9TH EDITION

INJECTABLES SUMMIT 2019

REGISTER BY FRIDAY, MAY 31 TO SAVE $1100!

September 24 - 26, 2019 • San Diego, CA

www.pfs-injectables.com

"Informative, engaging and networking! This conference provided a good mix of different topics that were relevant to issues we are currently facing. It was nice to bench mark where we are at as a company compared to our peers and share best practices."

Zoetis, 2018 Attendee

Be Part of the Device Engineering Evolution: From Smart Injectors to Delivering Quality Patient Care

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

Delma Broussard
Director, Clinical Safety Physician
CSL Behring

Paul Upham
Head, Smart Devices
Roche/Genentech

Dennis Lee
Senior Program Officer, CMC
Bill & Melinda Gates Foundation

Daniel Latham
Head of Device Development & LCM
Novartis

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WELCOME TO THE 9TH EDITION INJECTABLES SUMMIT

Uniting the Injectable Community to Advance Innovative Delivery Solutions for Our Patients

ABOUT US

After building our community for 9 years, the injectables industry has now arrived at a crossroads whereby we need to continually improve on-market devices quality as well as future proofing next generation injectable formats to enhance patient care.

This September, the **9th Edition Injectables Summit** will help you to bridge the engineering and innovation gap for drug and device developers with a focus on:

- The possibility of advanced medicinal therapy injectable devices formats, including high viscosity and high concentration delivery
- How to progress quickly from PFS to auto-injectors and other types of injectables, such as wearable technology
- The translation from mechanical to connected and electro-mechanical device
- Understanding your patients' needs to enhance your product design

We would like to thank you our expert speaker panel including **Novartis, Bill & Melinda Gates Foundation, Janssen, Roche/Genentech** and **Merck.**

Join them to gain actionable takeaways and unparallel information needed to succeed in this fast evolving space!

SPOTLIGHT CASE STUDIES

1. **CSL Behring** will help you understand the FDA's expectation for PMSR for combination products

2. **Novartis** will present an end-to-end case study: Implementation of novel innovative drugs in auto-injectors maintaining safety and enhancing patient and user experience

3. **Crux Products Design Ltd.** will showcase their latest platforms to enhance injectable device innovations, accelerating speed-to-market and adhering to compliance standards

4. **Bill & Melinda Gates Foundation** will discuss their efforts in supporting vaccine and contraceptive injectable for developing countries in a cost-effective manner

5. **Roche/Genentech** will assess how to select digital health partners to deliver business value with connected devices

"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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PFS & Injectables
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EXPERT SPEAKER PANEL

Thomas Altobelli
Senior Manager, Device Quality & Risk Management
Janssen Pharmaceuticals

Steven Badelt
Founder & Managing Partner
Suttons Creek, Inc.

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

Delma Broussard
Director, Clinical Safety Physician
CSL Behring

Stuart Chisholm
Senior Manager, Global Devices R&D Operations
Teva Pharmaceuticals

Calvin Clark
Device Design & Development Engineer
Biogen

Richard Featherstone
Research Director – Human Factors Research & Design
Emergo by UL

Joel Gresham
Senior Mechanical Engineer
Crux Product Design Ltd

Katie Hansbro
CEO
Design Science Consulting Inc.

Thierry Jomini
General Manager
anteris helvetia AG

Erik Jin
Engineering Fellow, Combination Products & Device
Celgene

Dirk Kreder
General Manager & President of the Board
anteris helvetia AG

Dr Daniel Latham
Head of Device Development & LCM
Novartis

Dennis Lee
Senior Program Officer, CMC
Bill & Melinda Gates Foundation

John Majewski
Device Development Engineer
Gilead Sciences

Timothy Quigg
Senior Mechanical Engineer
Crux Product Design Ltd

Paul Upham
Head, Smart Devices
Roche/Genentech

Leonel Vanegas
Director, Global Quality Devices & Combination Products
Merck

Darin Zehrung
Senior Program Director
PATH

PRE-CONFERENCE WORKSHOP DAY
TUESDAY, SEPTEMBER 24

Workshop A 08.00 – 11.00

The Buzzword – QMRS: From Regulatory to CMC to Product Management

A well thought-through and robust quality risk management device program is necessary to uphold product integrity and patient care. It should be embedded throughout the device team and product lifecycle. This session will involve practical case studies and discussions to help you not only avoid pitfalls, but deliver excellent care for your patients and remain compliant.

This session will give you actionable takeaways on:

- What a good QMRS looks like
- Risk management and approaches to handling change throughout lifecycle
- When you should act on your feedback and complaints
- CAPA: it's important to understand the root cause to avoid mistakes
- How can it help you to extend your product lifespan?

WORKSHOP LEADER:

Leonel Vanega
Director, Global Quality Devices & Combination Product
Merck

Workshop B 11.30 - 14.30

Excellent Device R&D to Ensure Longevity of Your Injector

A successful and patient centric injector begins at the product R&D stage, and incremental changes to your product design can offer significant impacts on usability and commerciality of your injector.

This session will offer you a step-by-step guide on:

- The need to perform competitive analysis before commencing your R&D efforts
- Agile approach, how to make your device development more efficient
- Involving your users from the beginning into your R&D concept
- Is your device connected? How to digitalize your device cleverly
- Case studies of successful injectors lifecycle and evolutions

WORKSHOP LEADERS:

Thierry Jomini
General Manager
anteris helvetia AG

Dirk Kreder
General Manager & President of the Board
anteris helvetia AG

Workshop C 15.00 - 18.00

Connectivity – When, How and What?

While connected devices have sparked tremendous interests amongst drug and device developers, with huge potential benefits, there are a lot of challenges that the industry needs to overcome before being able to truly commercialize.

We will explore the following fast evolving topics to benchmark:

- Assess the quality, lifecycle, and regulatory impacts of digital health across your organization
- The importance of user and human factors testing for connected devices early on
- Creation of an integrated device solution and platform implementation
- Engineering considerations of your 'smart' injector
- Regulatory compliance, data privacy and ancillary services support
- The final question – does it make commercial sense?

WORKSHOP LEADER:

Steven Badelt
Founder & Managing Partner
Suttons Creek, Inc.

"It's a great meeting with quality audience, up-to-date talks and very well organized."
VP, Business Development, Sensile Medical

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CONFERENCE DAY ONE WEDNESDAY, SEPTEMBER 25

State-of-Play: The Fast Evolving Injectables Market

08.00 **Registration & Welcome Coffee**

09.00 **Chair's Opening Remarks**

09.10 **Opening Address: Understanding the FDA's Expectation for Postmarketing Safety Reporting (PMSR) for Combination Products**

- What does the regulatory agency expect under the PMSR final rule?
- Overview of combination product PMSR types
- Example/scenarios of case reports to illustrate how to comply with specific requirements of PMSR final rule

Delma Broussard
Director, Clinical Safety Physician
CSL Behring

09.40 **Why Risk Management is Key to Support Your Next Generation Injectable Development**

- Quality and risk management is key at the R&D stage
- Leveraging post-market surveillance and adverse event data to form part of your design roadmap
- Incorporating your clinical data to drive a robust product development before commercial release
- Lessons learned from this closed loop approach and how this can set you apart from other injectable devices

Thomas Altobelli
Senior Manager, Device Quality & Risk Management
Janssen Pharmaceuticals

10.10 **Quick Fire Debate: How Should You Address Regulatory Changes?**

Following the morning's presentations, the audience will have the opportunity to ask panellists their burning questions, debate and share their experiences, addressing key themes such as:

- How to handle adverse events reporting during post-market surveillance
- It's no longer a device – combination products as a whole
- What does EU-MDR mean to your launch plan in EMEA and beyond?
- The importance of your usability and functionality studies ahead of approval
- Post-approval changes – what the FDA expects from you

10.30 **Speed Networking**

11.10 Morning Coffee

Agility: From Formulation to Connectivity

11:40 **How Quality Can Help Drug and Device Teams to be Agile**

- How to become agile and flexible anticipating formulation changes before NDA/BLA filings
- Progresses from pre-filled into a different presentation format – the considerations and data you'll need to demonstrate to the regulatory agencies
- The role of quality and CMC during drug-device combination products evolution

Leonel Vanegas
Director, Global Quality Devices & Combination Products
Merck

12.10 **Quick Fire: How to Lay a Solid Foundation to Support a Robust Injectable Design**

This interactive panel debate will discuss what makes a combination product/injectable device successful. The audience will also have the opportunity to ask the panel experts their burning questions. Topics will include:

- Why early device design is critical to a product success and what to think about during commercialization
- When you should consider next generation development
- A competitive landscape analysis vs user case – it's a bottom-up approach

Chaired by:
Erik Jin
Engineering Fellow, Combination Products & Device
Celgene

12.40 Networking Lunch

13.40 **Panel Discussion: Human Factors Considerations for Connected Injection Devices**

The panel will discuss various topics related to Human Factors considerations for designing and evaluating connected injection devices, including:

- How to identify and mitigate against use-related risks associated with connectivity and associated software applications
- How to evaluate and validate connected injection devices within the user's ecosystem
- How to identify the best set of user interfaces for your connected injected devices (e.g., embedded, smartphone, tablet, desktop)
- How to account for device customization, the changing role of lay users, and implications for use-related risk

Chaired by:
Richard Featherstone
Research Director – Human Factors Research & Design
Emergo by UL

14.30 **Selecting a Digital Health Partner to Deliver Business Value with Connected Devices**

- The racing game into connectivity: Real commercial benefits of connected devices
- Who they should partner with?
- How to build a fully integrated connected ecosystem with your stakeholders and patients and risk considerations

Paul Upham
Head, Smart Devices
Roche/Genentech

15.00 **Expertise Talk: Device Development Using In-Silico Techniques within an FDA Framework**

Timothy Quigg
Senior Mechanical Engineer
Crux Product Design Ltd

15.30 Afternoon Coffee Break

16.00 **Device Design Consideration to Support Novel Formulations and Advanced Medicinal Therapy Products**

- The rise of highly viscous and high concentration products – challenges to delivery routes
- Can injectable device be a viable format?
- Engineering hurdles and breakthroughs
- Pain management for patients

Session Reserved for Program Partner

16.30 **Mastermind**

Connected device was the 2018 buzzword amongst drug and device developers. In 2019 we have seen a lot more initiatives and projects going live. It's clearly not just an add-on app, so what should we consider and what is the business case behind a connected device?

In this session we will split the audience into groups to develop a new connected device, with lifecycle management in mind:

- Your intended user and therapy designation
- Who are your stakeholders?
- Who should be involved – internally vs externally
- Regulatory landscape
- Risks and opportunities

17.00 **Chair's Closing Remarks & End of Day 1**

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

Senior Research Fellow, Ionis Pharmaceuticals

CONFERENCE DAY TWO THURSDAY, SEPTEMBER 26

The Art of Engineering

08.15 Morning Coffee

09.00 **Chair's Opening Remarks**

09.10 **Biogen's Journey in Primary Container Development to Support Injectable Device and Therapeutic Progresses**

- Therapeutic advancements with examples of monoclonal antibodies: why it matters to the device team
- The aspiration for a higher volume/ high viscosity delivery – primary container challenges
- From materials to sheer pressures, what device engineers should consider

Calvin Clark
Device Design & Development Engineer
Biogen

09.40 **Exploring Device Design Space with In-Silico Subcutaneous Injection Modeling**

- Developing a computational model to predict subcutaneous injection tissue behavior and device performance for challenging formulations
- The potential of such models in identifying key device parameters which impacts delivery prior to device component selection
- Learnings from these simulations can inform both device and formulation development

John Majewski
Device Development Engineer
Gilead Sciences

Joel Gresham
Senior Mechanical Engineer
Crux Product Design Ltd

10.10 **Primary Container Development and CCIT Development**

- Primary container material development to support next generation injectable drug products
- The transition into a 2ml container – what it means in practice
- Container closure integrity testing to ensure sterility at all times
- Validation testing and visual inspection

Session Reserved for Program Partner

10.40 Morning Coffee

11.10 **Commercialization of Your Combination Products – From Proof-of-Concept to Operations**

- Getting it right first time: excellent device design
- Tighten your control to avoid deviation: design control and risk management
- How to translate engineering success into commercialization
- Post-launch device operations and lifecycle management

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

Stuart Chisholm
Senior Manager, Global Devices R&D Operations
Teva Pharmaceuticals

11.50 **Panel Discussion: Enhancing Your Combination Products Usability and Functionality**

The success of your injectable device starts from initial design decisions through preparing submissions for regulatory bodies. While the last few years we have focused on the importance of human factors testing, we continue to see shortfalls and failing regulatory agencies' approvals, which subsequently results in delay in gaining approvals. Panellists will share their expert insights on:

- Discovering what users want and how your product can meet their needs to shape your design direction early on
- From the FDA to EMA – your product isn't limited to one country, nor should your study be
- From device design to packaging to user manual: visual development and UX testing

Chaired by:
Katie Hansbro
CEO
Design Science Consulting Inc.

CONFERENCE DAY TWO THURSDAY, SEPTEMBER 26

12.40 Networking Lunch

Translating Innovations into Real World Technologies – Novel Injector Development

13.40 **It's Time to Innovate – How Can Pharma Manage the Introduction of New Technologies Efficiently to Best Meet the Needs of Patients?**

- The rise of new technologies including cell & gene therapy and digital devices
- How pharma should manage such complexities and innovations, while ensuring quality and safety
- An end to end case study: Implementation of novel innovative drugs in auto-injectors maintaining safety and enhancing patient and user experience

Daniel Latham
Head of Device Development & LCM
Novartis

14.10 **The Bill & Melinda Gates Foundation's Efforts in Supporting Innovations in Injectable Development**

- Initiatives for developing drugs for the developing world
- Injectable delivery format and considerations – from device design to cost to supply chain challenges
- Collaboration with industry and grants to support further development
- Blue sky thinking – what are the potential opportunities in the injectable space?

Dennis Lee
Senior Program Officer, CMC
Bill & Melinda Gates Foundation

14.40 **Spotlight: PATH's Initiatives in Developing Next Generation Injectables – The Journey from Needle Free to Micro-Array Patches**

- PATH's overview and center of excellence in the UK to support injectable device and vaccine innovations
- Value proposition and cost modelling to compare with traditional PFS in vaccine delivery
- Clinical data to demonstrate efficacy and effectiveness of these novel 'devices'
- Engineering challenges and opportunities ahead

Darin Zehrung
Senior Program Director
PATH

15.10 **Chair's Closing Remarks & End of Conference**

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

Eli Lilly

"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

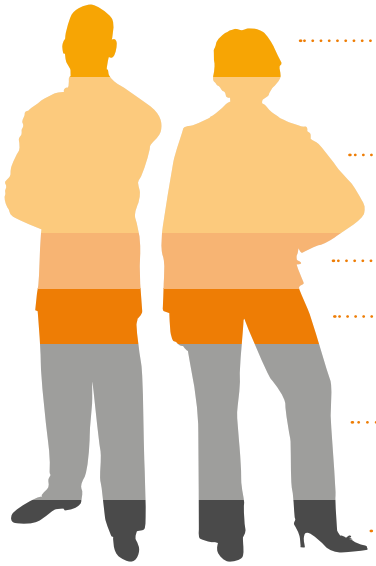
WHO WILL YOU MEET?

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 conference was excellent. Lots of really engaging topics and a very communicative crowd. It's great to share experiences across industry and I felt the conference was one of the most successful forums I have attended for awhile!"

Associate Director, Combination Products, Coherus Biosciences

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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 **9th Edition 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, particularly:

- ATMPs and novel formulation delivery
- Device material and constituents for smart platforming
- Advanced device testing and and validation solutions
- CMOs and device manufacturers for strategic platforming
- Digital and connectivity platforms

LET'S TALK

Sam Berrill, Partnerships Director
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Panel Partner

Founded in 1991, Design Science was one of the first consultancies to focus on the person/product interface for medical device design. We have deep roots in those product categories where usability is mission critical— particularly medical devices. We are retained by product-development teams to improve the usability, safety, and customer appeal of products. We creatively apply technical expertise from a variety of engineering, social-science, and design disciplines to support this mission.

www.dscience.com

Panel Partner

EMERGO by UL, formally known as UL-Wiklund, is a highly experienced human factors team that specializes in user research (including usability testing) and user interface design. Our consulting team has deep experience in the medical device and combination product domains. But it also serves several other industries, helping to ensure that consumer products, industrial products, software applications, and automotive products deliver a great user experience.

www.humanfactors.emergobyul.com

Exhibition Partner

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.

www.ima.it/automation

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CSS (Connecticut Spring & Stamping) is an advanced manufacturing company with more than 75 years of success. We engineer and manufacture precision metal springs, stampings, metal forms and assemblies, especially for the medical device industry. Our experience ranges from auto-injectors and wearable infusion devices, to instruments and sensors. We are ISO13485 certified. Leading OEMs and contract manufacturers partner with CSS for consistent volume production.

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Package Details	**Register by Friday May 31, 2019**	**Standard Rate**
Conference & 3 Workshops	$3596 (save $1100)	$4396 (save $300)
Conference & 2 Workshops	$3097 (save $1000)	$3897 (save $200)
Conference & 1 Workshop	$2598 (save $900)	$3398 (save $100)
Conference Only	$2099 (save $800)	$2899
Workshop Only	$599	

Solution Provider		
Package Details	**Register by Friday May 31, 2019**	**Standard Rate**
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Conference & 2 Workshops	$3497 (save $1000)	$4297 (save $200)
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For more information, please visit website here.

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