

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HALF-DAY PRE-CONFERENCE - WORKSHOP A

Tuesday 17th January 2017 | 08.30 – 12.30 | Copthorne Tara Hotel London Kensington, London, UK

The future of parenteral drug delivery - moving from drug delivery devices to therapy management ecosystems

Workshop leader: **Vaishali Kamat,** Head of Digital Health, **Cambridge Consultants**

Overview of Workshop:

This half day workshop will explore how the need for personalised medicine, enhanced patient experience and improved patient outcomes, will drive the development of digital therapy management ecosystems. It will provide insights on what the future of parenteral drug delivery devices will look like - as part of these ecosystems - and explore the ecosystems' different components. The workshop will examine the impact that wireless technologies, wearables and data analytics will have in a future which empowers pharmaceutical companies to develop better treatment solutions and supports patients to take control of their disease state.

About the Workshop Leader:

Vaishali Kamat is an Associate Director and Head of Digital Health at Cambridge Consultants, a leading technology and product development firm. Over the past 6 years, she has helped clients develop ecosystem solutions comprising of wireless medical devices, mobile applications, and services to improve health outcomes and increase revenues. She brings significant domain and technical expertise in the rapidly evolving digital health space including an understanding of the regulations and insight into financial models and market players. Vaishali is an engineer by training and has over 18 years' experience in medical device design and has several published articles to her credit. Prior to joining Cambridge Consultants, she worked in diagnostic imaging for GE Healthcare.

About the Organisation:

Cambridge Consultants develops breakthrough products, creates and licenses IP, and provides business consultancy in technology-critical issues for clients worldwide. For more than 50 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. Our auto-injector, inhaler and injection device development programmes extend from concept creation through to industrialisation, with a 'quality by design' approach and full compliance with international regulatory standards.

Programme:

08.30	**Workshop registration & morning coffee**
09.00	**Workshop leader introduction**
09.10	**Rise of the digital therapy: A look at ecosystems** • Driving a paradigm shift • Components of a digital care ecosystem • Challenges and opportunities for pharma and device players
10.30	**Morning Coffee & Networking Break**
11.00	**Key enabling technologies** • Wireless and mobile connectivity • Sensors, wearables, and digital biomarkers • Data analytics
12.00	**Discussion – Q&A**
12.30	**Closing remarks from Workshop leader and end of morning workshop**

Past attending organisations include:

FDA, MHRA, GSK, Pfizer, Amgen, Boehringer Ingelheim, Allergan, Actavis, Eli Lilly, Sanofi, Sanofi Pasteur, Janssen, Johnson & Johnson, Merck, Medimmune, Novo Nordisk, Novartis, F. Hoffman-La Roche Ltd., Sandoz, Biogen, AstraZeneca, Baxter, Baxalta, Mylan, Teva Pharmaceuticals, Shire, Regeneron, Fresenius Kabi, Genentech, Dr. Reddy's Laboratory, Cambridge Consultant, Bristol-Myers Squibb, BioMarin, Takeda, AbbVie, Abbott, Xeris Pharmaceuticals, Nemera, West Pharmaceuticals, 3P Innovation, AAF International, BD Medical, Medical Device Usability, Mitsubishi Gas Chemical, Owen Mumford, STERIS, Catalent, Noxilizer, Nipro, Team Technik, Team Consulting, Terumo, Zwick Testing Machines and many more!

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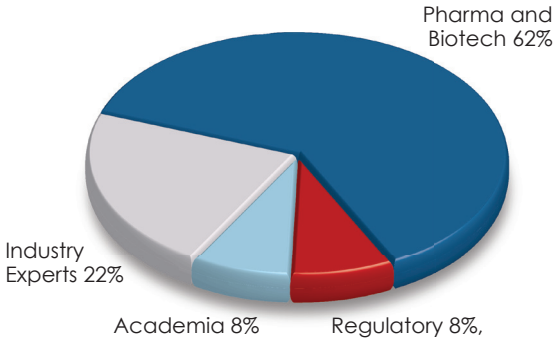

HALF-DAY PRE-CONFERENCE - WORKSHOP B

Tuesday 17th January 2017 | 13.30 – 18.15 | Copthorne Tara Hotel London Kensington, London, UK

Regulatory challenges at the interface of medicines and medical devices

Workshop leader: **Janine Jamieson,** Regulatory Consultant, **ex-MHRA assessor**

Overview of Workshop:

This half day workshop will explore the challenges that both companies and regulators face when preparing and reviewing submissions for medicinal products incorporating a medical device – challenges that will likely increase as combination products become more complex. Furthermore, the new EU Medical Device Regulations will introduce a requirement for review of device components by notified bodies; the workshop will consider how this could work, and what data and supporting information should be provided for MAA submissions.

About the Workshop Leader:

Janine has worked as a pharmaceutical assessor in the Medicines and Healthcare products Agency for over 18 years and over the last 10 years has developed an interest and focussed on products combining both medicines and medical devices. Through this role and participation in conferences, she has learned about the challenges at the interface of two quite different regulatory systems – and the need for collaboration to work towards pragmatic, risk based and proportionate regulation of such combination products.

Programme:

13.30	**Workshop registration & welcome coffee**
14.00	**Workshop leader introduction**
14.15	**EU regulatory developments - MHRA update** • EU developments on drug and biological/device combination products • Current data requirements and questions to expect • Future perspectives with increasingly complex combinations and impact of new Medical Device Regulations
14.45	**Interactive session – how can device manufacturers best support pharma in providing the most applicable data for MAA submission?**
15.30	**Afternoon Tea & Networking Break**
16.00	**Regulatory challenges in a global environment** • Case study One - same product different regulatory requirements in different regions • Experience of questions asked and challenges overcome • Industry view on how to involve notified bodies in assessment of integral device components
16.30	**Discussion with all participants on the case study with different approaches and experiences**
17.00	**Cross-industry initiatives to address development and licensing of biologics/device combination products**
18.00	**Closing remarks from Workshop leader and end of afternoon workshop**

Pre-Filled Syringes Europe
18th - 19th January 2017

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Medical Device Usability is an independent human factors/usability testing consultancy offering a turn-key service. MDU plans and performs formative and summative evaluations for a wide range of medical technologies, including prefilled syringes, pen injectors and autoinjectors. MDU tests globally for some of the world's largest pharmaceutical and medical device companies.
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Workshop: Tuesday 17th January 2017, London, UK

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