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SMi presents the West Coast's Leading, 3rd Annual Conference and Exhibition...

Pre-Filled Syringes West Coast

Crowne Plaza San Diego - Mission Valley, CA, USA

WORKSHOPS: 6TH
CONFERENCE: 4TH - 5TH
JUNE 2018

Optimizing and developing novel industry methods from design to distribution

CO-CHAIRS FOR 2018:

- **Ron Forster,** Executive Director of Primary Container Engineering, Drug Product and Device Development, **Amgen**
- **Darin Oppenheimer,** Executive Director, Drug Device Center of Excellence, **Merck**

LEADING PHARMACEUTICAL SPEAKERS:

- **Michael Song,** Senior Manager, Drug Delivery and Device Development, **MedImmune**
- **Paul Upham,** Senior Principal, Smart Device Technology Center, **Genentech**
- **Arnaz Malhi,** Associate Director, Device Development Lead, **Shire**
- **Michael Regn,** Director, Packaging Design & Development, **Allergan**
- **Ed Israelski,** Consultant – Technical Advisor on Human Factors, Retired Director Human Factors, **AbbVie**
- **Maria Toler,** Quality Portfolio Support and Innovation-Drug Delivery Systems and Medical Devices, **Pfizer**
- **David Post,** Director, Science and Technology, **AbbVie**
- **Tina Rees,** Associate Director, Human Factors, **Ferring**
- **Torsten Vilkner,** Senior Associate Director, Manufacturing Operations, **Boehringer Ingelheim**

NEW FOR 2018:

- Explore and engage with the evolving industry of pharmaceutical **manufacturing related to PFS**, from cross-site development to navigating injection technologies through the **design life-cycle**
- Assess **quality control systems** and **risk-based control strategies** for drug delivery devices
- Consider the importance of **Human Factors Engineering**, from Rate of Return to the Design History File
- Highlights on **emerging trends of technologies and studies** to assist device and drug formulation developers
- Perceive the regulatory expectations from **cross-border perspectives** in the EU and US and what can we do to face these challenges

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PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS
WEDNESDAY 6TH JUNE 2018, CROWNE PLAZA SAN DIEGO - MISSION VALLEY, CA, USA

A: "BUILD TO DISCOVER": HOW TO LEVERAGE TANGIBLES IN USER TESTING TO ENSURE SUCCESSFUL COMMERCIALIZATION OF INNOVATIVE PRODUCTS

Workshop Leaders: Dr Kate Stephenson, Academic Partnerships and Business Development, **iO Lifesciences**
Maria Lund Jensen, Lead, Human Factors Engineering, **iO Lifesciences**

8.30 - 12.30

B: QUALITY RELATED ASPECTS IN CREATING DIGITAL CONNECTIVITY FOR DEVICES

Workshop Leaders: Mark Paxton, Managing Director, **AcceleratoRx**
Michael Song, Senior Manager, Drug Delivery and Device Development, **MedImmune**
Harry Kochat, Director of Operations & Business Development, Plough Center for Sterile Drug Delivery Solutions, **University of Tennessee Health Science Center**
Michael Rush, Executive Director - Global Health Policy, **Temptime Corporation**

1.30 - 5.30

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LETTER FROM THE CHAIRS:

We are delighted to welcome each of you to SMi's 2018 Pre-Filled Syringes West Coast conference in San Diego, California.

Over the past decade, pre-filled syringe venues have grown significantly in terms of content and attendance. We believe the increased interest in this area is directly attributed to the opportunities and challenges associated with the development of pre-filled syringes and therapeutic delivery products.

These products have undoubtedly improved the countless lives of the patients and caregivers who administer and rely on these products. As such, as an industry, we share a responsibility to continue to develop and evolve these delivery products as emerging technologies to further enhance treatment delivery, in order to meet or exceed the needs of our patients and improve upon therapeutic options.

The meeting will therefore allow for the face-to-face convergence of subject matter experts, thought leaders, researchers, and manufacturers in disciplines related to the development of pre-filled syringes and other therapeutic delivery products, and thereby provide a tremendous opportunity for meaningful discourse.

We look forward to seeing you there!

Ron Forster, Executive Director of Primary Container Engineering, Drug Product and Device Development, **Amgen**

Darin Oppenheimer, Executive Director, Drug Device Center of Excellence, **Merck**

8.30 **Registration & Coffee**

9.00 **Chairman's Opening Remarks**
Ron Forster, Executive Director of Primary Container Engineering, Drug Product and Device Development, **Amgen**

THE EVOLVING INDUSTRY OF PHARMACEUTICAL MANUFACTURING RELATED TO PFS

KEYNOTE ADDRESS

9.10 **Facing the challenges of biopharmaceutical manufacturing in the PFS industry**
- Understanding the product life cycle for biopharmaceuticals
- Technology transfer and validation and new product licensure in the PFS
- Boehringer-Ingelheim's flagship biopharmaceutical manufacturing facility start-up

Torsten Vilkner, Senior Associate Director, Manufacturing Operations, **Boehringer Ingelheim**

9.50 **Making the economic case for Human Factors Engineering for medical products: Examples of Rate of Return on HFE investment**
- Understand dimensions of the benefits of human factors engineering for medical devices
- Types of business cases to show economic benefits of HFE
- Examples of calculations for Return on Investment, Rate of Return and payback period

Edmond Israelski, Consultant – Human Factors, **AbbVie**

10.30 **Morning Coffee Sponsored by** ZEON

11.00 **Pairing advances in drug development with advances in drug delivery**
- Ensuring consistency of injection time for drug products >2mL
- Strategic drug delivery options for drugs of higher viscosity
- Implications of complex dosing requirements and patient compliance

Carl Dabruzzi, Senior Manager, Product Management, **West Pharmaceutical Services, Inc.**

11.40 **Navigating injection technologies for reliable incorporation between drug and packaging: The design life-cycle**
- Considering the challenges at the interface of formulation and primary packaging
- Incorporating patient centricity into the development process
- Preparing for a successful launch and ensuring a lasting post-approval legacy
- Leveraging tools to improve outcomes and promote a design culture

Michael Regn, Director, Packaging Design and Development, **Allergan**

12.20 **Networking Lunch Sponsored by** West

WHERE ARE WE BENCHMARKING AGAINST IN THE COMPLEX INJECTABLE DRUG-DELIVERY LANDSCAPE?

1.20 **Leveraging Preformative Research to Inform Lifecycle Management of Combination Products for Complex Disease States**
- Empathizing with total disease burden for complex disease states
- Challenges of managing drug delivery (use steps) from patient perspective
- How to identify opportunities to reduce complexity for patients
- Two case studies (Hemophilia & Primary Immunodeficiency Disease)

Joke Maes, Product Manager, **Terumo Pharmaceutical Solutions**
Molly Larson-Wakeman, Lead Clinical Analyst, **Matchstick**

2.00 **Design of a combination product for manufacturability**
- Identifying critical processes in design
- Implications to scale up
- Lifecycle of design improvement

David Post, Director, Science and Technology, **AbbVie**

2.40 **Session Reserved for Nemera Representative**

3.20 **Afternoon Tea Sponsored by** ZEON

3.50 **Container & Closure System Integrity Testing (CCIT) – Options, Approaches, and Future Trend**
- Maintaining container closure integrity during manufacturing and product shipping
- Container Closure Integrity test methods and appropriate applications
- Optimizing and developing novel methods to meet new challenges
- Approach to detecting container closure integrity for complex drug delivery devices
- Applying CCIT approaches to determine container closure integrity during high altitude shipping

Michael Song, Senior Manager, Drug Delivery and Device Development, **MedImmune**

4.30 **Design of a connected device ecosystem**
- Identifying the strategic drivers
- Defining the unmet needs
- Creating a platform framework
- Delivering hardware and software technologies

Paul Upham, Senior Principal, Smart Device Technology Center, **Genentech**

5.10 **Impulse Pressure Waves: Understanding the First Milliseconds of Device Activation**
- Large molecule drug product development trends are moving to high concentration and high viscosity products
- Current available delivery technologies struggle with maintaining injection time regulatory requirements with high viscosity products
- High powered delivery systems can impart highly transient events and forces which can result in component failure
- Device development for delivery high viscosity products' need to consider dynamic system

Julian Jazayeri, Senior Engineer, **Amgen**

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

8.30 Registration & Coffee

9.00 **Chairman's Opening Remarks**
Darin Oppenheimer, Executive Director, Head Drug Device Centre of Excellence, **Merck**

DEVELOPMENTS IN THE PRODUCTION LINE TO ADVANCE OVERALL MANUFACTURING PROCESS AND PRODUCT REGULATORY ADHERENCE

KEYNOTE ADDRESS

9.10 **Challenges of Pre-Filled Syringes in a regulated combination product environment: A cross-border perspective**
- What are the challenges manufacturers face today?
- What challenges are on the horizon for pre-filled syringes in the EU and US?
- What can we do to prepare for upcoming unique challenges and opportunities in this space?

Darin Oppenheimer, Executive Director, Drug Device Centre of Excellence, **Merck**

9.50 **Bringing it all together – the Design History File**
- Creating Design History Files for less and more complex combination products
- The Design History File from early development to commercial
- Addressing human factors / usability throughout the product lifecycle
- Challenges in later stage development and post-market Design History File maintenance

Maria Toler, Quality Portfolio Support and Innovation-Drug Delivery Systems and Medical Devices, **Pfizer**

10.30 Morning Coffee Sponsored by ZEON

11.00 **Early Stage Device Development: Challenges and Opportunities**
- Engage with product teams (Clinical and Commercial) early to identify unmet needs and opportunities for delivery related innovation
- Tools such as Target Device Profile and User Research help drive alignment
- Identify critical technology risks and focus on proving feasibility

Arnaz Mahli, Associate Director, Device Development Lead, **Shire**

11.40 **Technical update - ZEONEX/ZEONOR, Cyclo Olefin Polymers for Pre-Filled Syringes**
- 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

ZEON **Toshiro Katayama,** Product Manager, **Zeon**

12.20 Networking Lunch Sponsored by West

THE DEVICE LANDSCAPE FOR PATIENT-CENTRED DESIGNS AND COMBINATION PRODUCTS

1.20 **Transitioning syringe system qualification process to incorporate design verification deliverables upfront, to better integrate with combination product requirements**
- Eliminating duplicate or redundant work by identifying parallels between qualification process and verification process
- Qualification / verification hybrid - allows for the verification of base platform container requirements as defined by industry requirements (i.e. ISO and pharmacopeia), while still ensuring the container is suitable for use in manufacturing and / or product specific applications
- Verification of a platform container system subassembly, to fit into a "modular" platform combination product DHF

Veneza Yuzon, Container Science and Engineering, **Amgen**

2.00 **Extractables and Stability Studies of OXYCAPT Multilayer Plastic Syringe**
- Comparison between glass and plastic syringe
- Benefits of plastic syringe
- Latest extractables study with 6 solvents representing typical biologics
- Latest stability study with typical biologics

MITSUBISHI GAS CHEMICAL **Shota Arakawa,** Researcher, **Mitsubishi Gas Chemical**

2.40 Afternoon Tea Sponsored by ZEON

PANEL DISCUSSION

3.10 **The future of PFS injection devices from cross-industry expertise perspectives:**
- What trends do we see coming?
- What challenges will those trends bring?
  - Post-approval changes for combination products
  - Human factors considerations
  - Manufacturing updates
  - Regulatory considerations

MODERATOR:
Darin Oppenheimer, Executive Director, Head Drug Device Centre of Excellence, **Merck**

PANELLISTS:
Tina Rees, Associate Director, Human Factors, **Ferring**
Michael Song, Senior Manager, Drug Delivery and Device Development, **MedImmune**
David Post, Director, Science and Technology, **AbbVie**
Maria Toler, Quality Portfolio Support and Innovation-Drug Delivery Systems and Medical Devices, **Pfizer**
Paul Upham, Senior Principal, Smart Device Technology Center, **Genentech**

3.50 **Session Reserved for Worrell**
WORRELL **Speaker to be confirmed**

4.30 **Regulator expectations, guidance and approaches to Human Factors Validation of Injector Systems**
- FDA's expectations for HF validation of injector systems
- Human Factors guidance, and examples of approaches that have been successful and unsuccessful
- Common pitfalls of Human Factors validation in injector systems
- Validating biosimilars in injection platforms

Tina Rees, Associate Director, Human Factors, **Ferring**

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

HALF-DAY POST-CONFERENCE WORKSHOP A
WEDNESDAY 6TH JUNE 2018 | 8.30 - 12.30
CROWNE PLAZA SAN DIEGO - MISSION VALLEY, CA, USA

Workshop Leaders:
Dr Kate Stephenson, Academic Partnerships and Business Development, **iO Lifesciences**
Maria Lund Jensen, Lead, Human Factors Engineering, **iO Lifesciences**

"BUILD TO DISCOVER": HOW TO LEVERAGE TANGIBLES IN USER TESTING TO ENSURE SUCCESSFUL COMMERCIALIZATION OF INNOVATIVE PRODUCTS

Workshop Overview
This workshop will provide insights on successfully using prototype mock-ups to collect user input and usability insights from the inception stage, and dives into creating a strategy to use these approaches to effectively and systematically de-risk a new drug delivery device project and ultimately pass summative usability testing.

You will learn
- How to process inputs from all the stake holders and identify key areas to focus for patient-centric device development without sacrificing compliance, time or budget
- Ways of deliberately and systematically experimenting with features, experiences, environments, and systems that produce design inputs linked directly to user data and insights

Why you should attend
- Be able to present a clear value proposition to your management to support early stage prototyping efforts as part of usability testing
- Develop practical experience in creating a cohesive tangibles strategy that maximizes the value generated by user testing
- Get to master insights generation with respect to users' physical and cognitive capabilities as well as preferences to increase both product safety, ease-of-use and UX
- Learn to prioritize and accelerate different kinds of testing based on project risks unique to a particular drug delivery application
- Take away practical methods for rapidly generating effective objects and experiences to support usability testing
- Meet people, make stuff, have fun!

About the workshop leaders
Dr. Kate Stephenson:
Between obtaining her MS in Biomechanical Engineering and returning to Stanford University to complete a Mechanical Engineering PhD, Dr. Stephenson spent ten years in the medical device industry as a Senior Design Engineer and Project Manager. She has worked on over eighteen different devices, ranging from insulin pumps to annuloplasty rings. During her PhD she taught courses in design and entrepreneurship as part of Stanford's world class design program. She also completed a two-year stint as the Resident Clinical Bioengineer at Stanford Children's Hospital Gait and Motion Lab, where she advised on complex orthopaedic surgery cases and worked directly with patients. She has recently joined iO life science, where she works with early stage medical device companies on their design and manufacturing strategies. Her current role at iO is in business development and academic partnerships.

Maria Lund Jensen:
With an educational background in informatics and design and innovation engineering (Copenhagen, Denmark, and Singapore) and a strong belief in participatory and user-centric design approaches, Ms. Jensen holds a broad theoretical knowledge of design of systems, services and hardware as well as software products. Her career has been devoted completely to the medical device industry, working in R&D for an IVD instruments and syringes manufacturer, bridging design and design controls with particular focus on Human Factors Engineering (HFE), as well as in consultancies, integrating HFE with agile, innovative design for healthcare clients. Ms. Jensen's practical experience includes definition of HFE/Usability and UX processes, activities, tools and templates, and planning, execution and documentation of user research, user testing and any other aspect of Human Factors Engineering.

About the organisation
iO life science is a full-service medical device development partner, trusted by established and start-up healthcare innovators. We exist to improve the lives of patients by transforming our clients' technologies into unique and attractive products with user needs at the core. We accelerate compliance with our agile and ISO13485-approved QMS. **www.iolifescience.com**

Programme
8.30 **Workshop Registration and Morning Coffee**

9.00 **Workshop Leaders' Opening Remarks and Introduction**

9.15 **Segment 1 - Usability testing: Context and challenges**

9.30 **Segment 2 - Overview of Building Tangibles for Usability**
- Build Smart – Defining a clear strategy based on de-risking projects
- Build Early – How to use tangible experiences to drive design from the earliest stages
- Build Fast – Minimize extra cost to your project by leveraging efficient and creative ways of creating tangibles

10.00 **Morning Coffee and networking break**
- Groups are assigned and get to spend a few minutes getting to know each other

10.30 **Assignment of case study challenges**
- 3 different potential drug delivery applications are introduced, and each assigned to a team

11.00 **Practical application of concepts to case studies**
- Build a tangibles strategy to complete user testing for a specific drug delivery application
- Map out user test milestones from early concept to summative testing for the case study
- Practice rapid building techniques to generate prototypes to collect usability data
- Test artefacts by conducting tests on members from other teams

12.00 **Group review of strategies & insights learned**

12.30 **Closing Remarks from Workshop Leaders and End of Workshop**

HALF-DAY POST-CONFERENCE WORKSHOP B
WEDNESDAY 6TH JUNE 2018 | 1.30 - 5.30
CROWNE PLAZA SAN DIEGO - MISSION VALLEY, CA, USA

Workshop Leaders:
Mark Paxton, Managing Director, **AcceleratoRx**
Michael Song, Senior Manager, Drug Delivery and Device Development, **MedImmune**
Harry Kochat, Director of Operations & Business Development, Plough Center for Sterile Drug Delivery Solutions, **University of Tennessee Health Science Center**
Michael Rush, Executive Director - Global Health Policy, **Temptime Corporation**

QUALITY RELATED ASPECTS IN CREATING DIGITAL CONNECTIVITY FOR DEVICES

Workshop Overview
Digital Connectivity between manufacturers and HCPs and patients has been facilitated by numerous advances, including recent regulatory requirements. This is true not just in the US, but globally. Unfortunately, it doesn't appear that these incredible advances have been incorporated into pre-filled syringes and often, not even in secondary packaging. This is changing.

Why you should attend
Even with existing digital connectivity solutions, there are are regulatory pitfalls. This includes compliance with 21 CFR Part 11 requirements (computer system validation), and ensuring data collected maintains its integrity. In this work shop, we will explore some of the solutions that are available for pre-filled syringes and other injectable products. We will also discuss compliance requirements under recent FDA guidance, and how manufacturers are incorporating additional information to support patient health. Finally, we will also have an open discussion on what it means to validate and qualify these solutions as they are integrated into fill and finish lines, as well as packaging lines.

About the workshop leader
Mark S. Paxton is founder and Managing Director, AcceleratoRx, LLC. Prior to that, he served as CEO of RX-360, an international pharmaceutical supply chain consortium dedicated to patient safety. Mark's role at Rx-360 followed his service as a Regulatory Counsel in the CDER Office of Compliance where he was responsible for developing supply chain security policies, both domestically and internationally, including serving as the overseer of a major global initiative under Asia-Pacific Economic Cooperation (APEC) to establish best practices for ensuring product quality moving in international commerce. Before joining FDA, Mark served as Associate Vice-President, International Regulatory Affairs at the Pharmaceutical Research and Manufacturers of America ("PhRMA"). In that capacity, Mark established a number of on-going dialogs and work programs with drug regulatory authorities throughout, Japan, China, East Asia, India, Europe and Latin America. These efforts were designed to assist regulators and constituent companies operating in these markets to better understand complex regulatory issues arising from the globalization of the pharmaceutical industry.Mark is a regulatory attorney by education, experience, and training, and prior to joining PhRMA was in private practice in Lexington, Kentucky where he focused his practice on food and drug law. Mark received his B.S. (1991) and M.S. (1993) degrees in Economics from the University of Kentucky, and his J.D. from the University of Dayton School of Law in 1998.

About the organisation
After leaving Rx-360, Mark Paxton founded **AcceleratoRx** to support synergistic relationships within and among the industry. AcceleratoRx focuses on regulatory support for implementation of digital connectivity strategies throughout the biopharmaceutical lifecycle, including clinical trials and commercial products.

Programme
1.30 **Workshop Workshop Registration and Welcome Coffee**

2.00 **Workshop Leader Introduction - Mark Paxton, AcceleratoRx**
- Overview of Serialization under DSCSA and examples of where industry is with digital connectivity

2.15 **Unintended Benefits Associated with DSCSA: Going beyond statutory requirements - Mike Rush, Temptime Corporation**

2.45 **Session 2: Ensuring Quality with computer system validation, and cautious expectations regarding data integrity - Harry Kochat, The Plough Center, University of Tennessee - Mark Paxton, AcceleratoRx**

3.30 **Afternoon Tea and Networking Break**

4.00 **Session 3: Stress testing digital technologies in a Quality environment - Michael Song, MedImmune**

5.00 **Session 4: Open discussion with panel and workshop participants**

5.30 **Closing Remarks from Workshop Leader and End of Workshop**

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Workshops: Wednesday 6th June 2018, Crowne Plaza San Diego - Mission Valley, CA, USA

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