Biopharmaceutical Production Series

Informa Life Sciences' Inaugural

With pre-filled syringe technology revenues expected to reach $3.9bn in 2015, make sure you are aware of the quality and analytical standards needed to keep your product on the market

Pre-Filled Syringes & Injector Devices for Biologicals

Europe's leading industry event for developing cutting-edge device designs, establishing robust quality systems and enhancing biological product performance

Wednesday 5 – Thursday 6 December 2012
Radisson Blu Hotel, Berlin, Germany

SMEs and Academia can attend for less than £900

Keynote Presentations for 2012

Dr Donna French, *Senior Director, Device Development,* Genentech, USA

Dr Mathew Cherian, *Director, Pharmaceutical Development,* Hospira, USA

Dr Parag Kolhe, *Group Leader-Senior Principal Scientist,* Pfizer Inc, USA

Leading Industry Case Studies

Dr Ignace Wallaert, *Principal Scientist, Packaging Development,* Janssen Pharmaceutica, Belgium

Dr David Fela, *Associate Director, Analytical Development,* NPS Pharma, USA

Dr Jonas Fransson, *Director,* Swedish Orphan Biovitrium, Sweden

Dr Jim Janimak, *Head of Devices - NPI Secondary,* GlaxoSmithKline Vaccines, Belgium

Dr Angel Z. Velez, *Senior Engineer, Process Development,* Amgen Manufacturing, USA

Dr Paul Seminara, *Consultant, Medical Device Development,* Roche, Switzerland

Dr Li Shi, *CEO,* Shanghai Zerun Biotechnology Co. Ltd., China

Dr Esohe Idusogie, *Associate Director, Analytical, Process Development,* OncoMed Pharmaceuticals, USA

Dr Andrew Feilden, *Principal Consultant,* Smithers Rapra, UK

Dr Hoss Dowlat, *Vice President, Regulatory Affairs Worldwide,* PharmaBio Consulting, Germany

Dr Mike Regan, *Consultant, Quality Assurance and Validation,* Altran AG, UK

Essential Reasons to Join Europe's Leading Industry-Led Conference on Developing Cutting-Edge Parenteral Devices

- ✔ **Benchmark** your delivery device platform against leading industry players including **Genentech, Pfizer, Amgen, BMS, Roche, GSK Vaccines** and more
- ✔ Quiz the experts with **3 interactive discussion panels** on future delivery device trends, glass v.s plastic syringes and successful fill and finish strategies
- ✔ **Optimise product performance by understanding** the latest injector devices and syringe technologies with your drug
- ✔ **Accelerate development** by fully understanding material selection and its affect on product quality
- ✔ **Ensure product stability** by effectively detecting sub-visible particulates and extractables and leachables
- ✔ **Discover the most effective device development approaches** with practical case studies on lifecycle management and QbD

Maximise your Time out of the Office with these Interactive & Practical Training Sessions

Pre-Conference Workshop W: Tuesday 4 December 2012

Practical Investigations of Drug Change during Development: Early Stages Through to Commercialisation

Leaders: **Dr Parag Kolhe,** Pfizer, USA &
Dr Hoss Dowlat, PharmaBio Consulting, Germany

Practical advice for best monitoring your product through full lifecycle

Evening Seminar X: Wednesday 5 December 2012

Minimising the Effects of Extractables & Leachables in Pre-Filled Syringes

Leader: **Dr Andrew Feilden,** Smithers Rapra, UK

Essential understanding of detecting, monitoring and avoiding E&Ls

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PRE-CONFERENCE WORKSHOP W: Tuesday 4 December 2012 **W**

Practical Investigations of Drug Change during Development: Early Stages Through to Commercialisation

Registration 08.30 – Start 09.00 – End 15.30 – Workshop material, refreshments and lunch will be provided

Fully understanding how your product changes throughout development is essential to ensure product quality, efficacy and safety. When your product meets the delivery device, a variety of alterations can occur, and it is vital for product approval to monitor, understand and avoid these changes. This interactive workshop discusses real life examples of what to consider, how to assess and how to avoid to ensure a marketable product.

- How does the drug changes when in a vial
- Common causes
- Fitting pre-filled syringes/containers/delivery devices into a QbD strategy
- Methods for monitoring product changes: NMR, spectra
- Important and non-important attributes to focus on
- Variables that need to be considered to maintain product quality

Hear real-life applications on correctly assessing product quality throughout development

Workshop leaders:
Dr Parag Kolhe, *Group Leader-Senior Principal Scientist,* **Pfizer,** USA
Dr Hoss Dowlat, *Vice President, Regulatory Affairs Worldwide* **PharmaBio Consulting (Life Sciences),** Germany

DAY ONE: WEDNESDAY 5 DECEMBER 2012

08.00 Registration

08.55 Chairperson's Opening Remark

The Future of Injectable Devices for Biologicals

09.00 **KEYNOTE PRESENTATION ON THE CURRENT PRE-FILLED SYRINGE MARKET**
Key market, regulatory and technical trends in combination products for biopharmaceuticals
This presentation will discuss the market trends in combination products, delving into the current industry challenges including meeting human factors and clinical testing requirements and current and future technology trends for injectables.
Dr Donna French, *Senior Director, Device Development,* **Genentech,** USA

Recent Developments in Pre-Filled Syringe Design

09.40 **The latest pre-filled syringe designs for improve robustness and usability**
To find out more about this presentation, please visit the conference website at **www.informa-ls.com/prefilled**
Dr Jonas Fransson, *Director,* **Swedish Orphan Biovitrium,** Sweden

10.20 Morning Coffee and Poster/Exhibition Viewing

10.50 **FEATURED PRESENTATION ON CHOOSING YOUR DELIVERY PLATFORM**
Considerations for marrying product with device
It is essential to understand the key considerations and parameters outlined for choosing what delivery device to use for your biological product. How to choose your delivery platform and what the dimensions and considerations for tolerance are will be explored.
Dr Li Shi, *CEO,* **Shanghai Zerun Biotechnology Co. Ltd.,** China

11.30 **Packaging approaches for novel parenteral products and devices**
The latest updates on packaging, delivery and device applications for the biological products being developed at Janssen Pharmaceutica will be outlined, with a specific focus on the novel design approaches being used, regarding pre-filled syringes and other devices.
Dr Ignace Wallaert, *Principal Scientist, Packaging Development,* **Janssen Pharmaceutica,** Belgium

INTERACTIVE DISCUSSION PANEL

12.10 **DISCUSSION PANEL**
Future design efforts for parenteral drug delivery
- Future applications for single-use and multi-use pre-filled syringes
- Autoinjector devices: quality concerns and safety patient considerations
- Industry applications of safety devices: what is currently available?
- Human factors in device design

Contributions from:
Dr Donna French, *Senior Director, Device Development,* **Genentech,** USA
Dr Hoss Dowlat, *Vice President, Regulatory Affairs Worldwide,* **PharmaBio Consulting,** Germany
Plus other speakers of the day

12.30 **SPOTLIGHT PRESENTATION**
These sessions are hosted by leading companies operating in the field of pre-filled syringes and injector devices, and offer an opportunity to learn about the latest developments in the industry. If you would like to host a spotlight presentation, please contact **james.miguel@informa.com** or **+44 (0) 207 017 5011**

13.00 Lunch and Networking Time

Primary Containers: Novel Systems and Material Selection for Enhanced Product Efficacy

14.30 **Insight into the drafted ISO standards on pre-filled syringe design/ testing**
This presentation will look at connectors of specific delivery devices and how to best comply and demonstrate compatibility. The integration and standardisation of plastic syringes will be discussed and insight into new pre-filled syringe design, testing and specifications presented. Finally, key differences in material requirements of the USP, JP and EP will be discussed.
Dr Hector J. Macias, *Senior Equipment Engineer,* **Bristol-Myers Squibb,** USA

INTERACTIVE DISCUSSION PANEL

15.10 **DISCUSSION PANEL ON MATERIAL SELECTION**
Glass v.s plastic: What are the benefits?
- Current considerations with delamination
- Glass breakage and scratching: How detrimental is this to the product?
- Improving stability issues with change of material: How well does this work?
- Limitations of plastics- are they really the future for biological products?

Contributions from:
Dr Jim Janimack, *Head, Devices- NPI Secondary,* **GlaxoSmithKline Vaccines,** Belgium
Dr Paul Seminara, *Consultant, Medical Device Development,* **Roche,** Switzerland
Dr Hoss Dowlat, *Vice President, Regulatory Affairs Worldwide,* **PharmaBio Consulting,** Germany

15.40 Afternoon Tea, Poster/Exhibition Viewing Time and High-Speed Networking

16.10 **Regulatory guidelines applications for pre-filled syringe manufacture**
To find out more about this presentation please visit the conference website at **www.informa-ls.com/prefilled**
Dr Angel Verez, *Senior Engineer, Process Development,* **Amgen Manufacturing,** USA

16.50 **Rubber v.s TPE: what are the benefits and limitations when used in a pre-filled syringe?**
A full understanding of the potential effects certain materials can cause on your biological is essential to ensure that your product will perform as expected. The potential benefits and limitations of rubber and TPE, effects on product stability and overall risks of use will be presented.
Dr Mike Regan, *Consultant, Quality Assurance and Validation,* **Altran AG,** UK

17.30 Closing Remarks from the Chairperson and End of Day One

GAIN RECOGNITION FROM THE INDUSTRY AND PRESENT A POSTER FOR FREE!

SHARE YOUR DATA WITH THE INDUSTRY BY PRESENTING A POSTER
Have you got new research data or a technology that you want to present to your peers? If so, Informa Life Sciences' poster exhibition will be an ideal platform to promote your latest findings to a highly targeted audience.

How to submit your poster application:
You must be booked on as a delegate to be able to present a poster. To apply please send your abstract of 200 words or less, written in English, listing the principle author and all contact details to susanna.benaim@informa.com. Last date for submissions is **Friday 9 November 2012**.
- Posters submitted by biopharmaceutical companies and academic institutions will not be charged
- Poster submitted by service providers/vendors are welcome and will be subject to evaluation by the scientific advisory board. Upon approval a fee of £399 + VAT will apply

EVENING SEMINAR X: Wednesday 5 December 2012 X

Minimising the Effects of Extractables & Leachables in Pre-Filled Syringes

Registration 18.30 – Start 18.45 – End 20.30 – Dinner and refreshments will be provided

This interactive seminar delves into the essential information needed to test extractables and leachables and best ensure that these do not jeopardise the quality of your product. Through industry case studies, discussions and exercises provided, this is the most informative and educational platform to ensure how to best apply testing processes.

What will be discussed?

- Regulatory guidelines
- Breakage of glass parameters- contribution to leachables?
- Common causes
- Extractable and leachable testing approaches
- Analytical methods of detection
- Potential for prevention and avoidance

Gain a thorough understanding of how material selection can improve performance

Seminar leader:
Dr Andrew Feilden, *Principal Consultant,* **Smithers Rapra,** UK

DAY TWO: THURSDAY 6 DECEMBER 2012

08.55 Opening Remarks from the Chairperson

Formulation and Stability Concerns: Technical Advances

09.00 **Compatibility of biological formulation: how best to analyse?**
This presentation will discuss issues with how silicone can alter protein stability, as well as the role of MFI in formulation and delivery systems design. Finally, ways of overcoming the difficulties in analysis of lyophilised products will be explored.
Dr David Fela, *Associate Director, Analytical Development,* **NPS Pharma,** USA

09.40 **Closure systems: functional property testing**
Overcoming complications with break-force and reduced syringe movement is a common issues for syringe developers. This presentation will discuss novel designs that can improve syringe performance, and current tests available to test product integrity, sterility and stability.
Dr Parag Kolhe, *Group Leader-Senior Principal Scientist,* **Pfizer Inc,** USA

10.20 Morning Coffee and Poster/Exhibition Viewing

10.50 **Detecting and monitoring sub-visible particulates in biological products**
To find out more about this presentation please visit the conference website at **www.informa-ls.com/prefilled**
Dr Esohe Idusogie, *Associate Director, Analytical, Process Development,* **OncoMed Pharmaceuticals,** USA

Strategic Approaches Towards Improved Device Development

11.30 **FEATURED PRESENTATION ON QbD FOR PRE-FILLED SYRINGE MANUFACTURE**
Using a Quality by Design (QbD) approach for manufacture of pre-filled syringes and combination devices
This presentation will discuss the regulatory guidelines on design space, including industry insight into key considerations for experimental design and the key parameters for development of pre-filled syringes and combination devices. Approaches for successful technology transfer and design for manufacture will also be discussed.

Dr Paul Seminara, *Consultant, Medical Device Development,* **Roche,** Switzerland

12.10 **SPOTLIGHT PRESENTATION**
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If you would like to host a spotlight presentation, please contact **james.miguel@informa.com** or **+44 (0) 207 017 5011**

12.40 Lunch and Networking Time

13.45 **FEATURED PRESENTATION IN BIOSIMILAR DEVELOPMENT**
Biosimilar products: Improving product through device choice
- Biosimilar lifecycle management: Potential devices for these products
- Insight into the recent FDA guidelines: Can a new device be applied to improve the quality/capability of the product?

Dr Mathew Cherian, *Director, Pharmaceutical Development,* **Hospira,** USA - pending final confirmation

14.25 **DISCUSSION PANEL**
Fill and finish: device engineering and key considerations
INTERACTIVE DISCUSSION PANEL
- Stability concerns, practical ways of monitoring and engineering approaches to improve
- Demonstrating due diligence and establishing efficient supply chain
- Choosing the correct outsourcing partner
- Ensuring device compatibility

Contributions from:
Dr Hoss Dowlat, *Vice President, Regulatory Affairs Worldwide,* **PharmaBio Consulting,** Germany
Plus other speakers of the day

15.05 Afternoon Tea and Poster/Exhibition Viewing Time

15.35 **Lifecycle management of pre-filled syringes**
Understanding and demonstrating comparability and bioequivalence is vital for a product to successful progress throughout development. This presentation discusses the latest tools to help demonstrate this as well as clinical study criteria when a change in formulation occurs,
Dr Li Shi, *CEO,* **Shanghai Zerun Biotechnology Co. Ltd.,** China

16.15 **Risk assessment: approaches to ensure dose accuracy within a EU/US regulatory compliance framework**
To find out more about this presentation please visit the conference website at **www.informa-ls.com/prefilled**
Dr Hoss Dowlat, *Vice President, Regulatory Affairs Worldwide,* **PharmaBio Consulting,** Germany

16.55 Closing Remarks from the Chairperson

17.00 End of Conference

SPONSORSHIP & EXHIBITION OPPORTUNITIES 2012

Informa's Pre-Filled Syringes & Injector Devices for Biologicals conference brings together key decision-makers from across regulatory, technical, manufacturing and strategic departments and is the ideal platform for showcasing your latest technologies and services to a highly targeted audience.

Reasons why you should choose this event:
- **Access 2 audiences over for the price of one:** 1. Pre-Filled Syringes & Injector Devices for Biologicals and 2. Biocompatibility Testing & Evaluations for Medical Devices
- **Partner wit**h senior-level decision-makers with the authority to purchase new instruments and products

For further information on Sponsorship and Exhibition opportunities, please contact:
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Pre-Filled Syringes and Injector Devices for Biologicals

Wednesday 5 – Thursday 6 December 2012
Radisson Blu Hotel, Berlin, Germany
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Pre-Conference Workshop	CQ3476W
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Step 1. Select your workshops

❑ Pre-Conference Workshop W: Practical Investigations of Drug Change during Development: Early Stages Through to Commercialisation

❑ Evening Seminar X: Extractables and Leachables

Step 2. Select your pass

Event Selection	Code	Book Before Friday 14th September 2012	Save	Book Between Friday 14th September 2012 & Friday 2nd November 2012	Save	Book after Friday 2nd November 2012	Save	SME/ACADEMIC RATE - 50% DISCOUNT
2 Day Pass: Conference Only	CQ3476C	£1399 +19% VAT= £1664.81	£200	£1499 +19% VAT= £1783.81	£100	£1599 +19% VAT= £1902.81	-	£799.50 + 19% VAT = £951.41
2 Day Pass: Conference + Evening Seminar	CQ3476CX	£1898 +19% VAT= £2258.62	£200	£1998 +19% VAT= £2377.62	£100	£2098 +19% VAT= £2496.62	-	£974.50 + 19% VAT = £1159.66
3 Day Pass: Conference + Pre Conf Workshop	CQ3476CW	£2098 +19% VAT= £2496.62	£200	£2198 +19% VAT= £2615.62	£100	£2298 +19% VAT= £2734.62	-	£1049.50 + 19% VAT = £1248.91
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