

Pre-Filled Syringes - To book online go to: management-forum.co.uk/1556

Book Before 12 January 2018
and SAVE £100 / €140

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Date and venue

21 March 2018

Ref: 10206

The Cavendish Hotel
81 Jermyn Street
London SW1 6JF
Tel: +44 (0)20 7930 2111

(Note: Entrance via Duke Street)

Programme schedule

Registration and refreshments: 09.00
Start of course: 09.30
Close of course: 17.00

Accommodation

When available we have arranged a preferential rate for accommodation at the venue. To take advantage of this price please mention that you are attending the **Management Forum seminar** when booking your accommodation. <http://www.thecavendish-london.co.uk/>
info@thecavendishlondon.com

For information on alternative accommodation please visit our website: management-forum.co.uk/venue



Three ways to book



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Fees and payment

EARLY BOOKING DISCOUNT Book BEFORE 12 January 2018
£599.00 + VAT = £718.80 • €839.00 + VAT = €1006.80

FULL PRICE Book AFTER 12 January 2018
£699.00 + VAT = £838.80 • €979.00 + VAT = €1174.80

Multiple booking discount for 2nd or subsequent delegates - 15%
£595.15 + VAT = £712.98 • €832.15 + VAT = €998.58

Payment options

1. Invoice which can be paid by bank transfer or credit / debit card
2. Online through our secure website when registering

Register on the **Injectable Drug Delivery** conference **22-23 March 2018**, in addition to the **Pre-Filled Syringe** seminar and receive a **£200/€280** discount

In-house training

This course is also available in-house and can be tailored to your specific needs. Our experts come to you, saving you time and money. For more information contact **Customer Services** on **+44 (0)20 7749 4730** or email: inhouse@management-forum.co.uk

The small print

FEE: The fee includes all meals and refreshments for the duration of the course and a complete set of course materials. If you have any particular requirements please advise customer services when booking.

HOW TO REGISTER AND PAY: A VAT invoice and booking confirmation will be sent within 7 days, please contact us if you have not heard anything after that time. Payment can be made by credit/debit card, by bank transfer (for bank account details please see payment details section on our website). VAT no GB 341232109. Any questions please contact Customer Services on +44 (0)20 7749 4730. **ALL PAYMENTS MUST BE RECEIVED IN ADVANCE OF THE EVENT.**

MULTIPLE BOOKING DISCOUNTS: This discount may not be used in conjunction with any other offer

CANCELLATIONS AND TRANSFER: Once we have received your booking the place(s) are confirmed.

Delegate	Up to 28 days before course	27 to 14 days before course	13 to 0 days before course
Cancellation	10% admin fee	100% admin fee	100% admin fee
Transfers	Free	10% admin fee	100% admin fee
Substitution	Free	Free	Free

A maximum of one transfer is allowed. After the transfer no cancellation can be accepted and the full invoiced fee will be charged. Transfers are subject to payment of the difference on higher value courses. All cancellations must be received in written form.

For event cancellation policy and T&Cs see our website

Pre-Filled Syringes

Quality, Quality, Quality - from manufacture, through fill/finish to final inspection

21 March 2018 London



Key topics to include:

- Pre-filled syringes for biotech
- Syringe manufacture: fit-for-purpose
- Filling: PFS and multi-format PFS filling machines
- Packaging: inspection, assembly and final packaging
- An Insider's look at a PFS fill/finish facility
- Design verification testing of device function for PFS

Expert presenters:

Dr Dale Charlton, ATS Sortimat

Horst Koller, HK Packaging Consulting

Dr Andreas Rothmund, Vetter Pharma

Includes: Interactive sessions

Introduction

This seminar has been designed to provide a comprehensive, practical and useable overview of the production of pre-filled syringes and will provide the latest information on manufacture, packaging for fill/finish through to final (post-fill) inspection. Quality will be a key focus for the day and topics such as quality of syringe manufacture, quality of syringe components and why, quality of filling (volume check, reject reduction), quality of inspection and product release will be discussed in detail.

Who should attend

Those working in the area of pre-filled syringes with responsibility for device programmes, product development, product life cycle management, regulatory affairs, quality assurance, combination products, drug delivery specialists, business development managers and product development managers.

Why should you attend?

- **Gain** a comprehensive update of the manufacture of pre-filled syringes from experts in the field
- **Discuss** key areas of quality in syringe manufacture
- **Know** the requirements for inspections and how to implement them
- **Share** an insider's look at a PFS fill/finish facility

Please note we are also running our **Annual Injectable Drug Delivery** conference on the **22-23 March 2018** and should you wish to attend both the **Pre-Filled Syringes** and the **Injectable Drug Delivery** events, there is a further **£200/£280 discount**

In-house training

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Expert presenters

Dr Dale Charlton, ATS Sortimat. Dale has spent a life long career in life sciences and biotechnology covering work in both the academic and industrial sectors. Following his first degree in biological sciences and spells at Porton Down and Pittman Moore vaccines (Formerly Glaxo Animal Health) developing vaccines/adjuvant systems, he settled back into the biotech industry developing therapeutic Monoclonal Antibodies at Celltech. Dale successfully undertook a PhD at Pfizer Drug Discovery and the University of Nottingham on peptide drug candidates before moving out of academia and into the supply industry in the field of robotics and automation for the biopharmaceutical industry. He progressed from Product Specialist to Managing Director of an independent life science company until moving to his role as Director of Business Development for the Optima Group pharma, Germany and more recently to ATS Sortimat.

Dr Andreas Rothmund is Qualified Person at Vetter Pharma-Fertigung in Ravensburg, Germany, an independent contract manufacturer specialised in the aseptic production of pre-filled application systems. He started his industrial career in 1985 as a lab manager. After two years he took over production responsibility for a German company specialised in eye drops and eye ointments, a position he held for nearly eight years. He joined Vetter in 1994, where he has held several positions, including Head of Production for one of Vetter's aseptic production units.

Horst Koller started his professional career in 1994 to work for a large pharmaceutical company in Germany managing the Process Engineering Group. He holds a degree as Dipl. Ing (FH) in Biotechnology. In 2000 he joined Schott in the business segment pharmaceutical packaging. He has been a key player in building the manufacturing unit for the Schott TopPac® polymer syringe within Schott AG. He held different positions including Quality Manager, Head of R&D, Manager Scientific Advisory and Manager Global Regulatory Affairs and Quality R&D. He is now CEO of HK Packaging Consulting GmbH. He is an active member as expert of ISO/TC 76/ working groups and a frequent speaker at extractables and leachables as well as pre-fillable syringe conferences.

Programme

- 09.30 ▶ Welcome and introductions**
- 09.40 ▶ Pre-filled syringes for biotech: improvement in the manufacturing process development**
- 10.10 ▶ PFS systems**
 - New PFS formats
 - Safety devices
 - Self injection devices
 - Leachable and extractable considerations
- 10.50 ▶ Discussion**
- 11.00 ▶ Refreshments**
- 11.20 ▶ Syringe manufacture from components to the final product - an overview**
 - The initial choice - bulk or pre-sterilised components?
 - Siliconisation, not beloved, but required
 - Secondary packaging and more - assembly of PFS into auto-injectors
- 12.00 ▶ The next step: fill/finish for nested syringes, vials and cartridges**
 - A unique machine for processing pre-sterilised syringes, vials and cartridges
 - Integrated capping
 - Maximum product yield by using special start up and end of production filling processes
 - State-of-the-art peristaltic pump technology together with a combi filling station
 - State-of-the-art single use filling technology including data from the performance qualification
 - Mock up study for optimised use of barrier system
 - Upstream processes for bringing the different containers to the point of fill
- 12.40 ▶ Discussion**
- 12.45 ▶ Lunch**
- 13.45 ▶ Visual inspection of pre-filled syringes**
 - Why do we inspect? - regulatory requirements
 - Inspection basics
 - Defects – classification and defect evaluation lists
 - Pros and cons of different inspection methods
 - Automated visual inspection of syringes – scope and limitations
 - Current developments
- 14.30 ▶ Secondary packaging of PFS**
 - Materials
 - Dimensional requirements
 - Compatibility with existing filling lines
- 15.10 ▶ Discussion**
- 15.20 ▶ Refreshments**
- 15.40 ▶ Design verification testing of device function for PFS**
 - Meeting the US FDA requirements for "Combination Products"
 - Meeting the essential requirements of the Medical Device Directive (MDD) in the EU
 - Identifying and verifying the critical functional and performance requirements for the components and finished pre-filled syringes
- 16.20 ▶ State-of-the-nation address for PFS and summary**
- 16.50 ▶ Discussion**
- 17.00 ▶ Close of seminar**