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7th Edition PFS & Injectables Summit 2017

September 26 – 28, 2017 | **San Diego, USA**

Enhancing Injectables Device Quality through Scientific & Engineering Excellence

Hear From 18 Speakers, Including:

Molly Story
Senior Director, Global Usability Engineering & Risk Management, MED
Sanofi US

Paul Upham
Senior Principal
Roche/Genentech

Thomas Miller
Vice President, Device Research & Innovation
Novo Nordisk

Joyce Zhao
Associate Director, Device Engineering & Development
Dr. Reddy's Laboratories

Vijay Damodaran
Director, Quality, Medical Devices & Combination Products
Eli Lilly & Company

"Excellent conference with a diverse speaker panel that covers multiple aspects of PFS research and development!"

Pfizer

www.pfs-injectables.com

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Welcome to the 7th edition PFS & Injectables Summit

With the uncertainty that comes with new regulatory guidelines and an ageing patient population, experts within the injectable community are facing critical challenges in **ensuring a compliant, safe and timely product development program**.

Building on 6 years of experience and success, the **PFS & Injectables Summit** returns with the latest trends and developments to help you accelerate your patient-centric device program.

Join the conversation with fellow senior executives in this space to:

- **Understand the global regulatory environment** and ensure smooth approval process, for combination products in particular
- **Evaluate the latest technologies** to enhance the quality of device
- **Benchmark against best practice** of risk assessment for your device

This must attend forum will give you access to **practical case studies providing actionable insights** which you can implement immediately to keep up with the rapidly changing landscape of injectable devices.

Your 5 Key Takeaways

1. **Sanofi** demonstrates why early human factors study can give your device a competitive edge
2. **Shire** shares tips on how to refine your device lifecycle management approach
3. **Bristol-Myers Squibb** reveals how to mitigate contamination risks – learn about their latest CCIT testing results
4. **MedImmune** shares insights on connected injectable device platforms: Stay abreast of future opportunities
5. **Kiang Consultant Services, Human Factors MD** and **UserWise, Inc.** provide an interactive 360° guide to developing your injectable device program

Hear What Previous Attendees Have To Say:

"This conference exceeded all of my expectations. The topics, speakers and suppliers were very relevant to my interests. I was able to walk away with many ideas and contacts to benchmark with!"

GSK

"The meeting and workshop bring together the top experts in the field of PFS; the size of the conference and quality of participants are optimal for healthy and fruitful discussions at every level."

Glenmark Pharmaceuticals SA

"I enjoyed the discussions and meeting our colleagues at the conference!"

Bristol-Myers Squibb

Expert Speakers

Molly Story
Senior Director, Global Usability Engineering & Risk Management, MED
Sanofi US

Willow DiLuzio
Director of Formulation & Device Development
Takeda

Thomas Miller
Vice President, Device Research & Innovation
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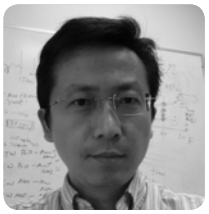
Chin-Wei Soo
Senior Regulatory Program Director
Genentech

Young Chun
Principal Engineer - Human Factors Lead
Shire

Bobbijo Redler
Associate Principal Scientist
Merck

Shawn Olsson
Director of US Opioid & Syringe Technology Portfolio
Pfizer

Steve Bowman
Device Program Lead
Shire



Xu Song
Principal Engineer, Manufacturing Science & Technology
Bristol-Myers Squibb

Joyce Zhao
Associate Director, Device Engineering & Development
Dr. Reddy's Laboratories

Michael Song
Snr. Manager, Drug Delivery & Device Development
MedImmune

Patty Kiang
Principal
Kiang Consultant Services

Tim Reeves
Managing Director
Human Factors MD

Christina Mendat
Partner & Senior Technical Director
Human Factors MD

Shannon Clark
Principal
UserWise, Inc.

Gopi Vudathala
Head, Quality Advocacy Liaison
GSK Vaccines

"This was one of the best conferences I've been to in years. Specific to the business needs, applicable to current situations facing pharma!"

Sanofi

Pre-Conference Workshop A

Navigating Through the Global Regulatory Frameworks for PFS & Injectables

Date: Tuesday, September 26 | Time: 08.00 – 11.00

The regulatory requirements for PFS and injectables, particularly combination products, have been evolving rapidly over the last 12 months. While the FDA is taking the lead on defining their expectations, EMA and MHRA are following suit.

Nonetheless, there still exists uncertainty and discrepancies in the interpretation of such guidelines and expectations.

This workshop will aim to provide you with a holistic view and help you prepare for product review, to ensure a smooth approval process for a timely launch in market.

You will learn about:

1. The FDA regulation for combination products comprised of any combination of a drug and a device; a device and a biological product; a biological product and a drug; or a drug, a device, and a biological product. A combination product remains subject to the regulatory requirements associated with its constituent parts. Our focus will be on the Single Entity combination products for pre-filled syringes or injection devices.
2. The streamlined CGMP approach for drug product and delivery devices. The importance of human factor studies to evaluate the user interface of a product is required. The impact of the quality of primary container/closure systems to the success of the combination products will be discussed.
3. The different approaches of EMA and MHRA regulations on pre-filled syringes and injection devices.
4. The global technical and quality requirements for pre-filled syringes and injection devices.

Workshop leader

Patty Kiang, Principal,
Kiang Consultant Services

Dr. Kiang specializes in pharmaceutical packaging and delivery devices for liquid and lyophilized products, prefilled syringe systems and injection devices, and CMC filing for combination products. She is a consultant for bio/pharm industry in the area of combination products development, quality assurance and regulatory affair. She was Head of Device Development for Genentech, led the development of a new autopen injector for human growth hormone, and was CMC leader for prefilled syringe combination product development.

Pre-Conference Workshop B

Use-Related Risk Management – Develop a Safe & Usable Medical Device

Date: Tuesday, September 26 | Time: 11.30 – 14.30

This hands-on workshop offers a deep dive exploring how to bring a safe and usable medical product to market. Combining presentations, multimedia and interactive activities, participants will gain a sense of what it means to develop products with the user foremost in mind.

This workshop will outline:

- The application of FMEAs and human factors in risk management
- What is use-related risk analysis and how does it guide design decisions relating to safety?
- Acceptance criteria for usability validation study
- Compliance documentation and international regulation related to use-related risk management

Join this workshop to address your critical questions, including:

- What do I need to know about Use-Related Risk Analysis as an R&D Engineer, Marketing specialist, complaints manager, or quality engineer?
- What is the difference between "normal use" and " abnormal use"?
- Why do we exclude "abnormal use" from a Use-Related Risk Analysis?
- How do I know when a Use-Related Risk Analysis is "complete" and has captured all use-related risks?
- Why does the FDA recommend conducting a Task Analysis and how do I create one?
- How do I write and trace mitigations in a Use-Related Risk Analysis?

Workshop leader

Shannon Clark, Principal, **UserWise, Inc.**

Shannon Clark is founder and CEO of UserWise, a consultancy that helps medical device manufacturers and start-ups to design safe and easy-to-use medical devices. The consultants a UserWise conduct usability testing for a variety of medical devices ranging from surgical robots to home-use injection platforms. UserWise consultants also perform safety assessments to comply with U.S. and international regulations related to Human Factors.

Pre-Conference Workshop C

Avoiding Pitfalls & Optimizing Human Factors for Prefilled Syringes & Autoinjector

Date: Tuesday, September 26 | Time: 15.00 – 18.00

Since the inception of HE75 and the more recent Final Guidance (*Applying Human Factors and Usability Engineering to Medical Device, February 2016*) and Draft Guidance (*Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development*), human factors is no longer a "nice to have" but a necessity for a number of combination devices submissions.

Despite this guidance, however, companies still struggle with understanding and navigating the expectations of the FDA. A more recent draft guidance (*Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA, January 2017*), has resulted in increased grey areas around expectations.

The first focus of this workshop is to better understand your device (and its features) from an HF perspective. There is much that can be accomplished before testing has even started.

1. Pitfalls of common PFS and AI designs
2. Features to consider even when procuring off the shelf-solutions
3. When to consider labeling and packaging (it may be sooner than you think)

Another focus of this of this workshop is to understand how to design human factors studies. Not all studies are created equally but there are basic expectations that should be met.

1. Who should you test? Who are your "unique" user groups?
2. What should you test? What should be considered?
3. When should you test?
4. Where should you test?

A third focus of this workshop is to spend time discussing other pertinent device scenarios.

1. What if the device has been on the market for 20+ years?
2. What if the device is a generic?
3. What if studies have been conducted in another country?
4. What if data has been collected in clinical trials similar to human factors data?

Workshop Leaders

Tim Reeves, Managing Director, **Human Factors MD**

Tim founded the company in early 2001. He has 20 years of commercial experience evaluating and designing usable, effective, and safe medical devices. He is a Certified Human Factors Professional, and as a member of the AAMI's Human Factors Committee, is an contributor to HE:75. He has been an invited speaker at several professional meetings, including the AAMI/FDA sponsored Human Factors and Patient Safety for Medical Devices and the first IBC's conference on Human Factors and Combination Products. Tim is the lead faculty for AAMI's popular Human Factors for Medical Device Design course. Tim has a PhD in cognitive psychology and human factors from the University of Toronto.

Christina Mendat, Partner & Senior Technical Director, **Human Factors MD**

Christina has conducted numerous formative and summative studies, and led clients successfully through regulatory approval process. For Human Factors MD, Christina provides technical oversight to our HF team and is an expert at translating research findings such as user needs, requirements, product strengths and weaknesses into compelling design directions and solutions. She brings over a decade of experience in human factors having spent more than 5000 hours in surgical suites, medical device usability studies, and outpatient facilities. She has presented papers to the Human Factors and Ergonomics Society and the American Psychology Society and has been providing multiple workshops and lectures on navigating the latest standard, HE75, and human factors integration in quality management systems to groups including PDA (Parenteral Drug Association), ISPE (International Society for Pharmaceutical Engineering), and ASQ (American Society for Quality). Christina has a PhD in experimental psychology and ergonomics from North Carolina State University.

Conference Day One | Wednesday September 27, 2017

	8.00	**Breakfast & Registration**
	9.00	**Chairman's Opening Remarks**

Navigating Through the Global Regulatory Framework

Gopi Vudathala, Head, Quality Advocacy Liaison, **GSK Vaccines**	9.10	**Keynote Address: What is a Quality Device? Applying Risk-Based Design & QbD Approaches** • Ensuring QbD and design validation encompassing ICH Q9 risk management approach • Taking a risk-based approach during device design and control strategy • Applying software for accurate simulation and evaluation to increase confidence level
Vijay Damodaran, Director, Quality, Medical Devices & Combination Products, **Eli Lilly & Company**	9.40	**Combination Products Part 4 Compliance & Implementation at Multi-Site Networks Including CMOs** • Evaluating key cGMP requirements for combination products • How to perform effective compliance oversight when multiple sites are involved in the design, development and manufacturing of combination products? • Ensuring compliance to EU requirements for drug/device medicinal products • Achieving inspection readiness for combination products
Chin-Wei Soo, Senior Regulatory Program Director, **Genentech**	10.10	**Post-Market Surveillance Requirements – How to Implement?** • Evaluating the final rule of post-marketing safety reporting requirements for combination products • Discussing the implementation challenges, and opportunities for regulator and industry • Establishing an on-going and rigorous post-market surveillance strategy to identify product, design, and process improvements
	10.40	**Morning Refreshments & Speed Networking**

Technical Innovations for PFS & Injectables

Joyce Zhao, Associate Director, Device Engineering & Development, **Dr. Reddy's Laboratories**	12.10	**Interface from PFS to Auto-Injector** • Exploring the undeniable benefits of auto-injectors over PFS for patients • Assessing considerations during the device development cycle: viscosity, biocompatibility, patient user group and costs • Addressing the challenges of quality control and device assembly for auto-injectors • What's next? Discovering how wearable injectors can deliver a higher volume and viscous drug
Steve Bowman, Device Program Lead, **Shire**	12.40	**Lifecycle Management of Your PFS & Injectable** • Analyzing product life cycle management from vial to PFS and beyond • Evaluating specific requirements and considerations for combination product development • Discussing the impact of connectivity on lifecycle management • Emphasizing the importance of user research to maximize device lifespan

Conference Day One | Wednesday September 27, 2017

13.10 Lunch & Networking

Young Chun, Principal Engineer - Human Factors Lead, **Shire**

14.10 Success Story of Developing a Patient-Centric Device

- Assessing HF roles from start to finish and beyond
- From pre-filled syringes to autoinjectors to other devices: Lessons learnt on HF study
- Tackling the challenge of conducting HF study for rare diseases/orphan drugs
- Exploring techniques that can help collate and incorporate user feedback to device design

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Molly Story, Senior Director, Global Usability Engineering & Risk Management, MED, **Sanofi US**

14.40 The Human Touch – Develop a Patient-Centric Injectable Device

- Achieving design validation – 21 CFR Part 820:30 and ISO 62366; benchmark against clinical evaluation and user feedback
- Defining your intended users and testing group: Trained vs. untrained?
- Understanding the process and feedback loop to enhance device quality and minimize delay in development plan
- How early human factors study can give your device a competitive edge?

15.10 Afternoon Refreshments & Networking

Joined by Speakers of the Day

15.40 **The audience can choose a specific topic to discuss and share their challenges with colleagues. Through open dialogues, we hope to facilitate knowledge exchange and inspire innovative ways to find solutions to your daily problems.**

Roundtable Discussion

Track 1: How to conduct human factors studies as part of your clinical development program?

Track 2: Quality issues: Update PQRI guidelines and best practice to E&L and viscosity issues in injectable devices?

Track 3: Regulatory pathways for combination products in PFS and injectables

Track 4: Future digital device – how should we envisage the connected platforms to drive patient-centricity?

Thomas Miller, Vice President, Device Research & Innovation, **Novo Nordisk**

16.20 Next Generation Dose Delivery Devices

- Identifying new ways to support patients
- Lessons learned so far – incorporating formative human factors study into your user-testing for smart devices
- Looking into the future – what's next and what are the potential challenges?

16.50 Chairman's Closing Remarks

17.00 Close of Day One

"Great networking opportunities. The talks were informative and well presented. I had access to number of important KOL's."

Ambry Genetics

Conference Day Two | Thursday September 28, 2017

8.00 **Breakfast & Registration**

9.00 **Chairman's Opening Remarks**

Accelerating PFS & Injectable Device & Production

Willow DiLuzio, Director of Formulation & Device Development, **Takeda**

9.10 **Case Study: Drivers & Challenges of Developing High Concentration Injectables**

- Achieving device design that enables high concentration dosage
- Tackling the problems of high viscosity
- Needle consideration – length and width to enhance subcutaneous delivery with passive safety measures

Xu Song, Principal Engineer, Manufacturing Science & Technology, **Bristol-Myers Squibb**

9.40 **Container & Closure System Integrity Testing (CCIT)**

- Maintaining the container closure integrity (CCI) at all times during manufacturing process and later product shipping
- Utilizing several test methods to detect the potential breach of CCI, while simulating the syringe plunger stopper movements during the plunger rod insertion process and the stopper movement during high altitude shipping
- Demonstrating how there is low CCI risk in the manufacturing process as well as during product shipping

10.10 **Morning Refreshments & Speed Networking**

Quality Engineering & Flexibility

Bobbijo Redler, Associate Principal Scientist, **Merck**

10.40 **Should We Switch? Syringe Material & E&L Considerations**

- Analyzing the rise of complex therapeutics and component selection – glass, COC, COP
- Assessing Advanced E&L profiling
- Stress testing your material for stability and quality primary container choice

"The meeting was well organized, the agenda well balanced and there was enough flexibility to engage in discussion. The networking sessions were great."

Gilead

Conference Day Two | Thursday September 28, 2017

Moderated by:
Shawn Olsson, Director of US Opioid & Syringe Technology Portfolio, **Pfizer**

11.10 **Master Mind: The Winning Team – Bridging the Gap between Technical, Strategy & Commercial Elements for a Quality Injectable Device**

It is not uncommon or unheard of that there are misunderstandings between formulation scientists and drug device development groups. Despite the continued emphasis on early dialogues amongst different functions to ensure a good device development program, decision makers are often caught up with day-to-day work.

This roundtable session will split the audience into discussion groups to share their thoughts on key objectives and challenges that technical, strategy and device engineering groups should bring during the following phases:

- Drug discovery and formulation
- Clinical Trial Ph1
- Clinical Trial Ph2-3
- Launch

At the end of this session, each group will share their ideas of how to lay out a best practice plan to takeaway and implement at work with a wider device team.

12.00 **Lunch & Networking**

Next Generation PFS & Injectables

Michael Song, Snr. Manager, Drug Delivery & Device Development, **MedImmune**

13.00 **The Future of Connected Injectable Device Platform**

- Digitalization: Benefits of electronic-enabled drug delivery devices to enhance patient adherence
- Discussing real-time patient experience monitoring in clinical device study
- Tackling hurdles of connectivity for combination products: cost, technology, regulatory and time-to-market considerations
- Evaluating add-on platforms as a step towards integrated device ecosystem
- Exploring opportunities for pharma, patient and HCP engagement through connected injectable devices

Paul Upham, Senior Principal, **Roche/Genentech**

13.30 **Digital & Connected Platforms – Roche/Genentech Case Study**

- Sharing digital connectivity technology development challenges and lessons learned so far
- How can a connected device enhance remote monitoring and patient adherence?
- Embedding RWE into your smart injectable development program and clinical study

Joined by speakers of the day

14.00 **Customization of Your Device, Is This Realistic?**

- Addressing innovations and tailoring your device to your therapeutic needs
- Ensuring flexibility in customization – limitations with CDMOs and cost?
- Developing a commercially successful platform for biotechs and emerging therapeutics with a patient-centric focus

Roundtable Discussion

14.30 **Chairman's Closing Remarks**

14.40 **Close of Conference**

Why Partner

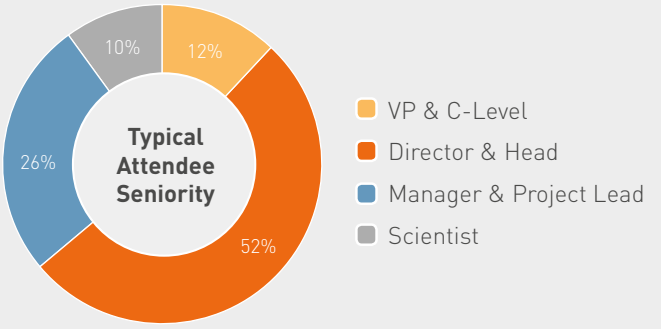
The last 12 months have been marked with significant milestones for pharma and device manufacturers.

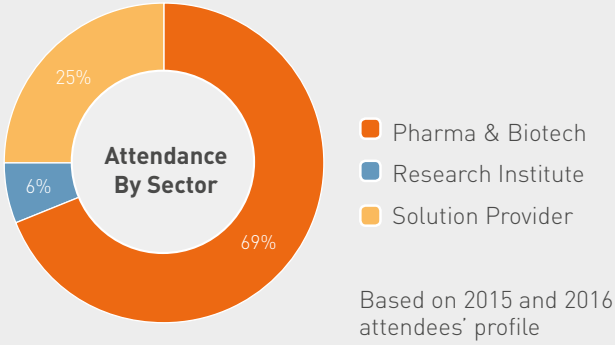
With the latest focus on combination products and the associated regulatory guideline updates, **our audience is urgently seeking solutions in the following areas:**

- CDMOs who can facilitate customized and cost-effective device solutions
- Automated fill/finish and sterilization technologies
- Risk assessment and management solutions for device development
- Human factors study and design validation
- Integrity and material testing to ensure device safety

If you have a solution or product to help our community, please get in touch to discover partnership opportunities that will connect you with them.

Who Will You Meet





Based on 2015 and 2016 attendees' profile

Previous PFS Summit Attendees:

AMGEN, AstraZeneca, Bayer, Bristol-Myers Squibb, FDA, Fresenius Kabi, Genentech, GSK, Lilly, Merck, Novartis, Pfizer, Shire, Teva, UCB, Sanofi, Janssen

Engage with 100+ VPs, Directors, Heads and Managers of:

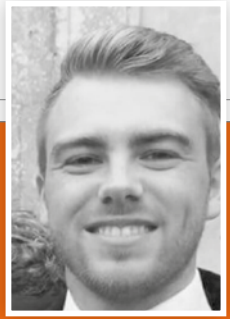
- PFS/Injectables
- Device Strategy & Engineering
- Regulatory Affairs
- Human Factors
- QA
- Fill/Finish, Device Manufacturing

From pharmaceutical and biotechs

"Great opportunity to exchange directly with the industry on case studies, suppliers and regulators. Very good organization!"

Ypso-Facto

Become a Partner



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Pricing

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> "Very invigorating conference! Bringing a group of like-minded people together to share common stories."
>
> **Eli Lilly**

Industry			
	Register & Pay before Friday July 14, 2017	**Register & Pay before Friday August 18, 2017**	**Standard Prices**
Conference + 3 Workshops	$3596 **(save $900)**	$3896 **(save $600)**	$4196 **(save $300)**
Conference + 2 Workshops	$3097 **(save $800)**	$3397 **(save $500)**	$3697 **(save $200)**
Conference + 1 Workshop	$2598 **(save $700)**	$2898 **(save $400)**	$3198 **(save $100)**
Conference Only	$2099 **(save $600)**	$2399 **(save $300)**	$2699
Workshops (each)	$599		

Solution Provider			
	Register & Pay before Friday July 14, 2017	**Register & Pay before Friday August 18, 2017**	**Standard Prices**
Conference + 3 Workshops	$4796 **(save $900)**	$4996 **(save $700)**	$5096 **(save $600)**
Conference + 2 Workshops	$4097 **(save $700)**	$4297 **(save $500)**	$4397 **(save $400)**
Conference + 1 Workshop	$3398 **(save $500)**	$3598 **(save $300)**	$3698 **(save $200)**
Conference Only	$2699 **(save $300)**	$2899 **(save $100)**	$2999
Workshops (each)	$899		

Venue

DoubleTree by Hilton Hotel San Diego - Mission Valley
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