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SMi Presents the 7th Annual Conference on...

Pre-Filled Syringes

Assessing manufacturing capacity and capabilities to enhance device developments

Marriott Regents Park Hotel, London, UK

28 - 29
JAN
2015



CHAIR FOR 2015:



Alphons Fakler,
Senior Packaging Engineer,
Novartis Pharma AG

KEY SPEAKERS INCLUDE:

- **Ignace Wallaert**, Principal Engineer, Primary Container & Drug Delivery Devices, **Janssen**
- **Shun Ogawa**, Research Manager, **Mitsubishi Gas Chemical Company Inc.**
- **Carsten Worsøe**, Principal Scientist, **Novo Nordisk**
- **Stephen Barat**, Executive Director, Scientific Affairs - Pharmacology and Toxicology, **Forest Laboratories, a subsidiary of Actavis**
- **Patrick Garidel**, Head of Pharmaceutical Basic Development, **Boehringer Ingelheim**

WHY ATTEND IN 2015:

- This is a **must attend** event for those focusing on the **latest developments** and **enhancements** in the design and **manufacturing** of pre-filled syringes and injection devices.
- Insights from **Key Opinion Leaders** to **benchmark** against and gain understanding on current factors and market benefits of pre-filled syringes
- **Delivery systems are evolving** and quality is key in developing and **enhancing delivery systems**, take note from those **accelerating** in the design and development field of new PFS technologies
- Detailed **regulatory considerations**, new developments, industry challenges and **risk assessment** will be addressed to enhance product development, **cost efficiency and efficacy**

PLUS TWO INTERACTIVE HALF-DAY PRE-CONFERENCE WORKSHOPS

Tuesday 27th January 2015, Marriott Hotel Regents Park, London, UK

The Development of Pre-fillable Syringe Systems

Workshop Leader: **Schott Schweiz AG**
8.30am – 12.30pm

Non-clinical considerations for developing a small volume parenteral drug product

Workshop Leader: **Stephen Barat**, Executive Director, Scientific Affairs - Pharmacology and Toxicology, **Forest Laboratories, a subsidiary of Actavis**
1.30pm – 5.30pm

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7th Annual Pre-Filled Syringes

Day One | Wednesday 28th January 2015

8.30 Registration & Coffee

9.00 Chair's Opening Remarks

Alphons Fakler, Senior Packaging Engineer, Novartis Pharma AG

PRODUCT INNOVATION AND DEVICE DEVELOPMENT

OPENING ADDRESS

9.10 Development of pre-filled syringe for intravitreal (IVT) administration: Challenges and lessons learned

- What are the requirements specific to syringes and components for intravitreal administration?
- What would an ideal injection device for intravitreal administration look like?
- Which technology trends could open new opportunities for future products?

Alphons Fakler, Senior Packaging Engineer, Novartis Pharma AG



9.50 Identifying new style technology formulations

- Dealing with PFS to obtain better care characteristics regarding quality and ease of use for patients
- What are the possibilities for PFS to ensure an efficient drug delivery system?
- For consideration - integrating a pre-filled syringe into a device

Christian Olesen, Manager, Finished Products & Medical Devices, NNE Pharmaplan A/S



10.30 Morning Coffee

KEYNOTE ADDRESS

11.00 Innovative safety system solutions addressing human factors engineering and combination product regulations

- In an environment where final drug products are more and more often made of a combination of components, designing innovative safety solutions that match customer's needs while maintaining a high standard of quality, efficacy and safety for the end-user has become a key challenge
- This session will explore how human factors engineering and close partnership between drug delivery system components' suppliers and drug manufacturers are becoming essential to tackle this challenge while delivering value to both pharmaceutical companies: by facilitating regulatory approval process, and their end-users: by maximizing patient adoption

Dirk Van Caelenberg, European Commercial Development Manager (Safety), BD Medical



Helping all people live healthy lives

MATERIAL IDENTIFICATION AND STABILITY

PART ONE

11.40 OXY-CAPTTM Multilayer Plastic Syringe with Oxygen Absorbing Resin

- Mitsubishi Gas Chemical (MGC) introduces glass-alternative "OXY-CAPTTM Multilayer Plastic Syringe" made of oxygen absorbing resin and COP
- OXY-CAPTTM has great features including glass-like oxygen barrier, extremely low water vapor permeability, extremely low extractable, low protein adsorption, glass-like transparency and others
- OXY-CAPTTM will maintain glass-like oxygen and water vapor permeability for several years, so MGC recommends using them for oxygen-sensitive bio drugs and vaccines

Shun Ogawa, Research Manager, Mitsubishi Gas Chemical Company, Inc



12.20 Networking Lunch

1.30 How do you determine what material is right for your drug product?

- Assessing the validation of new syringe formats
- Considerations on choosing the material - early factors in manufacturing
- What material and component considerations need to be applied to make a PFS?

Ignace Wallaert, Principal Engineer, Primary Container & Drug Delivery Devices, Janssen



2.10 Technical Data Update - Cyclo Olefin Polymer (COP) for Pre-Filled syringes

- Update on protein adsorption study on material surfaces
- Results of a syringe glass delamination study comparing to COP syringes
- Summary key benefits and features of COP for primary pharmaceutical packaging

Stuart Harris, Sales and Market Development Manager, Zeon Chemicals Europe Ltd.



2.50 Afternoon Tea

3.20 High concentrated protein solution in Pre-Filled syringes

Patrick Garidel, Head of Pharmaceutical Basic Development, Boehringer Ingelheim

4.00 Round Table Discussion - Plastic vs. Glass... the ongoing debate!

- What are the different interactions in glass and plastic syringes?
- Reviewing the stability of biologic drug products in plastic and glass PFS
- How could novel plastic PFS features impact device design?
- Could more be done with the design features of a plastic syringe?

Leaders:

Ignace Wallaert, Principal Engineer, Primary Container & Drug Delivery Devices, Janssen

Shun Ogawa, Research Manager, Mitsubishi Gas Chemical Company, Inc

Stuart Harris, Sales and Market Development Manager, Zeon Chemicals Europe Ltd.

Dr. Nicolas Brandes, Business Development Manager Daikyo Crystal Zenith (CZ), West Pharmaceuticals



4.40 Chair's Closing Remarks and Close of Day One

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or email: jrotar@smi-online.co.uk

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Register online at: www.pre-filled-syringes.com • Alternatively fax

8.30 Registration & Coffee

9.00 Chair's Opening Remarks

Alphons Fakler, Senior Packaging Engineer, Novartis Pharma AG

SAFETY ASSESSMENT

9.10 Case study: Extractables and leachables assessment in Prefilled Syringe drug products

- Rubber Components - the unavoidable assessment of stoppers, shields, plungers etc
- Relationship between extractables, simulated leachables and leachables
- What is the optimal tool to predict leachables in a prefilled syringe ?
- How to perform a simulated study for a prefilled syringe
- Case studies on simulated studies in prefilled syringes

Carsten Worsøe, Principal Scientist, Novo Nordisk A/S



9.50 Safety Assessment of Leachables in pre-filled syringe drug products - approaches and best practices

- Background on the origin of leachables in pre-filled syringe drug products
- Reasons why safety assessment for leachables is critical and expected
- Safety assessment of leachables for pre-filled syringe drug products, based on PQRI best practice recommendations for parenteral drugs
- Working examples to illustrate the application of most current PQRI best practice recommendations with emphasis on pre-filled syringes

Stephen Barat, Executive Director, Scientific Affairs - Pharmacology and Toxicology, Forest Laboratories, a subsidiary of Actavis



10.30 Morning Coffee

MATERIAL IDENTIFICATION AND STABILITY

PART TWO

11.00 What is the best choice for your product? Glass or polymer PFS?

- Review the benefits and limitations of glass PFS
- Options for polymers PFS on the market
- Benefits and limitations of polymer PFS
- How can pharma companies choose the best option for their product?

Anil Kumar Busimi, Head of Global Product Management, SCHOTT SCHWEIZ AG



SCHOTT
glass made of ideas

11.40 Daikyo Crystal Zenith® Prefillable Syringe and Cartridge Systems: A Containment Alternative to Glass



- Advantages and Challenges of Polymer Containers
- CZ 1ml Long Insert Needle Syringe - Silicone Oil free for improved drug compatibility
- Future evolution of polymer-based systems like West SmartDose™ electronic wearable injector

Dr. Nicolas Brandes, Business Development Manager Daikyo Crystal Zenith (CZ), West Pharmaceuticals



12.20 Networking Lunch

MANUFACTURING CAPACITY AND CAPABILITIES

KEYNOTE ADDRESS

1.30 Manufacturing strategies - What new approaches should be considered?

- Assessing the manufacturing developments and considerations - what's the outlook for 2015 onwards!
- Discussing innovative solutions and forward thinking to enhance manufacturing capabilities
- Injector design - reviewing the latest developments

Session reserved for leading pharmaceutical company

2.10 Round Table Discussion - PFS Manufacturing

- Sterilisation – What sterilisation processes are being considered and what alternatives are on the market?
- Reviewing quality by design in manufacturing for pre-filled syringes
- Parenteral container manufacturers - smaller batch sizes, customised medication

Leaders:

Stephen Barat, Executive Director, Scientific Affairs - Pharmacology and Toxicology, Forest Laboratories, a subsidiary of Actavis
Carsten Worsøe, Principal Scientist, Novo Nordisk A/S



REGULATORY FOCUS

2.50 Regulatory challenges - Case Study

- Responsibility for the device and control around it, what guidance can be given in light of this?
- What's the future of PFS in parallel with the regulatory guidance?
- How can safer pre-filled syringes be developed regarding compliance?

Session Reserved

3.30 Chair's Closing Remarks and Afternoon Tea

Media Partners:



HALF-DAY PRE-CONFERENCE WORKSHOP A

Tuesday 27th January 2015 | 8.30am – 12.30pm | Marriott Hotel Regents Park, London, UK

The Development of Pre-fillable Syringe Systems

SCHOTT
glass made of ideas

Workshop Leader: **Schott Schweiz AG**

Programme details to be confirmed.

About the Organisation:

SCHOTT Pharmaceutical Packaging 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.

HALF-DAY PRE-CONFERENCE WORKSHOP B

Tuesday 27th January 2015 | 1.30pm – 5.30pm | Marriott Hotel Regents Park, London, UK

Non-clinical considerations for developing a small volume parenteral drug product

Actavis

Workshop Leader: **Stephen Barat**, Executive Director, Scientific Affairs - Pharmacology and Toxicology, **Forest Laboratories, a subsidiary of Actavis**

Overview of workshop:

This workshop will provide an overview of the non-clinical aspects of developing a small volume injectable drug product. Discussion points will consist of the non-clinical safety program for the active pharmaceutical ingredient, formulation and leachables.

Who should attend this workshop:

- Non-clinical
- Clinical
- Regulatory professionals

Programme:

- 1.30 **Registration and Coffee**
- 2.00 **Intro and Overview**
- 2.30 **Assessing the non-clinical considerations**
- 3.30 **Coffee Break**
- 4.00 **Reviewing the non-clinical safety program for the API, formulation and leachables**
- 5.00 **Discussion and Q&A**
- 5.30 **End of Workshop**

About the workshop host:



Dr. Barat has nearly 20 years of experience with global drug development and registration. He is currently Executive Director, Scientific Affairs for Forest Laboratories, a subsidiary of Actavis, where he has responsibilities for branded drug nonclinical development, is a senior member of the research and development executive council and the scientific affairs/CMC council for matters concerning impurities. Dr. Barat is also a member of the PQRI PODP working group for leachables and extractables for parenteral and ophthalmic drug products. He has spoken on the subject of leachables at numerous international venues for pre-filled syringes, drug/device combinations and impurities.

About the Organisation:

Forest Laboratories, a subsidiary of **Actavis**, which is headquartered in Dublin, Ireland, is a unique specialty pharmaceutical company focused on developing, manufacturing and commercializing affordable generic and innovative branded pharmaceutical products for patients around the world.

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Pre-Filled Syringes Americas, April 2015, New Jersey, USA | 2nd Annual Event

3 days of presentations, panel discussions and interactive workshops

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MITSUBISHI GAS CHEMICAL

Mitsubishi Gas Chemical

Mitsubishi Gas Chemical (MGC) has successfully developed multilayer plastic vial and syringe. They have the characteristics of glass-like oxygen barrier, extremely high water barrier, extremely low extractables, high transparency and others. MGC recommends using them for oxygen-sensitive bio drugs, vaccines or diagnostics as an alternative for glass containers. www.mgc.co.jp/eng



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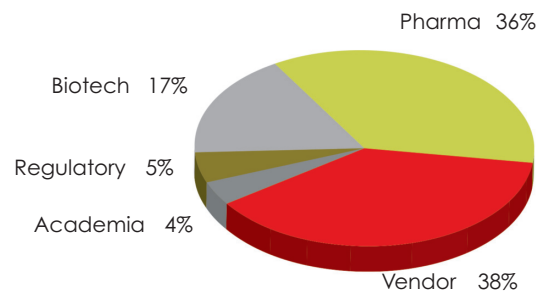
Who should attend this conference:

You should attend this event if you work in the Pharmaceutical Industry with responsibilities in Manufacturing, Packaging, Device Development and Regulatory Affairs.

Job titles include:

- Principal Scientist
- Head of Device Development
- Head of Global Product Management
- Senior Packaging Engineer
- Manager, Finished Products & Medical Devices
- Head of Prefilled Syringes and Liquid Vials
- Senior Director, Packaging, Device and Delivery

Previous Attendee Profile

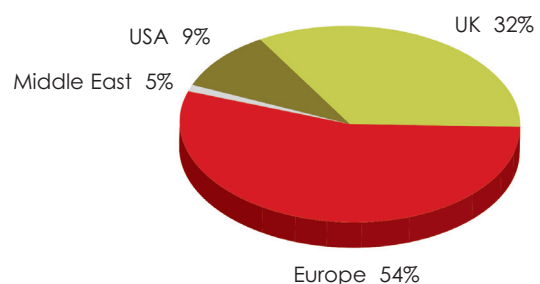


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PRE-FILLED SYRINGES

Conference: Wednesday 28th & Thursday 29th January 2015, Marriott Hotel Regents Park, London, UK Workshops: Tuesday 27th January 2015, London

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 Book by 31st October to receive £100 off the conference price

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