INJECTABLE DRUG DELIVERY
Day One | Wednesday 15th May 2019

8.30 Registration & Coffee

9.00 Chairman’s Opening Remarks
Joel Richard, Head of Technical and Pharmaceutical Operations, MedinCell

FORMULATION DEVELOPMENT AND DEVICE OPTIMISATION

9.10 OPENING ADDRESS
Overcoming the challenges in formulation development for injectable protein formulations
• High viscosity that exceeds the capabilities of current manufacturing practices or available parenteral delivery methods
• High concentration leading to stability and aggregation concerns and the associated material required for a robust development strategy
• High volume biologic challenges and strategies to overcome them
• Proteins and injectable gels
Vasco Filipe, Formulation and Drug Process Development Section, Head for Biologics, Sanofi

9.50 Thinking real-world data collection: the added-value of digital enhancement to serve patient treatment compliance and HCP security
• How injectable drug delivery could be optimized within hospital block chain
• Human Factor Engineering: where smart injectable drug delivery is saving lives in emergency scenarios
Adeline Meilhoc, VP and Head of Sales & Marketing, Eveon

10.30 Morning Coffee

11.00 Formulation development for long acting injectables
• Considerations for long-acting formulation development
• Overcoming challenges
• A game-changing delivery system for long acting injectables
• Future prospects
Joel Richard, Head of Technical and Pharmaceutical Operations, MedinCell

11.40 KEYNOTE ADDRESS
Development of Visisure®, a novel low volume high accuracy syringe for delivery of Lucentis® to neonates
• Background on Retinopathy of Prematurity and impact to patients
• Drivers and constraints for development: user, business, and regulatory
• Technical challenges overcome: device, packaging, manufacturing, and HFE
• Final product configuration and supply chain
Steve Paboojian, Senior Project Leader for Device Development, Novartis

12.20 Networking lunch

13.20 Ethical principles in human factors studies and developing a code of conduct
• Overview of current HF study trends
• Ethical considerations of HF Studies
• Proposed considerations for ethical code of conduct
Miranda Newbery, Human Factors Consultant, Inspired Usability
Louisa Harvey, Medical Device Director & Human Factors Consultant, Harvey Medical Ltd

14.00 Partners in evolution: Challenges and changes in parenteral drug delivery
• A summary of key trends and changes in the device landscape
• Highlight potential pitfalls to avoid
• The device as an enabler rather than a barrier to market success
John Burke, Senior Industrial Design Consultant, Team Consulting

14.40 Afternoon Tea

REGULATORY UPDATES AND PATIENT SAFETY

15.10 A convergent approach to the regulatory framework for combination products
• An overview of current approaches for combination product regulations
• Avoiding divergence, proposed convergent approach to ensure compliance and improve practice
• Potential implications on the industry
Blake Green, Regulatory Affairs Senior Manager, Devices, Amgen

15.50 An industrial perspective on ICH Q12 and EU MDR
• Changes in the global regulatory environment and processes for incorporating emerging trends into internal regulatory strategies
• Guiding innovative development with regulatory leverage
• Control strategies and compliance with quality systems for a medical delivery device
• Compliance with quality systems and medical devices
• Examples of how to direct a team for late stage parental development
Bjørg Kaae Hunter, Device Engineering Manager, GlaxoSmithKline

16.30 Chairman’s Closing Remarks and Close of Day One

8.30  Registration & Coffee

9.00  Co-chairman’s Opening Remarks
Singrid Van Dyck, Senior Director, Technical Operations Parenteral Platform Lead, Johnson & Johnson

INJECTABLE DEVICE CONNECTIVITY

9.10  Driving innovation in the Injectable Drug Delivery market
• Future of drug delivery market – an overview
• How we can improve patient adherence with connectivity and innovation
Mayur Patel, Principal Consultant Medical Devices, PA Consulting

9.50  Partnering for drug delivery innovation progress and AstraZeneca’s strategic considerations in successful outsourcing
• AstraZeneca’s approach to seeking and engendering innovation in its drug delivery organisation
• Structuring deals to leverage the expertise of outsourcing partners – key considerations for commercial success
• An overview of the search for key technologies and solutions to support the portfolio of activities and developments
• Learning points from a recent case
Terry Reed, Director of Business Development, AstraZeneca

9.30  Morning Coffee

11.00  KEYNOTE ADDRESS
Development of electronic injectables – from concept to manufacture
• Overview of the development process – the do’s and don’ts
• The challenges and learnings of electronic and connected drug delivery devices
• User experience and patient-centric design: what do patients really want from electronic auto-injectors?
Quentin Le Masne, Head of Engineering Team for Electro-Medical Drug Delivery Devices, Merck

11.40  Digital rapid prototyping-using the latest prototyping methods to unlock the value of digital propositions faster
• Case studies of navigating through the risks and rewards of deploying digital into their healthcare products and services.
• Learn how we uncover surprising insights in human factors and product development
• We’ll share several toolkits and approaches we use which help us to better quantify user experiences; highlighting where the value in digital can be captured and monetised
Tom Lawrie-Fussey, Digital Services Specialist, Cambridge Design Partnership

12.20  Networking Lunch

MANUFACTURING, FILLING AND QUALITY CONTROL

13.20  High viscosity vs high volume – a case study of injection tolerability and influence on design formulation and devices
• Patient tolerability and safety
• Patient centric formulation design
• Safety considerations
• Optimal design strategy
Session reserved for leading pharmaceutical company

14.00  The route to patient centric drug delivery
• Patient considerations and pharmaceutical connectivity limitations
• Cost vs. Adherence, where does the benefits lie?
• Contamination control where disposables are not an option – patient safety focus
• Realistic patient experience approach
Olaf Lebau, Design Engineer for Medical Device and Combination products, Boehringer Ingelheim

14.40  Afternoon Tea

15.10  KEYNOTE ADDRESS
Manufacturing, filling and quality control
• Device design – Long acting injectables and Biologics
• Design for Manufacturing – Filling, Automated inspection and Packaging
• Quality assurance considerations
Sigrid Van Dyck, Senior Director, Technical Operations Parenteral Platform Lead, Johnson and Johnson

15.50  Manufacturing inspection trends
• Manual inspection
• Automated Inspection
• Future Trends
Paul Kinsey, Product Leader – Visual Inspection & Leak Detection, GSK

16.30  Chairman’s Closing Remarks and Close of Day Two

Use-related Risk Analysis throughout a Design and Development Project

Workshop Leader:
Paula Woods, Director, Human Factors Centre Ltd

Workshop overview:
This workshop will help delegates better link use-related risk management throughout the product development process. Delegates will come away with a greater awareness of how to link Human Factors activities to ensure use related risks are identified and mitigated appropriately early and throughout the design process.

Why you should attend:
If you want to broaden your knowledge on use-related risk management and if you want to understand how Human Factors relates to the overall design and development process.

Programme:
13.30 Registration & Coffee
14.00 Workshop leader introduction
14.10 What is Use-Related Risk Analysis and how does it differ from other risk analyses?
• Understand what critical tasks are, how they are identified and treated throughout the Usability Engineering Process
15.00 Practical: Task Analysis and PCA on an injectable device
15.15 How to identify critical tasks
How to write User Interface Requirements
• Understand how to write User Interface Requirements and how to link these to other design requirements
15.30 Morning Coffee and Networking Break
16.00 Human Factor’s studies
• Understand the main differences between Formative and Summative Studies. Learn more about considerations when planning, executing and reporting on these types of studies
16.20 Practical: Data Collection
16.40 Feeding data (findings) back into a use-related risk analysis
• Understand how data collected from studies should be handled post-study
17.00 What is data bias and why is it important to mitigate against it? How to avoid data bias
• Learn about data bias and ways to mitigate the risks associated with this
17.20 Closing Remarks
17.30 Close of workshop

About the Workshop Leader:
Paula has a background in Human Factors, Usability, User Research, User Experience and Product Design. Paula specialises in both Medical Device Human Factors and Human Factors for Combination Products. She is a certified Practitioner and has moderated numerous Formative and Summative Evaluations across Europe, USA and China. Paula is also a licentiate fellow of the Institute of Training and Occupational Learning and provides Human Factor’s training to both Pharmaceutical and Medical Device manufacturers.

About the organisation:
The Human Factors Centre is a Human Factors and User Research consultancy who specialise in Human Factors and User Research within Medical devices and Drug delivery domains. Over the years, we have helped consult and train numerous companies on how to successfully conduct front end user research, usability test their products and navigate the needs of regulators with relation to FDA requirements, IEC62366 and ISO14971. Our training courses include how to develop HFE files, how to plan, execute and report Formative and Summative studies and how to effectively moderate studies.