

# Pre-Filled Syringes East Coast

Boston, MA, USA

11-12  
APRIL  
2018



SMI's 5<sup>th</sup> Annual Conference and Exhibition

## Pre-Filled Syringes East Coast 2018

Main Conference: April 11 - 12th

Pre-Conference Workshops: April 10th

SHERATON BOSTON HOTEL

Boston, MA, USA

[www.pfsamericas.com](http://www.pfsamericas.com)

### Timed programme

#### Main Conference: DAY 1 – April 11, Wednesday

**8:30** REGISTRATION & COFFEE

**9:00** CHAIRMAN'S OPENING REMARKS

**Steve Bowman**, Device Program Lead, **Shire US Inc**

**9:10** SYRINGE FILLING OF HIGH-CONCENTRATION MONOCLONAL ANTIBODY FORMULATION: CHALLENGES AND SOLUTIONS

**Kashappa-Goud Desai**, Associate Fellow, **GSK**

**9:50** SILICONE RELATED CONCERNS ASSOCIATED WITH PREFILLED DEVICES AND INNOVATIVE STRATEGIES OF RISK MITIGATION

**Janice Adkins**, Associate Director, Regional Marketing Manager, **BD Medical - Pharmaceutical Systems**

**10:30** MORNING COFFEE SPONSORED BY ZEON

**11:00** COP - TECHNICAL DATA UPDATE

**Toshiro Katayama**, Product Manager, **Zeon Chemicals L.P.**

**11:40** DRUG-DEVICE COMBINATION PRODUCT DEVELOPMENT CHALLENGES

**Amit Khanolkar**, Director, New Product Development Quality Engineering, **Janssen**

**12:20** SAFETY EVALUATION OF LEACHABLES WHEN DEVELOPING A PRE-FILLED SYRINGE DRUG PRODUCT

**13:00** NETWORKING LUNCH SPONSORED BY TERUMO

**14:00** SESSION RESERVED FOR NEMERA

**Adrien Tisserand**, Key Account Manager, **Nemera**

**14:40** PRE-FILLED SYRINGE SECOND SOURCE INITIATIVE: A DUAL SOURCE IDENTIFICATION TO REDUCE SUPPLY USING QUALITY-BY-DESIGN (QBD) PRINCIPLES

**Kashappa-Goud Desai**, Associate Fellow, **GSK**

**Nathan Heacock**, Associate Scientist, **GSK**

**15:20** THE BEST PLASTIC SYRINGE FOR BIOLOGICS

**Shota Arakawa**, Researcher, Mitsubishi Gas Chemical America Inc

**16:00** AFTERNOON TEA SPONSORED BY ZEON

**16:30 CASE STUDIES: UNCOVER USER NEEDS THAT CAN TRANSLATE INTO DESIGN INPUTS**  
**Serge Dubeau**, Vice President of Design and Human Factors, **Worrell**

**17:10 INTEGRATING DRUG-DEVICE COMBINATION PRODUCT DEVELOPMENT**  
**Justin Lacombe**, Senior Manager Process Development, **Teva Pharmaceuticals USA**  
**Henri Akouka**, Associate Director of Product Development, **Teva Pharmaceuticals USA**

**17:50 DEBATING THE CHALLENGES AND SOLUTIONS FOR PFS DEVELOPMENT AND THE INCREASING TRENDS TOWARDS BIOLOGICS**  
**Steve Bowman**, Device Program Lead, **Shire US Inc**  
**Justin Wright**, Global Head of Innovation, **Novartis**

**18:30 CHAIRMAN'S CLOSING REMARKS AND CLOSE OF DAY ONE**

## **Main Conference: DAY 2 – April 12, Thursday**

**8:30 REGISTRATION & COFFEE**

**9:00 CHAIRMAN'S OPENING REMARKS**  
**Michael Doyle**, Director, Medical Device Regulatory, CMC, **Pfizer**

**9:10 KEYNOTE ADDRESS: THE CRITICAL IMPORTANCE OF RECOGNIZING THE CONSIDERATIONS, DECISIONS AND TRADE-OFFS INHERENT IN ALL COMBINATION PRODUCT DEVELOPMENT**  
**Steve Bowman**, Device Program Lead, **Shire US Inc**

**9:50 THE CHALLENGES OF PLATFORMIZATION**  
**Molly Story**, Head, Global Usability Engineering and Risk Management, **Sanofi Pharmaceuticals**

**10:30 MORNING COFFEE SPONSORED BY ZEON**

**11:00 LEVERAGING PREFORMATIVE RESEARCH TO INFORM LIFECYCLE MANAGEMENT OF COMBINATION PRODUCTS FOR COMPLEX DISEASE STATES**  
**Joke Maes**, Product Manager, **Terumo Pharmaceutical Solutions**  
**Chris Franzese**, Lead Clinical Analyst, **Matchstick**

**11:40 PANEL DISCUSSION: WHAT IS MISSING FROM THE HUMAN FACTORS STUDIES AND WHY IS THIS STILL A PREVALENT ISSUE?**  
**Gary Mills**, Associate Director, Drug Product Development, **TESARO**  
**Molly Story**, Head, Global Usability Engineering and Risk Management, **Sanofi Pharmaceuticals**

**12:20 NETWORKING LUNCH SPONSORED BY TERUMO**

**13:20 SMART LABELING SOLUTIONS FOR PRE-FILLED SYRINGES: PATIENT CENTRICITY ENHANCED**  
**Eric Caro**, Key Account Manager, **Schreiner Medipharm**

**14:00 LESSONS LEARNED FROM HUMAN FACTOR STUDIES OF PRE-FILLED SYRINGES**  
**Tieming Ruan**, Associate Director of Device Development, **Takeda**

**14:40 NEW DEVELOPMENTS IN LOW TEMPERATURE VHP TERMINAL SURFACE STERILIZATION AND PFS MATERIAL COMPATIBILITY**  
**Juha Mattila**, Senior Product Manager, **STERIS FINN-AQUA**

**15:20 COMPOSITE DIGITAL MONITORING BIOMARKERS COME OF AGE: THE FRAMEWORK OF UTILIZATION**  
**Justin Wright**, Global Head of Innovation, **Novartis**

**16:00 AFTERNOON TEA SPONSORED BY ZEON**

**16:30** PFS TECH TRANSFER OF IN-LINE PRODUCTS NOT ORIGINALLY DEVELOPED AS COMBINATION PRODUCTS

**Maria Linzmayer**, Associate Director, Drug Delivery Devices, **Merck**

**17:10** FUTURE OF DIGITALLY CONNECTED DEVICE AND CHANGING PARADIGM IN DISEASE MANAGEMENT

**Michael Song**, Sr. Manager, Drug Delivery and Device Development, **MedImmune Inc**

**17:50** CHAIRMAN'S CLOSING REMARKS AND CLOSE OF DAY TWO

## **Pre-Conference Workshop A: April 10<sup>th</sup> - Tuesday**

### **DESIGN CONSIDERATIONS FOR THE WORLD OUTSIDE THE CLINIC**

Workshop leaders:

**Annie Diorio-Blum**, Principal Industrial Designer, **Battelle**

**Scott Ulrich**, Senior Industrial Design Leader, **Battelle**

**8:30** REGISTRATION & COFFEE

**9:00** WORKSHOP LEADERS' OPENING REMARKS AND INTRODUCTION

**9:10** EXPLORING DIVERSE USERS AND USE ENVIRONMENTS

Breakout Groups - How to draft profiles for users and environments with design inputs in mind

**10:10** GETTING THE MOST OUT OF EARLY USER RESEARCH

Case Studies - How user environment profiles inform plans for early user research

**10:30** MORNING COFFEE

**11:00** MAPPING USER NEEDS TO USER INTERFACE REQUIREMENTS

Case Studies - How to trace user research findings to user needs and user interface requirements

**11:30** PROVIDING A COMPLETE SUPPORT SYSTEM

Discussion - Use outside the clinic requires multiple forms of support

Discussion - Instructions for Us are part of the user interface and should be created using a Human Centric Design approach

**12:30** CLOSING REMARKS FROM WORKSHOP LEADERS' AND END OF MORNING WORKSHOP

## **Pre-Conference Workshop B: April 10<sup>th</sup> - Tuesday**

### **HUMAN FACTORS FOR CONNECTED DRUG DELIVERY SYSTEMS**

Workshop leaders:

**Melanie Turieo**, Director, Human Factors Engineering, **Cambridge Consultants Ltd**

**Karen Unterman**, Group Leader, Human Factors Engineering, **Cambridge Consultants Ltd**

**13:30** WORKSHOP REGISTRATION AND WELCOME COFFEE

**14:00** WORKSHOP LEADER INTRODUCTION

**14:15** OVERVIEW OF HUMAN FACTORS FOR MEDICAL DEVELOPMENT

Human Factors Engineering process

Regulatory requirements  
Commercial goals

**14:45** OVERVIEW OFF THE REGULATORY LANDSCAPE FOR DIGITAL HEALTH

Is it a medical system or not?

Consumer digital systems

Medical digital systems

**15:10** AFTERNOON TEA AND NETWORKING BREAK

**16:00** BRINGING DIGITAL INTO THE HF PROCESS

How does it impact the process?

What is the UX and how is it interpreted for hybrid systems?

Tools, methodologies and best practices

**16:30** VALIDATION OF THE DIGITAL HEALTH

**17:00** CLOSING REMARKS FROM WORKSHOP LEADER AND END OF WORKSHOP

Full details about event at [www.pfsamericas.com](http://www.pfsamericas.com)