5TH ANNUAL PRE-FILLED SYRINGES SUMMIT

JUNE 23RD-25TH 2015

SAN DIEGO, CA

- **Customizing Drug Delivery**
- **Successful Regulatory Compliance**
- **Novel Injectable Technologies**

Experts including:

Chris Meuenzer
Drug Delivery Device Engineer
Roche

Suzette Roan
Associate Director, Regulatory Affairs, CMC, Combination Products
Biogen Idec

Scott Gibson
Director, Advanced Device Technology
Amgen

Yuhua Li
Co-Founder & VP R&D
Foresee Pharmaceuticals

Paolo Mangiagalli
Senior Director, Head PFS/Primary Container Platform
Sanofi

LEAD PARTNER

TERUMO

SPOTLIGHT PARTNERS

ORATECH

NIPRO

EXHIBITORS

SCHOTT

ALTHEA

VULCAN SPRING

www.prefilled-syringes.com

Tel: +1 212 537 5898 | **Email:** info@hansonwade.com

RESEARCHED & DEVELOPED BY:

hansonwade
love what you do

Welcome to the 5th Annual PFS Summit

Guarantee the success of your parenteral drug delivery device through clarity on regulatory guidelines. Identify novel technologies and overcoming syringe process challenges to create customized products.

The **5th Annual PFS Summit** is a **must attend event** for those focusing on the latest advances and enhancements in the development and manufacturing of pre-filled syringes and injectable devices.

There is a constant requirement for idea sharing and face to face collaboration to harmonize the PFS ecosystem and ensure future success. As innovation continues to flourish, the PFS Summit 2015 will focus on **efficacy, compliance & accuracy** in the customized design and development & manufacture of pre-filled syringes.

With a line-up of expert speakers you've never seen before, giving you **brand new perspectives**, the **PFS Summit** is your opportunity to go beyond incremental gains and significantly **move your development and manufacturing forward.**

2015 is the year for positive innovation to further stimulate PFS development and alignment throughout the industry. Leave the PFS Summit with the knowledge and connections you need to **accelerate your PFS products to market.**

10 REASONS YOU NEED TO ATTEND PFS SUMMIT 2015

1. **Compliance:** Ensure regulatory compliance by gaining clarity on compliance guidelines from the likes of **Eli Lilly & Biogen Idec**
2. **Innovation:** Discover the latest technology and material innovation set to impact the drug delivery industry through a panel discussion with **MedImmune & Eli Lilly**
3. **Building:** Ensure you have the right team and the right partners to set you up for success with insight from **Sanofi & Glenmark Pharmaceuticals**
4. **Materials:** Plastic or glass? The challenges with material selection given the nature of the drug as explored by **Terumo**
5. **Formulations:** Ensure drug stability within your drug delivery mechanism by assessing drug viscosity and material compatibility
6. **Engineering:** Design your device with the drug and patient in mind to ensure successful commercialization with top tips from **Amgen & Genentech**
7. **Customization:** Be part of this year's hottest conversation and discuss how to create a PFS that is bespoke and fit for purpose
8. **Optimization:** Streamline your process development and supply chain to ensure operational efficiency
9. **User Friendly:** Understand human factors requirements to maximize how your device is compliant and patient friendly
10. **Regulatory Compliance:** Gain insight from **Biogen Idec, Boehringer Ingelheim & Amgen** on regulatory CMC and design control considerations

SPEAKERS

Jean-Rene Authelin
Global Head, Pharmaceutical Engineering
SANOFI

Bill Beierschmitt
Research Fellow
Pfizer

Kerstin Walke
Head, Global Drug Delivery Biopharmaceuticals
Boehringer Ingelheim

Kevin Constable
Director, Technology Development
TERUMO

Diane Doughty
Scientist, Drug Delivery & Devices
MedImmune

Sachin Dubey
Head of Formulation Development
glenmark

Yasser Nasheed-Samuel
Principal Scientist, Process Development
AMGEN

Shem Fischer
Medical Manager, Contract Manufacturing
ORATECH

Scott Gibson
Director, Advanced Device Technology
AMGEN

Yuhua Li
Co-Founder & VP R&D
ForeSee CCC

Paolo Mangiagalli
Senior Director, Head PFS/ Primary Container Platform
SANOFI

Tiffany McIntire
Human Factors Engineer
Lilly

Wendy Shieu
Engineer
Genentech

Suzette Roan
Associate Director, Regulatory Affairs, CMC, Combination Products
biogen idec

Ella Cozmi
Director, Human Factors Engineering,
Hospira

Chris Muenzer
Drug Delivery Device Engineer
Roche

Stephen Barat
Executive Director, Toxicology, Preclinical Pharmacology and Bioanalytical Strategy
Actavis

Bruno Reuter
Director Technology
NIPRO

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

Pfizer

CONFERENCE DAY 1

Wednesday June 24th 2015

8.00 **Breakfast & Registration**

9.00 **Chairman's Opening Remarks**
Stephen Barat, Executive Director, Toxicology, Preclinical Pharmacology and Bioanalytical Strategy, **Actavis**

Building the Right Team

9.10 **PFS Building Blocks: What We Know and Needs to be Discovered**
- Industry known challenges on PFS
- How can we share learning?
- How can we collaborate to solve remaining issues?

Paolo Mangiagalli, Senior. Director, Head PFS/Primary Container Platform, **Sanofi**

9.40 **Challenges of Developing Pre-Filled Syringes for a Small/Mid-sized Organization**
- Overcoming technical and logistic difficulties
- Assessment criteria's
- Choosing right partners: Being competitive and attractive

Sachin Dubey, Head of Formulation Development, **Glenmark Pharmaceuticals**

10.10 **Morning Refreshments & Speed Networking**

Device & Syringe Materials

11.10 **The Value of Polymer Syringes and Needle Technology or Sensitive or Viscous Biologics**
- A systems design approach to an innovative combination device for a ready to fill polymer based syringe
- Advantages of polymer syringes including strength, sterilization techniques, silicone oil free technology for reduced aggregation, and manufacturing techniques for low sub-visible particulates
- The value of i-coating™ stoppers, a silicone oil free technology for reduced aggregation
- Needle technology including 27G thin wall and 29-24G tapered needle technology

Kevin Constable, Director, Technology Development, **Terumo**

11.40 **Syringe and Device Regulatory Requirements**
- Review process of drug delivery devices
- How a company can ensure they have all the appropriate scientific data
- Requirements of syringes materials pertaining to regulatory compliance
- How human factors plays a role in the submission

12.10 **Modern Syringe Manufacturing - Designed by Nipro Pharmapackaging**
- Laser Cutting – Reduction of Glass Particulate
- Forming – Process Control
- Automated inspection systems (Camera)
- Future X-Ray Inspection – needle piercing

Bruno Reuter, Director Technology, **Nipro Pharmapackaging**

12.40 **Lunch & Networking**

PFS & Device Innovation

14.10 **Your Turn-Key Custom PFS Partner**
- Concept/design/prototype
- Commercialization /scale up
- Production

Shem Fischer, Medical Manager, Contract Manufacturing, **Oratech**

14.20 **A Novel Class of Device Technologies: Wearable Bolus Injectors for Large Volume Subcutaneous Delivery**
- Rationale for large volume subcutaneous delivery
- Landscape of wearable bolus injectors
- Requirements of wearable bolus injectors

Diane Doughty, Scientist, Drug Delivery & Devices, **MedImmune**

14.50 **User-Centered Design: The Human Factors Perspective**
- A brief background of HF in medical devices, why HF is important
- Tips on how to prepare for formative to summative testing
- Best practices for reporting study findings

Tiffnay McIntire, Human Factors Engineer, **Eli Lilly**

15.20 **Panel: Ensuring Continued Innovation in the Field**
- How do we implement and generate creativity in the field?
- How do we ensure we understand the needs and wants of patients and healthcare providers?
- What are the challenges with producing bespoke products?
- What novel technologies are emerging in this space?

Tiffany McIntire, Human Factors Engineer, **Eli Lilly**
Diane Doughty, Scientist, Drug Delivery & Devices, **MedImmune**

15.50 **Afternoon Refreshments & Networking**

Roundtable Discussions

16.20 **Drive Your Own Learning, Crowdsource Ideas and Be Inspired!**
The PFS speaker faculty is second to none but there is just as much knowledge in the audience as there is onstage. Discover multiple perspectives on the key issues during roundtable discussions, specifically designed so you can learn from fellow PFS experts.

- **Testing Methods**
  - Determining the appropriate test methods
  - Developing new testing methods
- **Interpretation and Compliance of Standards**
  - How do you ensure success?
  - How can you ensure all partners and suppliers are compliant?
- **Emerging Markets Requirements**
  - Where is demand coming from?
  - How can you grow and supply these markets?
- **Plastic or Glass?**
  - Pros and cons of the two materials
  - Novel syringe materials and uses

Kevin Constable, Director, Technology Development, **Terumo**

17.25 **Chairman's Closing Remarks**
Stephen Barat, Executive Director, Toxicology, Preclinical Pharmacology and Bioanalytical Strategy, **Actavis**

17.30 **POSTER SESSION & NETWORKING RECEPTION**

HOSTED BY TERUMO

Interactive Session Networking Session

CONFERENCE DAY 2

Thursday June 25th 2015

8.00 **Breakfast & Registration**

9.00 **Chairman's Opening Remarks**
Bill Beierschmitt, Research Fellow, **Pfizer**

9.10 **Roundtable Industry Intelligence**
Missed a roundtable you wished you were at? Couldn't write down all the high level discussion? Fear not as our PFS moderators present back the most valuable discussion points. You won't miss a thing!
Kevin Constable, Director, Technology Development, **Terumo**

Formulations & Device Engineering: The Impacts on PFS

9.40 **Challenges in the Development of Sustained Release Formulation in Pre-filled Syringes**
- Discussing and ensuring the compatibility of the formulation and syringe
- Assessing formulation viscosity and overcoming the challenges involved
- Terminal sterilization considerations

Yuhua Li, Co-Founder & VP R&D, **Foresee Pharmaceuticals**

10.10 **Modeling of Autoinjectors**
- The physics involved with integrating a PFS into an Autoinjector
- Modeling of the Autoinjector, IJT distribution
- Estimating and assessing variability
- Impact of autoinjector usage on the design methodology

Jean-Rene Authelin, Global Head, Pharmaceutical Engineering, **Sanofi**

10.40 **Morning Refreshments & Networking**

11.10 **An Integrated Approach to Container and Device Development**
- Suitability of your PFS to an injection device
- Understanding dimensional fidelity concerns
- Stress factors and engineering challenges

Scott Gibson, Director, Advanced Device Technology, **Amgen**

11.40 **Panel: Formulation and Engineering Processes – What Each Team Needs to Know**
- How do we design a device with the drug product in mind?
- What are the engineering concerns with developing a combination product
- How do you ensure you account for the drug product chemistry?
- How do we assess drug viscosity and enable usage of PFS in drugs with high viscosities?
- What are the concerns of the formulations team when putting their drug into a PFS?
- How do we guarantee drug and device stability at all stages of development, storage and supply?

Scott Gibson, Director, Advanced Device Technology, **Amgen**
Wendy Shieu, Engineer, **Genentech**
Jean-Rene Authelin, Global Head, Pharmaceutical Engineering, **Sanofi**
Sachin Dubey, Head of Formulation Development, **Glenmark Pharmaceuticals**

12.40 **Lunch & Networking**

13.40 **The Process of Drug Delivery Device Design**
- Transforming user needs into devices
- Differences between medical devices and drug delivery devices
- How device companies can work with Pharma

Chris Muenzer, Drug Delivery Device Engineer, **Roche**

Fill/Finish, Sterility & Your Supply Chain

14.10 **Filling of High Concentration Monoclonal Antibody Formulations: Challenges in Nozzle Clogging and Filling Accuracy**
- Investigate key parameters affecting nozzle clogging
- Evaluate approaches in mitigating formulation drying and nozzle clogging
- Understand the underlying mechanism governing filling precision of low-volume fill of high-viscosity formulations

Wendy Shieu, Engineer, **Genentech**

Regulatory Affairs & Ensuring Compliance

14.40 **Title to be Confirmed**
Kerstin Walke, Head, Global Drug Delivery Biopharmaceuticals, **Boehringer Ingelheim**

15.10 **Regulatory CMC and Design Control Considerations for Pre-filled Syringes – Industry Perspective**
- Aligning your product with global regulatory guidelines
- Design control and risk management approaches for
- PFS Suggestions for submission content
- Strategies to facilitate regulatory approval

Suzette Roan, Associate Director, Regulatory Affairs, CMC, Combination Products, **Biogen Idec**

15.40 **Afternoon Refreshments & Networking**

16.10 **Pre-filled Syringe Extractables/Leachables and Impact on Parenterals**
- Prefilled syringes have Extractables/Leachables from many sources (tools, stopper, adhesive, etc.)
- Leachables can impact biologic drug productsProper supplier controls and formulation design mitigates potential
- Leachable impact to product resulting in robust safe systems

Yasser Nashed-Samuel, Principal Scientist, Process Development, **Amgen**

16.40 **PQRI – A Review of the Initiative and Current Status**
- Toxicological assessments
- Chemistry considerations
- Alignment of Quality by Design

Bill Beierschmitt, Research Fellow, **Pfizer**

17.10 **Chairman's Closing Remarks**
Bill Beierschmitt, Research Fellow, **Pfizer**

17.15 **Close of Congress**

Interactive Session **Networking Session**

WORKSHOP A

From Drug to Device: Creating an Autoinjector

Date: Tuesday June 23rd 2015 | Time: 9.00am – 12.00pm

Autoinjectors are taking drug delivery beyond just PFS. The market is experiencing healthy and consistent demand, resulting in an expansion of competition and multiplying device product lines.

Autoinjectors are fast becoming the future of parenteral drug delivery. With this several challenges are emerging, how can you ensure you are ahead of the game and overcoming these challenges?

This workshop allows you to learn all you need to know about AI, you will discuss:

- Integrating a PFS into an AI successfully and what this looks like in practice
- The device design and what factors to consider
- Assessing the right syringe materials to use and understanding the challenges and opportunities of plastic syringes
- How to ensure you are compliant to regulations but also fit for the patients use with human factors compliance
- How to create customer centric bespoke devices that are fit for purpose

Guarantee you have the knowledge to bring your drug delivery system into the future by attending this workshop.

Workshop leader

Jean-Rene Authelin
Global Head, Pharmaceutical Engineering
Sanofi

Jean-Rene coordinates the scientific activity of the Process Unit Engineering related to drug products including: Roller compaction, fluid bed drying and granulation, freeze drying, dissolution, emulsification, and PATs. He also has specific physical chemistry expertise in drug degradation kinetics & mechanisms, solubility and polymorphism.

WORKSHOP B

Harmonize Regulatory Approval: FDA and Human Factors

Date: Tuesday June 23rd 2015 | Time: 1.00pm – 4.00pm

In a rapidly advancing industry the regulatory bodies are constantly adapting and changing their guidelines, so how do you keep up to date?

This workshop allows you to discuss with the experts what you need and how you can get approval:

- Get a 360° view of the regulatory landscape and what you need to know about each aspect
- Submission requirements of PFS products as combination products
- Understand human factors and the necessity of ensuring your PFS is fit for patient use
- Discuss what you need for successful approval in emerging markets and how these regulations differ
- Ensure you have a how to guide on what you need to ensure regulatory approval

Learn from case studies to gain hands on experience as to how you can ensure your product gets approved.

Suzette Roan
Associate Director, Regulatory Affairs, CMC, Combination Products
Biogen Idec

Ella Cozmi
Director of Human Factors Engineering
Hospira

PFS SUMMIT 2015 PARTNERS

LEAD PARTNER

Terumo www.terumomedical.com

Founded in 1921, Terumo is a global research, development and manufacturing company. Our PLAJEX™ Ready-to-Fill Plastic Syringes have specific features that address several current issues with protein/peptide biopharmaceuticals, such as aggregation, and (sub-) visible particles.

Among these features, PLAJEX™ syringes are steam sterilized and utilize proprietary i-coating™ technology, to provide a silicone oil-free platform for applications requiring low reactive containers.

In addition to unique technology, Terumo produces plastic prefilled syringes through a fully integrated production model; capabilities include terminal sterilization and aseptic filling for biotherapeutics.

SPOTLIGHT PARTNER

NIPRO www.niproglass.com/en

NIPRO brand medical devices and glass products are used on a global scale.

Our product portfolio contains product for dialysis, transfusion, diagnostics, interventional, cardiopulmonary, pharmaceutical, and glass, which lead the world market. The NIPRO brand is highly regarded worldwide for its technological superiority and high quality. In the pharmaceutical business, we have experienced steady growth by providing various products, including pharmaceutical kit products, which accurately respond to the needs of healthcare professionals. In the business of contract manufacturing generic medicines to meet the increased demand anticipated with the amendment of the Pharmaceutical Affairs Law, we will provide safer and easier-to-use products, making best use of our broad expertise and innovative technologies.

SPOTLIGHT PARTNER

OraTech www.oratech.com

OraTech is a private contract manufacturer that develops custom products and delivers market-ready products to meet precise specifications.

OraTech's SMARTER TO MARKET turnkey services include:

- Contract Manufacturing Contract Packaging
- Formulation Testing
- Prototyping Printing
- Final production Consulting

OraTech has become the smart resource for numerous companies, in numerous industries, including several of world's largest professional and consumer healthcare companies. Many of our manufactured products are currently found in big box stores nation wide.

EXHIBITOR

Vulcan Spring www.vulcanspring.com

Founded in 1967, Vulcan Spring is a leading design and manufacturing company of constant and variable force springs. We specialize in partnerships with hi-tech manufacturers that require the utmost quality and reliability.

Vulcan is sponsoring the PFS Summit to spread the word about the advantages of constant force spring technology. Several partners in the industry already see the benefits over the more traditional round wire compression spring.

Our customers point to the following advantages:

- Smoother drug delivery
- Less priming force required
- No force degradation in loaded position
- Enough force at the end of range to deliver highly viscous drugs and biologics

EXHIBITOR

Althea www.altheacmo.com

Althea is a fully integrated, contract development and manufacturing organization providing clinical and commercial product development services. Althea offers cGMP drug product filling in both vials and syringes, and production of microbial-derived recombinant proteins and plasmid DNA. In conjunction with these manufacturing operations, Althea offers comprehensive development services including: upstream and downstream process development, analytical development, lyophilization cycle, complex formulation, product release and ICH-compliant stability testing. Althea is a leading expert in executing drug formulation and aseptic fill finish. We pride ourselves on being the manufacturing partner that delivers the relentless dedication and support our clients need.

EXHIBITOR

SCHOTT www.schott.com/pharmaceutical_sytems

SCHOTT Pharmaceutical Systems is one of the world's leading suppliers of primary packaging and specialized analytical lab services for the pharmaceutical industry. We provide our customers quality solutions while meeting their highest demands with our expertise and broad product portfolio; including ampoules, cartridges, vials and syringes made of glass and COC polymer. Our state-of-the-art production facilities and our products comply with the highest international quality standards for pharmaceutical needs.

VENUE

DoubleTree by Hilton
San Diego Downtown
1646 Front Street
San Diego, CA
92101

Overnight accommodation is not included in the registration fee, however accommodation options will be sent out with your confirmation email upon registering.

www.doubletree3.hilton.com

PRICES AND DISCOUNTS

PACKAGE PRICES	Standard Price
GOLD PACKAGE Conference + 2 Workshops	$3797 **(save $200)**
SILVER PACKAGE Conference + 1 Workshop	$3198 **(save $100)**
BRONZE PACKAGE Conference Only	$2599
Workshop Only	$699

TEAM DISCOUNTS*

3+ Delegates: 10% Discount
4+ Delegates: 15% Discount
5+ Delegates: 20% Discount

*Please note: Team discounts are only valid when three or more delegates from one company book and pay at the same time. 'Early Bird' discounts require payment at the time of registration (or prior to the cut-off date) to secure the applicable discount. All advertised discounts cannot be combined with any other offer.

TOP BENEFITS:

- Identify and secure a reliable supplier network to **ensure reliable customization** of your drug product
- Discover the very **latest innovation, technology & solutions** to help you produce bespoke PFS products
- Correctly interpret and **benchmark regulatory compliance** understanding with your peers to avoid future regulatory pitfalls

HOW TO REGISTER:

There are 3 simple ways to register:

1. Register your place quickly and easily online at **www.prefilled-syringes.com/take-part**
2. Contact us by email at **register@hansonwade.com** and we will get back to you within one working day
3. Secure your place over the phone: **+121 537 5898**

Code: 5159