8TH EDITION

PFS & INJECTABLES SUMMIT 2018

September 5 - 7, 2018 • San Diego, CA

www.pfs-injectables.com

REGISTER BY JUNE 15

SAVE UP TO $1000

"Although you have been in this industry for decades, you will still learn a lot from this conference!"

Principal Engineer, Shire

Turning Innovations Into Your Next Generation Patient-Centric Injectable

Jennifer Hefele Wald
Director, Global Regulatory Affairs Combination Products
Pfizer

Amy Wang
Director, Drug Delivery & Device Development
Alexion Pharma

Joseph Purpura
Executive Director, Medical Device Safety Physician Medical Devices
Allergan

Ella Stamler
Head of Device Quality & Management
Shire

Hung-Hsiang Chen
Strategic Director of Industrial Design
Eli Lilly & Company

E Guan
Director, R&D, Platform Device Development
MedImmune

Exhibition Partner

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WELCOME TO THE 8TH EDITION PFS & INJECTABLES SUMMIT

Uniting Industry Pioneers to Transform the Success of Your Injectable Products

ABOUT US

Over the last 12 months, the global injectable device market has shown no signs of slowing down despite the evolving regulatory landscape. Suppliers continue to launch new platforms; in particular connected solutions, more advancements in microneedles and wearable devices, and more robust manufacturing technologies for a quality injectable.

Aligning with market trends of capturing innovations and delivering a patient-centric product, the **8th Edition PFS & Injectables Summit** will focus on two key elements: **how integrating human factors validation into early device design** can increase commercial competitiveness, and the **assessment of next generation injectable opportunities**.

Incorporating insights from the likes of **Janssen**, **Teva**, **Bayer**, **Shire** and **Alexion**, and plenty of fresh content, you'll hear case studies of innovations and lessons learned to equip you with unparallel information needed to succeed in this space.

SPOTLIGHT CASE STUDIES

1. **Pfizer** and **Merck** will share their approach to regulatory agencies for combination products in the US and EMA to ensure a smooth approval process

2. **Allergan** and **Shire** will guide you through human factors study integration, improving safety measures for your device's intended users

3. **MedImmune** will showcase their optimized development plan from PFS to autoinjectors - increasing speed to market and minimizing risks

4. **Nemaura** will assess next generation injectable opportunities - effectiveness of microneedles

5. **Shire** and **Eli Lilly & Company** will dissect the buzz word 'connected device' - helping you to develop a quality and compliant digital solution to connect with patients

"I found this conference enjoyable and learned a lot. Speakers shared their own experiences and lessons learned, which I will be able to directly apply in my job."

Senior Director, Safety Risk Lead, Pfizer

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EXPERT SPEAKER PANEL

Jennifer Hefele Wald
Director Global Regulatory Affairs Combination Products
Pfizer

Amy Wang
Director Drug Delivery & Device Development
Alexion Pharma

Joseph Purpura
Executive Director, Medical Device Safety Physician, Medical Devices
Allergan

Ella Stamler
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Shire

Hung-Hsiang Chen
Strategic Director of Industrial Design
Eli Lilly & Company

E Guan
Director, R&D, Platform Device Development
MedImmune

Raihan Hossain
Associate Director CH I&D Medical Device Quality
Bayer

Jessical Gwinnup
Director, Mechanical Engineering, Delivery, Device & Connected Solutions
Eli Lilly & Company

Alasdair Young
Associate Director, Device Engineering
Coherus BioSciences

Gay Steinbrick
Lead Medical Device & Combination Products, Global Safety
Merck

Karthik Balasubramanian
Associate Director, Global Device R&D Operations
Teva Pharmaceuticals

Kesley Gallagher
Senior Regulatory Affairs Manager
Amgen

Young Chun
Principal Engineer, Human Factors Lead
Shire

Nick Zampa
Senior Engineer, Human Factors & Risk Management
Biogen

Alireza (Alie) Jahangir
Sr. Manager: Quality Engineering & Design to Value; Combination product and Emerging Technologies
Janssen Pharmaceutical

Eugene Wu
Combination Products Manager
Novavax

Scott Nunn
Manager, Device Development & Clinical Packaging Engineering
Gilead

Faz Chowdhury
CEO
Nemaura

Patty Kiang
Principal
Kiang Consulting Services

Edwin Bills
Principal Consultant
ELB Consulting

Joely Gardner
Chief User Researcher, **Human Factors Research**; Professor **UCSD Graduate Business School**

PRE-CONFERENCE WORKSHOP DAY
WEDNESDAY, SEPTEMBER 5

Workshop A 08.00 – 11.00

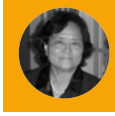
Develop a Fail-Proof Technical Documentation for Your Combo Products for Smooth Regulatory Approval

With regulations evolving rapidly around the world, how can drug/ device developers ensure a robust and thorough technical documentation for regulatory approval filing? What should you include and what do regulatory agencies expect from you?

This workshop session will give you a step by step guide in:

- Coordinating with multiple drug/device teams to draft a detailed submission plan for your combination products
- Ensuring quality control and quality assurance
- Anticipating changes and regulatory agencies' expectations: from the FDA to EMA
- Common pitfalls and tips for best practice

WORKSHOP LEADER:



Patty Kiang
Principal
Kiang Consulting Services

Workshop B 11.30 - 14.30

Developing a User-Friendly and Commercially Competitive Injectable

As human factor regulations advance, drug and device developers need to incorporate formative studies as early as possible. A well thought-through and integrated human factors program will also help drive commercial competitiveness and enhance patient experience. This doesn't just relate to device design but also labelling and packaging.

This workshop is designed to help attendees:

- Build a comprehensive end-to-end human factors program with other device functions
- Extrapolate meaningful data and establish a feedback loop to enhance usability and functionality of device
- Deliver beyond regulatory expectations and ensure smooth approvals from the FDA and EMA
- Post-launch human factors feedback management to drive next gen products and increase product life

WORKSHOP LEADER:

Joely Gardner
Chief User Researcher, **Human Factors Research**; Professor
UCSD Graduate Business School

Workshop C 15.00 - 18.00

Re-Define Your Risk Management Program for Combo Products throughout Lifecycle

Having a quality system and risk management program is critical to a compliant device/ combination product. Regulations are changing rapidly and as your device evolves, how confident are you that it still fits with regulatory framework? What are the parameters you should consider?

This workshop session will involve scenario-based exercises and discussions to help you:

- Stay up to date with the latest ICH Q9 and ISO 14971 risk management standard
- Revise your existing framework and approach to avoid common pitfalls
- Collaborate with your vendors to ensure transparent dialogue and implement a first class QA/ risk management program

WORKSHOP LEADER:

Edwin Bills
Principal Consultant
ELB Consulting

"It was a very well prepared conference and where participants were very engaged and brought good energy and engagement into the conference and the discussions.

Senior Regulatory Professional, Novo Nordisk

CONFERENCE DAY ONE THURSDAY, SEPTEMBER 6

08:00 **Morning Coffee & Registration**

09:00 **Chair's Opening Remarks**

Ensuring a Regulatory Compliant Injectable Device

09:10 **Opening Address: How Safe is Your Safety Device?**

- From Quality System Regulation (QSR) 21CFR820 to design control requirements – reassure your device's safety and effectiveness for the intended users, uses and use environments
- Can you identify possible use errors and mitigate the associated risks?
- Re-validate legacy product and collate feedback from users' post-launch to enhance safety features

Joseph Purpura
Executive Director, Medical Device Safety Physician, Medical Devices
Allergan

09:40 **Combination Products Regulatory Expectations from the Agencies**

- Combination products approval guidelines – what data is required for filing?
- Updates on CRF21 Part 4 – cGMP and multi-site manufacturing oversight

Jennifer Hefele Wald
Director Global Regulatory Affairs Combination Products
Pfizer

10:10 **Speed Networking & Morning Refreshments**

The Human Touch – Developing a User-Friendly Device for Your Patients

11:45 **How to Anticipate the 2020 Deadline – EU Medical Device Directive**

- Key changes with MEDDEV Rev 4
- Looking ahead to EU MDR
- Clinical evaluation reports for drug delivery device constituents

Gay Steinbrick
Lead Medical Device & Combination Products, Global Safety
Merck

12:15 **The New Beginning after Launch – A Device Regulatory Perspective and Journey**

- Post-launch regulatory considerations and executing a robust change system for device
- Regulatory affairs' role during the evolution of injectable devices – from PFS to on-body injector
- Case study: Amgen's success story and lesson learned

Kesley Gallagher
Senior Regulatory Affairs Manager
Amgen

12:45 **Tech-Show at Exhibition Hall**

- Live demos from our technology partners to showcase how latest PFS and injectable innovations.
- Delegates will get the chance to ask questions during this interactive sessions.

13:00 **Lunch & Networking**

14:00 **Human Factors Study – How, When, What and Who?**

- It's not a check box exercise: devising a thorough design plan for your HF study
- When should you conduct and what's the optimal sample size?
- Defining your sample pool for a meaningful study

Young Chun
Principal Engineer – Human Factors Lead
Shire

14:30 **Human Factors within the Device Design Control Paradigm**

- How can a human factors approach enable more robust risk management?
- Knowing your intended users to make risk-based decisions about device design.
- Integrating human factors as part of the broader device development process within Pharma/Bio-Pharma
- Post-launch: role of human factors during post-market surveillance?

Nick Zampa
Senior Engineer, Human Factors & Risk Management
Biogen

CONFERENCE DAY ONE THURSDAY, SEPTEMBER 6

15.00 **A Different Perspective – Biosimilars Combination Product Development Considerations and Challenges**

Alasdair Young
Associate Director, Device Engineering
Coherus BioSciences

- Biosimilarity and interchangeability:
  - A perspective on current HF guidance
  - The impact on technology selection
- Developing a biosimilar as a combination product:
  - Anticipating and addressing potential challenges with characterizing a reference product
  - Differentiation – managing technology platforms across products

15.30 **Panel Discussion**

This session will be hosted by our Panel Partner UL will focus on the importance of human factors' and challenges associated with injectable device development programs.

16.15 **Afternoon Refreshments & Networking**

Device Technology Innovations in Injectable Device

16.45 **Case Study: Journey of Drug-Device Integration**

Karthik Balasubramanian
Associate Director, Global Device R&D Operations
Teva Pharmaceuticals

- QbD thinking and design controls
- Risk-based approach to human factors study and validation
- Parameters and considerations for generic PFS and injectables
- Looking ahead: where do opportunities and challenges lie?

17.15 **Less is More – Delivering a High Volume, Highly Viscosity Drug with Precise Dosage**

Amy Wang
Director Drug Delivery & Device Development
Alexion Pharma

- With trends turning towards less frequent administration and larger dosing, what does it mean to existing formulation and drug delivery options?
- Addressing the challenges of highly concentrated and highly viscous drugs during injection
- Different platform selection criteria and considerations
- Challenges to work with confined parameters and lesson learned

17.45 **Downsizing: Microneedle Opportunity in Injectables**

Faz Chowdhury
CEO
Nemaura

- How micro can a microneedle injectable be?
- Formulation and efficacy challenges
- Applications and opportunities – patient adherence and ease of self-administration

18.15 **Chair's Closing Remarks**

18.20 **Close of Day 1**

"Great conference! I learned a significant amount of information."

Senior Research Fellow
Ionis Pharmaceuticals

CONFERENCE DAY TWO FRIDAY, SEPTEMBER 7

08.00 **Morning Coffee & Registration**

09.00 **Chair's Opening Remarks**

Injectable Development – Capitalizing on Innovations

09.10 **The Injectable Journey: From PFS to Wearable - Developing a Patient-Centric Device**

- The evolution and shift from PFS to other injectable formats – auto-injectors
- Designing a patient-centric device: Large volume autoinjector
- Opportunities and challenges: from formulation to patient experience

E Guan
Director, R&D, Platform Device Development
MedImmune

09.40 **How to Accelerate Product Innovation within Injectables: Case Study of Agile/RIC Approach**

- How can digitalization of your injectable device leverage safety and patient experience?
- The questions and challenges associated with the development and maintenance of connected platforms
- Lessons learned from adopting an agile approach

Hung-Hsiang Chen
Strategic Director of Industrial Design
Eli Lilly & Company

10.10 **Stay Connected via Connected Device – The Next Big Thing in Injectables**

- Connected device and platform – what do they mean?
- The questions and challenges associated with the development and maintenance of connected platforms
- What does the regulator think?
- Addressing cyber and data risks – cloud and security

Ella Stamler
Head of Device Quality & Management
Shire

10.40 **Tech-Show at Exhibition Hall**

Watch live demos from our technology partners to showcase latest technologies in PFS and injectables! Delegates will get the chance to ask questions during this interactive session.

10.50 **Morning Refreshments & Networking**

Quality Engineering and Flexibility

11:20 **The Art of Engineering – Developing a Patient Friendly Autoinjector**

- How to progress smoothly from PFS to autoinjector: from device design to development timeline
- Compatibility considerations and constraints
- Innovations in safety features to enhance patient experience

Jessical Gwinnup
Director - Mechanical Engineering, Delivery, Device & Connected Solutions
Eli Lilly & Company

11:50 **The Challenges with Device Providers – Platform Solutions vs. Customization**

- The challenges of buying devices off-the-shelf from suppliers from a human factors perspective
- Compatibility, customizatbility and ease of assembly
- Selecting a platform that reflects good HFE and will meet your users' needs

Raihan Hossain
Associate Director CH I&D Medical Device Quality
Bayer

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

Eli Lilly

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12.20 **Master Mind: Rethink Your Device Selection and Development Program**

Speed to market and compliance are critical to patients and commercial success. With more focus placed on lifecycle management and collaboration amongst internal/ external stakeholders, how can you optimize and streamline your device development programs?

This roundtable session will split the audience into groups for a discussion to share their thoughts of key objectives and challenges in the following areas:

- Getting it right from the start: which drug delivery route and device format?
- Who to partner with: what are your vendor selection criteria?
- Who do you collaborate? Identifying the key functional teams you'd need to engage and map out the timeline
- Development plan and lifecycle: parallel device development to shorten the timeline

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.

Moderated by:
Scott Nunn
Manager, Device Development & Clinical Packaging Engineering
Gilead

Roundtable Discussion

13.00 **Lunch & Networking**

14.00 **A Systematic Approach to Develop a Novel E2E Stability Program for Combination Products: A Unique Product Quality Management Perspective**

- Defining a unique approach to establish specific stability requirements for combination products, aligned with both drug and device guidelines, and beyond determination of expiration dating alone
- The critical role of the design control process in defining the scope of E2E stability paradigm for combination products
- Sterility and stability concerns – from pre-filled to autoinjectors to next generation injectables

Alireza (Alie) Jahangir
Sr. Manager: Quality Engineering & Design to Value; Combination product and Emerging Technologies
Janssen Pharmaceutical

14.30 **Simple as it Seems – How to Close Your Container?**

- The different approaches to container closure systems and deterministic methodology
- What are the parameters and considerations? Product stage, product type, container closure components and fill-finish platform
- Enhance your CCIT confidence to assure product integrity during manufacturing, shipping, storage, and through product shelf-life
- Lessons learned and challenges

Eugene Wu
Combination Products Manager
Novavax

15.00 **Chair's Closing Remarks**

15.10 **Close of Conference**

"This conference provides a unique opportunity to collaborate on key roadmap requirements set forth by the pharma & biotech companies and device manufacturers."

Director of Device Development, Genentech

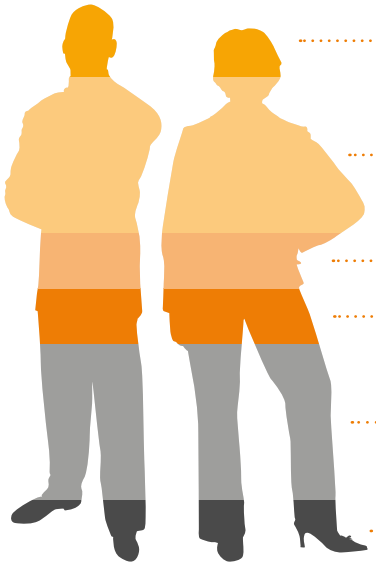
WHO WILL YOU MEET?

100+
ATTENDEES

12+
HOURS OF DEDICATED NETWORKING

3
INTERACTIVE WORKSHOPS

SENIORITY



- **11%** VP/C-Level
- **28%** Director
- **10%** Head
- **10%** Principal
- **28%** Manager
- **13%** Scientist & Engineer

COMPANIES BY TYPE

Pharma	**57%**
Biotech	**10%**
CMO	**16%**
Equipment Provider	**17%**

PREVIOUS ATTENDEES INCLUDE

Allergan, Alnylam, Althea, Amgen, antares pharma, Biogen, BioMarin, Bristol-Myers Squibb, Boston Biomedical, Cambridge Consultants, Dermira, Lilly, EMD Serono, Fresenius Kabi, Genentech, gsk, Ionis, kaléo, La Jolla Biologics, LEO, Momenta, novo nordisk, Otsuka, Regeneron, Takeda, Teva, ucb

"The networking opportunity was fantastic. The meeting had a broad range of topics which interested a diverse panel of participants".

Associate Director - Commercial Development, Safety & Systems-Self Administration Injection Systems

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PARTNER WITH US

The injectable community is eager to stay ahead of the curve through assessing innovative technologies. If your company offers services and solutions that would benefit our audience, we'd love to hear from you.

The 8th Edition PFS & Injectables Summit will once again bring together a global community of key decision makers from industry-leader pharma and biotechs. They are actively seeking collaborators to overcome challenges in developing the next generation injectables.

Partner with us to showcase your expertise and solutions at this unique plarform.

LET'S TALK

Peter Trebelev, Partnerships Director
E: peter.trebelev@hansonwade.com
T: +1 415 735 3289

PARTNERING WILL ALLOW YOU TO

SHAPE THE DEBATE

Raise your profile, share your experiences and position yourself as one of the go-to providers in your business area.

RAISE BRAND AWARENESS

If getting visibility within the injectables marketplace is your main objective, we can ensure your brand is prominently positioned at the event.

MEET AND NETWORK

Take advantage of the injectables community being together under one roof by planning your networking in advance.

PROVIDE A UNIQUE HOSPITALITY EXPERIENCE

Make your company the talk of the conference and provide an experience your clients won't forget. Align your brand with dynamic networking experiences throughout the event.

SHOWCASE YOUR PRODUCT

With a base in the exhibition area, you can showcase your innovative products and solutions, enhance your brand, host meetings at your booth, and network with our attendees.

Panel Partner

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IMA Automation North America designs and builds turn-key assembly and test systems for the medical device industry. Our engineered solutions support your assembly and test projects at every stage in the product life cycle. As part of the IMA Automation Group we offer local solutions for our global customers. From concept to prototyping, clinicals to commercialization, low to high volume production, we have the comprehensive experience and know-how to help you achieve your production goals.

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3 EASY WAYS TO BOOK

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Pharma & Biotech		
Package Details	**Register & Pay Before** Friday June 15	**Standard Rate**
Conference & 3 Workshops	**$3,596** (Save $1,000)	**$4,296** (Save $300)
Conference & 2 Workshops	**$3,097** (Save $900)	**$3,797** (Save $200)
Conference & 1 Workshop	**$2,598** (Save $800)	**$3,298** (Save $100)
Conference Only	**$2,099** (Save $700)	**$2,799**
Workshop Only	**$599**	

Solution Provider		
Package Details	**Register & Pay Before** Friday June 15	**Standard Rate**
Conference & 3 Workshops	**$4,696** (Save $700)	**$5,096** (Save $300)
Conference & 2 Workshops	**$3,997** (Save $600)	**$4,397** (Save $200)
Conference & 1 Workshop	**$3,298** (Save $500)	**$3,698** (Save $100)
Conference Only	**$2,599** (Save $400)	**$2,999**
Workshop Only	**$799**	

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20% DISCOUNT
5 DELEGATES +

Please note that discounts are only valid when 3 or more delegates from one company book and pay at the same time.

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Changes to Conference & Agenda: Hanson Wade reserves the right to postpone or cancel an event, to change the location or alter the advertised speakers. Hanson Wade is not responsible for any loss or damage or costs incurred as a result of substitution, alteration, postponement or cancellation of an event for any reason and including causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade or industrial disputes, terrorism or hostilities.

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