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SMi Group Proudly Presents the 6th Annual Conference...

Pre-Filled Syringes West Coast

Exploring advances for innovative and user-centric injectable device development

Hyatt Regency Mission Bay, San Diego, CA, USA

CONFERENCE: 13TH - 14TH
WORKSHOP: 15TH
JUNE
2022

CHAIRS FOR 2022:

Tina Rees,
Associate Director, Human Factors,
Regeneron Pharmaceuticals

Natalie Abts,
Head of Human Factors Engineering,
Genentech

FEATURED 2022 SPEAKERS INCLUDE:

- **Sriman Banerjee,** Head of Packaging Development & Commercial Device Engineering, **Takeda**
- **Amin Sedighiamiri,** Associate Director, Device Development, **AstraZeneca**
- **James Wabby,** Executive Director, Head of Regulatory Strategy, Emerging Technologies and Combination Products, **AbbVie**
- **Khaudeja Bano,** Vice President, Combination Product Quality, **Amgen**
- **Rachel Poker,** Associate Director, Human Factors, **AstraZeneca**
- **Kristina Li,** Sr. Engineer II, Technical Development, **Biogen**
- **Mark DeStefano,** Director, Combination Products and Device R&D, **Teva**
- **Sujani Nannapaneni,** Human Factors Principal Research Engineer, Combination Product Development, **AbbVie**

HIGHLIGHTS FOR 2022:

- **Discover** the latest advances in innovative device design for user-centric drug delivery
- **Assess** evolving approaches to platforms for advanced combination product portfolios
- **Uncover** the key considerations to ensure optimal lifecycle management for drug delivery devices
- **Explore** how the industry is evolving with global developments including case studies of sustainable practices for drug delivery devices and the industry's role in mass vaccination campaigns
- **Engage** in interactive sessions reviewing the landscape of on-body injectors for large volume delivery and the role of connectivity for wearable devices

PLUS INTERACTIVE POST CONFERENCE WORKSHOP
WEDNESDAY 15TH JUNE 2022, HYATT REGENCY MISSION BAY, SAN DIEGO, CA, USA

Testing of Drug Delivery Devices

Workshop Leader: **Michael Goehring,** Medical & Pharmaceutical Industry Manager, **ZwickRoell**
08.30 - 12.30

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Pre-Filled Syringes West Coast Conference

DAY ONE | MONDAY 13TH JUNE 2022

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Dear Colleagues,

It is with great pleasure that we welcome you to SMi's highly anticipated Pre-Filled Syringes West Coast conference taking place on the 13th-14th of June 2022 in San Diego.

The 6th annual conference will bring together expertise from individuals across a multitude of disciplines to address key areas of interest and recent developments in the industry. We are excited to bring together experts on drug delivery connectivity, on-body delivery systems, lifecycle management, EPRs for combination products, and innovations in device design with focus on user-centricity. With growing global pursuits towards environmentally friendly approaches in industry, this year's conference will also address what steps pharma and device developers are taking for advanced and sustainable injectable device development.

Furthermore, this year's conference will hold a post-conference workshop on testing of drug delivery devices, exploring international regulatory standards for injectable devices and the importance of developing a validation master plan for your parenteral combination product.

As chairs of this event, we look forward to welcoming you to this must-attend conference this coming June.

Yours Sincerely,

Natalie Abts,
Head of Human Factors Engineering,
Genentech

Tina Rees,
Associate Director, Human Factors,
Regeneron Pharmaceuticals

08.00 **Registration & Coffee**

09.00 **Chairs' Opening Remarks**
Natalie Abts, Head of Human Factors Engineering, **Genentech**
Tina Rees, Associate Director, Human Factors, **Regeneron Pharmaceuticals**

LIFECYCLE MANAGEMENT FOR DEVICE DEVELOPMENT

OPENING ADDRESS

09.10 **Postmarket safety reporting for combination products and injectable devices**
- How have we seen industry adapting to meet evolving regulations through effective compliance strategies
- Current guidance for industry on postmarket safety reporting for combination products
- Case study examples for effective approaches to efficiently maintain reporting for combination products and injectable devices
- Looking to the future how can we expect the global regulatory landscape to evolve for combination product reporting and advice to be best prepared

Khaudeja Bano, Vice President, Combination Product Quality, **Amgen**

09.50 **Post Commercial Launch Device Change Considerations and Management for Combination Products**
- Understanding and Evaluating Device-Related Changes
- Design Control and Change Assessment per ISO 20069 Guidance
- Vendor Communication and Collaboration
- Regulatory Considerations and Strategies

Kristina Li, Sr. Engineer II, Technical Development, **Biogen**

10.30 **Morning Coffee**

11.00 **Understanding the inconsistency in determining EPRs for injectable combination products**
- The industry does not have a consensus view on how to apply EPRs guidance
- BioPhorum collaboration has brought together experts to share their experiences on applying EPRs to injectable combination products
- The team had created a set of matrices that highlight the differences in opinion for several injectable devices (including PFS)

Session reserved for BioPhorum

ON BODY INJECTORS FOR LARGE VOLUME DELIVERY

11.40 **Tackling high-volume administration challenges with a smart, sustainable on-body injector platform**
- Challenges facing modern drug delivery devices
- Delivering large volumes at home in sustainable and user-friendly way
- A differentiated approach in the wearables' landscape: Nemera Symbioze platform

Cecile Gross, Global Category Manager, **Nemera**

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12.20 **Networking Lunch**

13.20 **An Introduction to emerging technologies for injectable drug delivery**
- Reviewing the current landscape of emerging technologies to support injectable drug delivery
- Assessing industry challenges in the emerging technology space
- The growing need for effective injectable subcutaneous devices and digital apps for large volume and high viscosity drug products

James Wabby, Executive Director, Head of Regulatory Strategy, Emerging Technologies and Combination Products, **AbbVie**

PANEL DISCUSSION

13.40 **On body delivery and LVIs device design and development**
- Challenges in administration: how are we adapting device design to allow for increased volume and viscosity delivery
- Improving acceptance rates: As we strive for self-administration, are we designing on body devices with the user in mind and how can we increase acceptance?
- Designing on body delivery devices through collaborative design and testing
- Developing platforms for parenteral wearable device portfolios

Panel Moderator
James Wabby, Executive Director, Head of Regulatory Strategy, Emerging Technologies and Combination Products, **AbbVie**
Panelists
Sujani Nannapaneni, Human Factors Principal Research Engineer, Combination Product Development, **AbbVie**
Shannon Clark, CEO, **UserWise, Inc.**
Candice Lee, Human Factors Engineer, **Genentech**
Megan Heft, Associate Director, **AstraZeneca**

14.40 **Afternoon Tea**

15.10 **Next generation subcutaneous injectables - Digital Applications and connected care for injectable devices and wearables**
- How have we seen digital and connected features being used for injectable devices and on body injectors
- What benefits have we seen for the user from the introduction of connected features and how can we look to enhance connected features for injectables?
- Considerations for the addition of connected features
- Looking forward how can industry and device developers work to get the most out of connectivity for on body injectors

Amin Sedighiamiri, Associate Director, Device Development, **AstraZeneca**

PANEL DISCUSSION

15.50 **Exploring the evolving landscape of connected features for injectable delivery devices**
- Perceived benefits of connected devices and what additional value being "connected" brings
- Barriers to widespread adoption and use of connected drug delivery devices
- Identifying connected features that provide beneficial user guidance and patient adherence
- Ensuring data is being used productively to aid the treatment process and improve outcome
- The future of connected devices. what we can expect to see

Panel Moderator
Amin Sedighiamiri, Associate Director, Device Development, **AstraZeneca**
Panelists
Natalie Abts, Head of Human Factors Engineering, **Genentech**
Shannon Clark, CEO, **UserWise, Inc.**
Mark DeStefano, Director, Combination Products and Device R&D, **Teva**

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

08.30 **Registration & Coffee**

09.00 **Chairs' Opening Remarks**
Natalie Abts, Head of Human Factors Engineering, **Genentech**
Tina Rees, Associate Director, Human Factors, **Regeneron Pharmaceuticals**

INNOVATIVE DEVICE DESIGN FOR USER-CENTRIC DRUG DELIVERY

OPENING ADDRESS

09.10 **The role of Human Factors for new product introduction and on-market products**

- The importance of having a strong connection between the human factors experts from development and commercial and operations teams
- How human factors can add value to patient support programs to help ensure safe and effective use of the product and set the product up for success on the market
- How to ensure appropriate connection between the use-related risk analysis, complaints data, defect categorization, complaints assessments, and periodic risk / annual product quality reviews
- How to feed post-market data into development of future similar products
- The role of human factors for post-validation design changes

Rachel Poker, Associate Director, Human Factors, **AstraZeneca**

09.50 **Incorporating Patient Centricity into Product Design**

- Consider both risk-based usability and user experience research in the development lifecycle
- Patient-centric activities that can enhance product design
- Balancing user needs and preferences
- The impact of patient engagement on final designs

Natalie Abts, Head of Human Factors Engineering, **Genentech**

10.30 **Morning Coffee**

11.00 **HF For On Body Delivery System Development**

- Human Factors Approach and Summary
- Summative Study Challenges (E.g. COVID, FDA feedback on protocol)

Sujani Nannapaneni, Human Factors Principal Research Engineer, Combination Product Development, **AbbVie**

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 Speciality Materials**

12.20 **Networking Lunch**

13.20 **Assessing human factors testing and validation approaches for combination product platforms**

- When can you use platform approaches?
- Strategies to save time developing combination product platforms
- Best practices on platform human factors validation protocol development

Tina Rees, Associate Director, Human Factors, Combination Product Development, **Regeneron Pharmaceuticals**

14.00 **Bridging Human Factors Data for Combination Products**

- What are some examples of successful bridging strategies for both new drugs and biosimilars/generics?
- What are Threshold Analyses and when are they sufficient?
- Biosimilars and Generics: What happens if my drug delivery device has non-minor differences compared to its reference device?

Shannon Clark, CEO, **UserWise, Inc.**

14.40 **Afternoon Tea**

A FUTURE OUTLOOK OF THE INJECTABLE DELIVERY INDUSTRY AND SUSTAINABILITY

15.10 **An overview of sustainability and recycling on devices**

- The current landscape and industry movement towards sustainable practices
- Examples of current approaches and steps to introduce recycling to the device delivery industry
- Challenges and barriers in recycling for drug delivery devices
- An outlook to the coming years of sustainability in pharma and recycling for drug delivery devices

Sriman Banerjee, Head of Packaging Development & CDE, **Takeda**

15.50 **Our sustainable future: integrating sustainability into operations, R&D, and manufacturing**

- A growing movement in laboratory sustainability: Green Lab certification
- Sustainability integration in development operations and R&D
- Benefits in time, cost and environmental impact
- Current techniques that align with sustainable best practices
- Case Studies and recommendations for implementation to your current practices

Christina Greever, Sustainability Program Manager, **My Green Lab**

16.30 **Chairs' Closing Remarks and Close of Day Two**

Pre-Filled Syringes West Coast Conference

Wednesday 15th June 2022, Hyatt Regency Mission Bay, San Diego, CA, USA

POST CONFERENCE WORKSHOP A
08.30 - 12.30

Workshop Leader:
Michael Goehring, Medical & Pharmaceutical Industry Manager, **ZwickRoell**

Testing of Drug Delivery Devices

Overview of the workshop:
Prefilled syringes and autoinjectors are devices that are prone to failure due to their complex action mechanics and sensitivity to storage. Due to high risk, these devices are strictly regulated by international standards.

Knowing the applicable standards is only one step. Companies must first develop a validation master plan. The key elements of this plan include a user requirements specification (URS), a risk Assessment (RA), design qualification (DQ), installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ).

Why you should attend:
- Engage with experienced device development experts sharing their insights into innovative solutions for drug delivery device testing
- Assess and understand the applicable regulatory standards to consider for development of a new drug delivery device
- Delve into pre-filled syringe examples of device testing, exploring spring simulation and considerations of user influences
- Navigate the applicable standards for various injectable devices including pen injectors, autoinjectors and on-body delivery systems

About the workshop leader:

Michael Goehring
BSEE – Instrumentation and System
– University of Connecticut, School of Engineering

Field Systems Engineer for materials and component test systems
Territory Manager for Laboratory Information Management Systems
District and Regional Sales Manager for materials and component test systems
America's Sales Manager for material preparation and analysis
Medical & Pharmaceutical Industry Manager – Testing Solutions

About the organisation
ZwickRoell has years of experience in delivering innovative solutions for the testing of drug delivery systems that reduce operator influence, which increases accuracy, repeatability, reproducibility, and traceability of test results. ZwickRoell's qualification services bridge include DQ to a URS, IQ, OQ, and soon we will be able to assist in the PQ Test Plan.

Programme

08.30 **Registration and Coffee**

09.00 **Opening Remarks and Introductions**

09.10 **Session 1: Drug Delivery Device Overview**
- Applicable ISO standards and referenced UPS
- Standard V Model from URS to PQ

09.50 **Session 2: (Prefilled) Syringe Testing and Spring Simulation**
- ISO 11040-4, -6, -8
- "Live" performing a Break Loose / Glide Force Test
- User influences and how to reduce or eliminate?

10.30 **Morning Coffee**

11.00 **Session 3: Autoinjector and Pen Injector Testing**
- Pen Injectors – Manual Dose or Automated Dosing – ISO 11608-3
- Autoinjectors - Full function tests – ISO 11608-5
- Wearables – ISO 11608-6

11.40 **Session 4: Regulatory Demands**
- 21 CFR Part 11 – Traceability (When, Who, What, Why and Who is Responsible
- Configuring Traceability and User Rights
- DQ, IQ, OQ and PQ

12.20 **Closing Remarks**

12.30 **End of workshop**

ZwickRoell

WE WANT TO HEAR FROM YOU!

In the run up to our series of Pre-Filled Syringes conferences taking place worldwide over the course of 2022, we at SMi have created a survey drawing upon the experiences of various pharmaceutical leaders across pharma companies, service and solution providers and consultants working in the industry. There is still time to add your views to the survey here:

www.surveymonkey.co.uk/r/Prefilledsyringesworldwidesurvey

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As a world-leading drug delivery device solutions provider, our purpose of putting patients first enables us to design and manufacture devices that maximize treatment efficacy. We are a holistic partner and help our customers succeed in the sprint to market of their combination products. From early device strategy to state-of-the-art manufacturing, we're committed to the highest quality standards. Agile and open-minded, we work with our customers as colleagues. Together, we go the extra mile to fulfill our mission.

Nemera leverages decades of experience in the parenteral device segment from full development to pure contract manufacturing, through customized solutions. **www.nemera.net**

Owen Mumford Pharmaceutical Services is a specialist in the design, development and manufacture of injectable drug delivery systems for the pharmaceutical, biotech & generics industries. These include single dose and multidose reusable and disposable auto-injectors, pens and syringes for subcutaneous and intramuscular administration. Our innovative products are designed to meet both the need of our pharmaceutical partners and their patients by facilitating ease of use and improving safety and patient compliance. Our devices are also designed with aim of reducing complexity and risk for the pharmaceutical & biotech industry in the development of their combination products. For more information please visit **www.ompharmaservices.com/**

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Pre-Filled Syringes West 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."

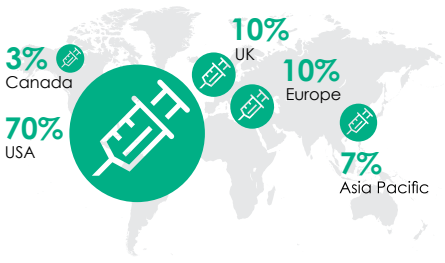
INFOGRAPHICS

NETWORKING

150+
Industry professionals from Europe and beyond

10+
Dedicated hours of networking

ATTENDEE GEOGRAPHY



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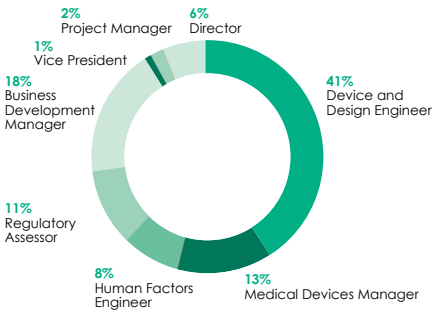

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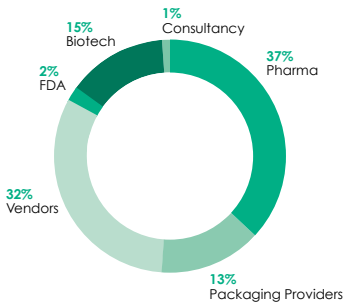

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PRE-FILLED SYRINGES WEST COAST 2022

Conference: Monday 13th & Tuesday 14th June 2022, Hyatt Regency Mission Bay, San Diego, CA, USA
Workshop: Wednesday 15th June 2022, Hyatt Regency Mission Bay, San Diego, CA, USA

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