4th Annual

PFS

Pre-Filled Syringes Summit

Device and Combination Product Innovation
Ensure Regulatory Compliance
Optimize Supply Chain Control

2nd-4th September 2014, **Washington DC**

"Very broad overview of PFS industry trend and update. Very useful and valuable information."

Novartis

"The conference was very informative of current trends and challenges and led to much to think about in syringe/device development."

Genentech

"A very deep dive into pre-filled syringes, including toxicology, siliconization, regulations and engineering aspects."

Baxter Healthcare

www.prefilled-syringes.com

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RESEARCHED & DEVELOPED BY:

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WELCOME FROM THE CHAIRMAN

Dear Colleagues,

I would like to extend a warm welcome to all those involved in the development of injectable drug products who are returning to the 4th Annual Pre-Filled Syringes Summit - and also a special welcome to all those who are newcomers to this growing community.

The PFS Summit is a leading forum where you can share knowledge and expertise with your peers to find solutions to specific challenges facing the the industry. Attend and you will gain clarity on regulatory guidelines, identify innovative PFS design features and optimize your fill/finish process.

PFS 2014 provides you with an opportunity to learn from and network with the most senior industry experts from pharma, biotech, CMOs and PFS manufacturers, in an open and focused setting rarely experienced by the field.

Attend this year's meeting and learn how to:

- Develop and register **commercially successful injectable drug products**
- Assess the optimal materials to ensure you have the **desired pre-filled syringe product**
- **Safeguard your drug products** through leachables and extractables analysis and safety evaluations
- Meet regulatory expectations of the combination products rule to **secure regulatory approval**
- Examine human factors studies and the development of pre-filled syringe drug products to **ensure your device is patient/user friendly**
- **Achieve operational efficiency** through discussions on manufacturing considerations including filling optimization and sterilization

Please join me and a whole host of experts to learn about all the most current practices and trends in this exciting area of drug delivery.

Sincerely,

Stephen Barat
Executive Director, Scientific Affairs, Pharmacology and Toxicology
Forest Laboratories

HEAR WHAT PREVIOUS PFS ATTENDEES HAVE TO SAY:

"Broad and comprehensive view into PFS from development through commercial manufacture."

Sanofi

"Balance of in depth research work and broad view of industry updates. The networking opportunity was great. The discussions were very fruitful."

Merck

"A good opportunity to network and gather valuable info about PFS."

GlaxoSmithKline

WHAT MAKES PFS 2014 SPECIAL?

Motivated People:

The people who come together at the PFS Summit care deeply about moving their companies and industry forward. The summit is always focused on commercial challenges and the PFS community welcomes those people that have the motivation and desire to drive change within their businesses.

Timely Topics:

The topics on the PFS agenda are thoroughly researched with industry experts such as you, to address current challenges and future opportunities that you face in your role. The PFS community then comes together to give you access to practically applicable solutions from the forward thinkers in PFS development and manufacturing.

Peer to Peer Communication:

Niche and focused formats give you ample opportunity to interact and share knowledge to develop and implement solutions you need to meet your objectives. At PFS 2014, you will engage with your peers who deeply understand how to overcome the specific challenges facing the development of injectable drug products.

SPEAKER FACULTY

Douglas Ball
Research Fellow, Regulatory Strategy & Compliance, DSRD
Pfizer

Stephen Barat
Executive Director, Scientific Affairs, Pharmacology and Toxicology,
Forest Laboratories

Jared Bee
Senior Scientist, Biophysics
MedImmune

> "Great gathering of experts in the industry - beneficial to understanding of widespread issues."
>
> **Roche**

Tage Carlson
Director, Medical Products Research and Development
Baxter

Edwin Chan
Site Manager, External Manufacturing Collaboration
Genentech

Ella Cozmi
Director, Human Factors, Engineering
Hospira

Jason Fernandez
Scientist, Protein Pharmaceutical Development
Biogen Idec

David Grote
Site Quality Head cGMP
Teva Pharmaceuticals

Mike Hrytsak
Manager, Device Development
Regeneron Pharmaceuticals

Catherine Kang
Senior Associate, Global Regulatory Affairs
Hospira

Nan Yung Lin
Consultant Engineer
Eli Lilly

Daniel Norwood
Research Fellow
Boehringer Ingelheim

Swaroopa Paratkar
Research Investigator
Bristol-Myers Squibb

Gretchen Vandal
Senior Manager, Regulatory-CMC, Combination Products
Biogen Idec

Russell Watt
Senior Research Associate, Pharmaceutical Development
Isis Pharmaceuticals

John Zowtiak
Director, Device Development
Johnson & Johnson

LinkedIn™

Join the community at
Pre-filled Syringes for Drug Developers Forum

CONFERENCE DAY 1 - Tuesday 2nd September 2014

8.00 **Breakfast & Registration**

9.00 **Chair's Opening Remarks**
Stephen Barat, Executive Director, Scientific Affairs, Pharmacology and Toxicology, **Forest Laboratories**

Toxicological Profiles of Pre-Filled Syringes

9.15 **Non-Clinical Considerations for Parenteral Drug Development and Registration**
- Guidance driving the design of a nonclinical program
- Toxicologic considerations for parenteral development
- Formulation Considerations

Tage Carlson, Director, Medical Products Research and Development, **Baxter**

9.45 **Safety Qualification of the Container Closure System Based for a Pre-Filled Syringe Based on Proposals Developed by the Product Quality Research Institute**
- Summarize PQRI proposed classification scheme & progress made on validation of proposed classification scheme
- Provide a PFS case study focusing on E&L qualification using the proposed PQRI classification scheme
- ·Demonstrate the utility of the ELSIE database in rapid assessment of the PFS E&L profile

Doug Ball, Research Fellow, Regulatory Strategy & Compliance, DSRD, **Pfizer**

10.15 **Leachable Evaluation and USP Guidance**
- Sources of leachables
- Risk assessments of the leachable profile
- USP Guidance

Daniel Norwood, Research Fellow, **Boehringer Ingelheim**

10.45 **Morning Refreshments & Speed Networking**

Identifying the Best Syringe Material for Your Drug

11.45 **Unleashing the Power of Plastic**
- Design possibilities for PFS
- Comparison of glass and plastic features
- Exploring potential design features for an autoinjector

John Zowtiak, Director, Device Development, **Johnson & Johnson**

12.15 **Stability of Biopharmaceuticals in Plastic Pre-Filled Syringes in Comparison with Glass Pre-Filled Syringes**
- Stability of biologic drug products in plastic in comparison with glass PFS
- Stability of biologic drug products in plastic PFS in response to mechanical stress
- Functionality of plastic PFS in comparison with glass PFS

Swaroopa Paratkar, Research Investigator, **Bristol-Myers Squibb**

12.45 **Interactive Solution Finding: Your Chance to Assess Which Material is Right for your Drug Product**
- What factors of the drug product influence selection of material?
- How can you look to convert from one material to the other?

Discussion Leaders:

Swaroopa Paratkar, Research Investigator, **Bristol-Myers Squibb**
John Zowtiak, Director, Device Development, **Johnson & Johnson**

1.15 **Networking Lunch**

Biological Drugs in PFS

2.15 **Assessing the Syringeability of Antisense Oligonucleotide Solutions**
- Study of viscosity vs. injection force
- Human volunteer testing
- Implications for appropriate dosing materials

Russell Watt, Senior Research Associate, Pharmaceutical Development, **Isis Pharmaceuticals**

2.45 **Special Considerations for Biologic Products in Pre-Filled Syringes**
- Stability concerns from environmental changes
- Ensuring Microbial Control through the product lifecycle
- Understanding the impact of silicone and trace materials on product

David Grote, Site Quality Head cGMP, **Teva Pharmaceuticals**

3.15 **Characterization of the Impact of Aging on the Silicone Layer of Empty PFS for Biologics**
- Impact of empty storage on the levels and distribution of silicone oil
- Assessment of impacts on initial functionality

Jared Bee, Senior Scientist, Biophysics, **MedImmune**

3.45 **Afternoon Refreshments**

Injectable Device Development

4.15 **Minimizing Variability When Developing Syringes and Devices**
- Variability in autoinjectors and syringes
- Product consistency and siliconization
- Meeting regulatory expectations

Mike Hrytsak, Manager, Device Development, **Regeneron Pharmaceuticals**

4.45 **Chair's Closing Remarks**
Stephen Barat, Executive Director, Scientific Affairs, Pharmacology and Toxicology, **Forest Laboratories**

5.00 **Close of Day 1**

Keynote Session | Interactive Session | Networking Session

CONFERENCE DAY 2 - Wednesday 3rd September 2014

8.00 **Breakfast**

9.00 **Chair's Opening Remarks**
Stephen Barat, Executive Director, Scientific Affairs, Pharmacology and Toxicology, **Forest Laboratories**

Regulatory Guidance for Successful Drug Approval

9.10 **A Common Sense Approach to the Combination Products Final Rule**
- PFS under design controls
- Merging medical device data into regulatory filings
- Aligning products with guidelines

Catherine Kang, Senior Associate, Global Regulatory Affairs, **Hospira**

9.40 **The Pre-Filled Syringe as a Combination Product: Design Control Considerations**
Gretchen Vandal, Senior Manager, Regulatory-CMC, Combination Products, **Biogen Idec**

10.10 **Utilizing Human Factors Studies to Ensure Approval of PFS**
- Reviewing recent trends with FDA requests for human factors studies
- Disputing the need for human factors and usability testing
- Developing studies that positively influence clearance & approval decisions

Ella Cozmi, Director, Human Factors, Engineering, **Hospira**

10.40 **Morning Refreshments**

10.10 **Roundtable Industry Discussions**
The PFS speaker faculty is second to none but there is just as much knowledge in the audience as there is onstage. Tap into this wealth of expertise and discover multiple perspectives on the key issues during Roundtable Industry Discussions, specifically designed so you can learn from fellow PFS development and manufacturing experts.

- **Product life cycle management**
  - What are the early considerations that need to be made for manufacturing a PFS?
  - What are the overall development considerations for a PFS?
- **Siliconization**
  - What are the alternatives to silicone oil in PFS?
  - What are the effects of silicone oil on drug stability and leachable and extractable profiles?
- **Design Controls**
  - What are the alternatives to silicone oil in PFS?
  - What are the effects of silicone oil on drug stability and leachable and extractable profiles?
- **Device integration**
  - What design considerations need to be made to integrate your PFS into a device?
  - What novel device technologies are available?
- **Regulatory Guidelines**
  - What regulations can you expect to need to comply with for your PFS product?
  - How do you ensure your suppliers and manufacturers are complying with regulations?

Roundtable Moderators:
Ella Cozmi, Director, Human Factors, Engineering, **Hospira**
Swaroopa Paratkar, Research Investigator, **Bristol-Myers Squibb**

12.40 **Networking Lunch**

Supply Chain Considerations

1.40 **High Viscosity Protein Fill/Finish Process Development and Scale Up**
- Effect of high viscosity products on the fill/finish process
- Use of pilot scale development
- Commercial scale syringe filling equipment

Nan Yung Lin, Consultant Engineer, **Eli Lilly**

2.10 **A Closer Look at Filling Optimization**
- Challenges of filling high concentration proteins
- Understanding the characterization of filling profiles
- Evaluation of fill accuracy and repeatability with different pump systems

Edwin Chan, Site Manager, External Manufacturing Collaboration, **Genentech**

2.40 **Interactive Solution Finding: Your Chance to Learn How to Ensure Operational Efficiency Within your Supply Chain**
- How can you ensure filling accuracy and reliability every time?
- What are the different considerations that need to be made when filling biological drugs?

Discussion Leaders:
Nan Yung Lin, Consultant Engineer, **Eli Lilly**
Edwin Chan, Site Manager, External Manufacturing Collaboration, **Genentech**

3.10 **Afternoon Refreshments**

3.40 **Feasibility Assessments of Novel Advancements in Pre-Fillable Syringes**
- Novel technologies
- Opportunity for development
- Platform for evaluating advancements

Jason Fernandez, Scientist, Protein Pharmaceutical Development, **Biogen Idec**

4.10 **PFS Roundtable 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!

4.40 **Chair's Closing Remarks**
Stephen Barat, Executive Director, Scientific Affairs, Pharmacology and Toxicology, **Forest Laboratories**

4.50 **Close of Congress**

Keynote Session **Interactive Session** **Networking Session**

CONFERENCE WORKSHOPS

OPPORTUNITIES AND CHALLENGES OF DEVICE DEVELOPMENT

Thursday 4th September 2014, 9.00am - 12.00pm

Plastic syringes have the advantages of being cheaper, have less oxygen permeability and fragility is not an issue. Therefore, plastic as a syringe material has grown in popularity with developers and manufacturers over the years. However, is there more we could be doing with the design features of a plastic syringe or even device?

This workshops will provide insight into plastic PFS and device development, attend to discuss:

- The design possibilities of plastic syringes molding
- How novel plastic PFS features could impact device design
- Ensuring the stability of biologic drug products in plastic PFS
- What material and component considerations do you need to apply to make your PFS a reality?

Join the PFS community at this workshop to discuss and debate novel and innovative possibilities for the future of Pre-Filled Syringe Development.

John Zowtiak

Director, Device Development
Johnson & Johnson

ABOUT YOUR WORKSHOP LEADER:

John has extensive expertise in development & commercialization of drug delivery systems for pharmaceuticals. He is currently with Johnson & Johnson where he is the Director for Device Development.

COMPLYING WITH REGULATIONS: HUMAN FACTORS PROCESS

Thursday 4th September 2014, 1pm - 4pm

The pressure from the FDA to conduct extra HF activities for combination products is becoming ever more important. However, with new updates and considerations all the time this has resulted in much confusion and uncertainty on how conduct these activities successfully.

This workshop will provide a guided tour on how to utilize human factors tools and ensure regulatory approval.

Attend this workshop to get to grips with:

- Human factors process and how you can prepare to meet regulatory expectations
- How you can use human factors process to identify device performance improvements
- How usability assessments can be used to positively influence regulatory approval

Have all your questions answered and leave this workshop with real life, hands on, practical experience to take back to the office on how to gain regulatory approval for your product every time.

Ella Cozmi

Director, Human Factors, Engineering
Hospira

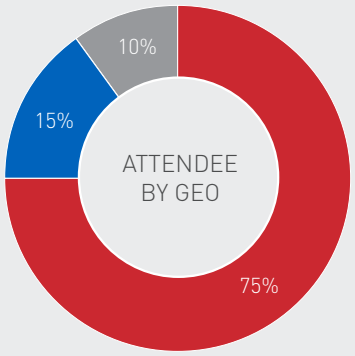
ABOUT YOUR WORKSHOP LEADER:

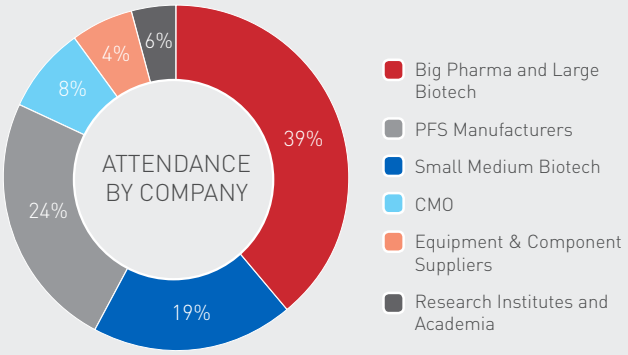
Ella Cozmi is the Director of Human Factors Engineering at Hospira, Inc. She is a seasoned medical device developer with a background in nursing, physics and engineering. Ms. Cozmi oversees the Human Factors program at Hospira, managing the specialty files for products ranging from prefilled syringes to infusion pumps. Prior to her current position, she served as Manager, Medical Device Development at Hospira, as well as held positions of increasing responsibility at Abbot Laboratories. Ms. Cozmi also serves on the Human Factors Committee at AAMI and occasionally contributes to the IEC Working Group 4 maintaining the IEC 62366:2007 Medical Devices- Application of Usability Engineering to Medical Devices. Ms. Cozmi is the author of several peer reviewed journal articles and regularly speaks at domestic and international conferences on the subject of Human Factors.

> "A unique mix of disciplines with a common interest."
>
> MedImmune

> "Great mix of theory and practice."
>
> Pacira

ATTENDEE BREAKDOWN





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DEPARTMENTS

Device Development
Drug Packaging
CMC
Research and Development
Device Manufacturing
Regulatory Affairs
Drug Delivery
Engineering
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JOIN THE PFS COMMUNITY

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VENUE

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USA

http://doubletree3.hilton.com/en/

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

PRICES AND DISCOUNTS

PACKAGE PRICES	Standard Prices
GOLD PACKAGE 2 day conference + 2 workshops	$3697 **(save $200)**
SILVER PACKAGE 2 day conference + 1 workshops	$3098 **(save $100)**
BRONZE PACKAGE 2 day conference only	$2499
Workshop (each)	$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.

REGISTRATION CHECKLIST

1. Have you checked if anyone else from your business is attending? If 3 or more of you register together, you will all benefit from reduced rates. ✔
2. Could you register your place early to take advantage of early booking rates? ✔
3. Have you carefully evaluated which package will best help you achieve your goals? ✔

When you've made your selections SECURE YOUR PLACE*

You can register your place quickly and easily online. Visit:

www.prefilled-syringes.com/register

Contact us:

If you require any further information on the event, or would like us to assist you in making your booking, please contact Hanson Wade via the contact details below.

TERMS & CONDITIONS

Full payment is due on registration. Cancellation and Substitution Policy: Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the four-teenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

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