

EUROPEAN PRE-FILLED SYRINGES SUMMIT

19th- 20th Sept 2018, Berlin



Innovations in Injectable Device Development

KEY TOPICS

- Future trends and predictions in the Prefilled Syringes (PFS) & Devices Market
- Novel Approach to Partnering – Organisational and Relationship Structure of Key Partnerships in PFS & Devices
- Industry Regulations Guidance
- Technical Advancement in Mechanisms, Application Systems and Devices
- Smart Devices & Digital Health Applications
- Next Generation Materials & Design of Prefilled Syringes
- Risk Management through Development and Commercialisation of PFS
- Developing Validation Strategy

For More Information & Registration:

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Commercial & Sponsorship Opportunities:

Tim Rowley-Evans +44 (0) 20 3141 0637 trowleyevans@acieu.net



The Conference

Biopharmaceutical packaging is changing. As pharmaceutical manufacturers embrace more flexible processes that limit the risk of product contamination, packaging and containment systems are being designed to facilitate manufacturing of smaller product lots and batches. Designers of primary packaging and delivery system components have had to change their approach to product development.

ACI's European Prefilled Syringes Summit will explore the advancements in regulatory guidelines, product development, manufacturing processes, risk mitigation, portfolio management and answer some infinite industry questions such as; how the industry is responding to disruptive technology, connectivity, speed to market, and next generation syringes. There are several elements that pose a severe challenge to the growth of the global prefilled syringes market, the primary one being the high costs associated with temperature controlled packaging required for temperature-sensitive drugs. Other more traditional factors inhibiting the market include product recalls due to breakages and leachables, the potential risk of interaction between prefilled syringes and drugs, and needle stick prevention.

Confirmed Topics for Discussion:

Market Insights –what is happening in the PFS & Devices Market

Regulation of the Manufacture and Control

Technical Advances in mechanisms, application systems and devices

Improving quality, connectivity, and cost control for combination products

Next generation materials & design of PFS

Balancing biopharmaceutical product portfolio for continual product innovation & Creating a lower-risk product development strategy

Smart devices: their emerging role in auto-injector systems & driving innovation

Shift from glasses pre-filled syringes to plastic prefilled syringes

Who Will Be Attending?

The two day conference will bring together the leading executives and experts from across the entire value chain uniting a variety of industry perspectives to discuss solutions and strategies for topical discussions, helping companies of all sizes to develop, prove and commercialise new and improved processes and technologies for biopharmaceutical manufacture with an emphasis on the competitive landscape.

Head of Device Development, Head of Product Management, Human Factors, Senior Application Specialists, Senior Packaging Engineers, Medical Devices Senior Director, Packaging, Head of Medical Devices

Registration is simple

If you would like to register for this event or wish to find out more information, please contact:

Mohammad Ahsan

+44 (0) 203 141 0606/ mahsan@acieu.net

Commercial & Sponsorship Opportunities

With leading companies and organisations from the pharmaceutical industry attending and speaking at our event, we have the perfect vehicle to provide outstanding exposure to a senior level audience. There are varying sponsorship packages available, including sponsorship of a cocktail reception on the first evening of the event and sponsorship of a networking lunches.

For further details, please contact:

Timothy Rowley—Evans

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DAY 1

Wednesday 19th September 2018

08:00 **REGISTRATION & COFFEE**

09:00 **CHAIRMAN OPENING REMARK**

Carsten Worsøe
Principal Scientist
Novo Nordisk

09:15 **SESSION ONE**

Future trends and predictions in the Prefilled Syringes (PFS) & Devices Market

- Novel approach to partnering – organisational and relationship structure of key partnerships in PFS & devices
- Access to emerging markets and role of PFS in drug delivery devices

10:30 **MORNING REFRESHMENTS**

11:00 **SESSION TWO**

Industry Regulations Guidance

- Manufacture and control regulation
- Latest guidelines in receiving PFS & overcoming complex requirements for approval
- Inspection and usability studies

12:15 **LUNCH**

13:15 **SESSION THREE**

Technical Advancement in Mechanisms, Application systems and Devices

- Technical collaborative success case study and product overview
- Patient acceptance or preference vs other solutions such as wearables and reconstitution devices
- The 'device ability' of filled syringes as key challenge needing stability and tolerance of critical dimensions and the precision of the manufacturing process
- Minimising interaction between the closure system and the drug formulation
- Novel technologies to properly manage prefilled syringes manufacturing processes: Robotics, big data, the Internet of things (IoT), smart vision
- How automation with robots can improve PFS production: Solutions and applications

15:05 **AFTERNOON REFRESHMENTS**

15:35

CONFERENCE PRESENTATION

Commercialisation of PFS

Nan Yung Lin
Associate Director, Product Development
Dermira

16:20

PANNEL DISCUSSION

Commercialisation of PFS and Device

- Business models of the future: Establishing an outcome-based business model between pharma and device providers, for the direct and measurable benefit of patients Partnering with device providers and manufacturers.
- Improving Safety Standards Driving high costs associated with prefilled syringes inhibiting widespread adoption
- Balancing biopharmaceutical product portfolio for continual product innovation, such as incorporating a new delivery component.
- Managing the Materials used to Construct Prefilled Syringes: Selection and Supply Chain Control
- Best practices in cost control

David Harrison
Senior Alliance Lead (Devices)
UCB

Nan Yung Lin
Associate Director, Product Development
Dermira

17:05

CHAIRMAN'S CLOSING REMARKS

17:15

END OF DAY ONE



DAY 2

Thursday 20th September 2018

08:30 **REGISTRATION & COFFEE**

09:00 **CHAIRMAN'S OPENING REMARKS**

Carsten Worsøe
Principal Scientist
Novo Nordisk

09:10 **SESSION FOUR**

Smart Devices & Digital Health Applications

- Smart and connected devices, together with patient apps and data infrastructure
- Case studies showing design and development parameters and challenges would be very interesting
- Lifecycle considerations for patient-centric and adherence-building drug delivery.
- Role played in the product strategy for PFS vs auto injectors vs electromechanical injectors

Paolo Mangiagalli
Sr. Director, Device Development Unit
Sanofi

11:00 **MORNING REFRESHMENTS**

SESSION FIVE

11:30 **Next Generation Materials & Design of Prefilled Syringes**

- Shifting from glass prefilled syringes to plastic prefilled syringes
- Case studies showing design and development parameters and challenges would be very interesting
- Syringe siliconization process investigation and optimisation
- Sustainability and environmental issues: Recycling the non-reusable devices
- What materials of the future will be available? Usability of PFS

12:30 **Material Selection and Risk Management of Component Change**

- Risk management for materials and components used in orally inhaled and nasal drug products

Andrew Feilden
Chemistry Operations Director
Smithers Rapra

13:00 **Panel Q&A**

13:20 **LUNCH**

14:20 **CONFERENCE PRESENTATION**

Extractable Study for two Plast Syringes

- What happened with the drugs at the hospital pharmacies?
- Extractable studies of two common used plastic syringes
- A practical approach for toxicologic assessment of the found extractable compounds

Iben Larsson
Scientific Senior Adviser
Amgros I/S

CONFERENCE PRESENTATION

15:05

Perspectives on PFS development and drug product compatibility

Yasser Nashed-Samuel
Principal Scientist
Amgen

15:50

CHAIRMAN'S CLOSING REMARKS

16:00

END OF CONFERENCE & AFTERNOON REFRESHMENTS




The European Prefilled Syringes Summit


Berlin, Germany

19th—20th
September
2018


Registration Is Simple

If you would like to register for this event or wish to find out more information, you can contact **Mohammad Ahsan** using any of the following methods:

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 <http://www.acius.net>

 ACI Europe, 10 Gough Square, London, EC4A 3DE, UK

Registration is Simple

Conference (Includes Documentation Packet) 19th & 20th September 2018	£1,595.00 (ex.Vat)
Documentation Packet Only	£470.00

Please Note.

Members and customers of all supporting organisations are entitled to a discount off their conference package.

For more information please call **Mohammad Ahsan** on +44 (0) 20 3141 0606

Documentation Packet Available

We are selling the European Prefilled Syringes Summit 2017 papers at just £395 (+£25 P&P). Simply tick the box on the booking form, send it with payment and your copy will be on its way to you after the meeting. This important manual will be a source of invaluable reference for the future.

About ACI

ACI, a UK owned company, has been running successful conferences in the USA since 1999. Headquartered in Chicago with offices all around the States, ACI opened its European head office at the end of 2005 and has expanded rapidly, launching a series of events in key industries including maritime, energy, oil & gas, cosmetics, chemicals & media.

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