



**Belgium
Affiliate**

ENGINEERING
PHARMACEUTICAL
INNOVATION

DISPOSABLES TECHNOLOGIES IN PHARMA INDUSTRY WITH TABLE TOP EXHIBITION

Practical information on :

- Why, Where and How disposables and disposable equipment can be used in pharmaceutical production.
- Benefits and drawbacks of the use of disposables technology
- Main supplier and products of disposables and equipment and future trends
- Qualification and validation aspects using disposables and - technology
- GMP issues related to the use of disposables
- Case study Pfizer with the implementation of a complete disposable process for formulation, storage and filling

24 MAY 2007

(from 9:00 h to 17:15 h)

Location: **Chateau de Limelette**
Rue Charles Dubois 87
B 1342 Limelette (Wavre near to E411)
Tel: 010/ 42 19 99



**Belgium
Affiliate**

ENGINEERING
PHARMACEUTICAL
INNOVATION

DISPOSABLES TECHNOLOGIES IN PHARMA INDUSTRY PROGRAM

8:30 - 9:00 Registration and coffee

9:00 - 9:05 ISPE Belgium welcome and introduction to the topic of the day.
(*ir. Jef De Clercq, Managing Director ESC and President ISPE Belgium*)

9:05 - 9:45 From glass and stainless steel to plastic.
(*Mr K. Hermansen, Senior Specialist Novo Nordisk Engineering, Denmark*)

9:45-10:25 Membrane chromatography applications in biopharma production.
(*Dr. S. Fischer-Fruehholz, Product manager Sartobind, Sartorius Division*)

10:25-10:45 Coffee break with table top and networking

10:45-11:25 Manufacturing strategy for single-use technology.
(*Mr K. Van Dongen, area manager JM Separations, The Netherlands*)

11:25-12:00 The utilization of disposable equipment for increased manufacturing flexibility
(*Mrs R. Landon, Group Product Manager Mobius Solutions, Millipore SAS*)

12:00-12:30 Validation of a single-use systems.
(*Mrs N. Pathier, Product manager Pall Corporate Division, France*)

12:30-14:00 Lunch with table top and networking

14:00-14:40 Implementation & Validation of single-use manufacturing from the design phase
(*Mrs M. Mongé, Marketing Director Stedim Biosystems, Stedim France*)

Contained transfer of powder and solids using disposable systems
(*Dr Ir F. Willocx, Product manager ATMI Belgium*)

14:40-15:40 Validation of a disposable manufacturing line including weighing, mixing and filling with single use isolator
(*Mr J-P Zambaux, Business development manager ATMI*)

15:40-16:00 Coffee break with table top and networking

16:00-17:00 Case study: Disposable Technology for Formulation, Storage and Filling of Aseptic Products.
(*Mr P. Sivertsson, Senior Manager New Products Pfizer Global Contract Manufacturing USA*)

17:00-17:15 General Q & A and conclusion of the day.



**Belgium
Affiliate**

ENGINEERING
PHARMACEUTICAL
INNOVATION

DISPOSABLES TECHNOLOGIES IN PHARMA INDUSTRY TOPICS TO BE DISCUSSED.

From Glass and Stainless Steel to Plastic. (K. Hermansen)

- Why disposables? Benefits versus challenges
- Where disposables? Upstream - downstream - filling
- How ? Two practical cases and some special issues.
- Main suppliers and products.
- Future trends.

Manufacturing strategy for single use technology (K. Van Dongen)

- Impact of integration of single use technology on manufacturing strategy, scale-up and process economics.
- Practical implementation of a single use cross flow filtration system in up- and downstream processes.
- Benefits of single use technology.

The utilization of disposable equipment for increased manufacturing flexibility (R. Landon)

- Market trends going for disposable solutions
- Integration of process know how to disposable manufacturing
- Validation of disposable solutions
- Product developments in disposables technologies

Implementation & Validation of single-use manufacturing from the design phase (M. Mongé)

- Optimization of the layout for new or retrofitted facilities using disposables
- Benefits: Reduce time to market and manufacturing cost, ease to use, superior process performance and flexible facilities
- Application based single-use technology risk analysis



**Belgium
Affiliate**

ENGINEERING
PHARMACEUTICAL
INNOVATION

Contained transfer of powder and solids using disposable systems (Dr Ir F. Willocx)

- URS and design for the implementation of disposables for the transfer of hazardous powders (API's) and solids.
- Glove boxes specs for handling products and carrying out maintenance activities (filter replacement)

Validation of a disposable manufacturing line including weighing,mixing and filling with a complete isolator (J-P Zambaux)

- Overview of the variety of disposables and – equipment
- Qualification and validation from clinical to production batches
- Reducing the risk of cross contamination and operator risks.

Validation of single use systems (N. Pathier)

- Practical validation aspects implementing disposables in biopharmaceutical manufacturing
- Design aspects to take into account in order to simplify validation
- Practical case studies

Disposable Technology for Formulation, storage and filling of Aseptic Products (P. Sivertsson)

- Practical case study of a disposable process for formulation, storage and filling
- GMP aspects
- Supplier strategies
- Regulatory considerations for implementation of a complete disposable process
- Lessons learned from the implementation project.

Who should attend:

- Directors, managers and supervisors working in the engineering department or process development unit.
- Managers, engineers and supervisors who are responsible for pharma and/or biopharmaceutical manufacturing.
- Maintenance management and supervision.
- QA/QC/QP management and supervision responsible for validation, registration and batch release .
- Qualification and validation people responsible for engineering quality and technology development.



**Belgium
Affiliate**

ENGINEERING
PHARMACEUTICAL
INNOVATION

DISPOSABLES TECHNOLOGIES IN PHARMA INDUSTRY:

24 May 2007

REGISTRATION FORM

Please return before May 17, to Mrs. M. Ladrière
by fax : +32 (0)10 85 80 35
or e-mail : Marianne.Ladriere@gskbio.com

PARTICIPANT :

Last name :	<input type="text"/>	First name :	<input type="text"/>
Title :	<input type="text"/>		
Company :	<input type="text"/>		
Street :	<input type="text"/>		
City :	<input type="text"/>	ZIP Code :	<input type="text"/>
Tel. :	<input type="text"/>	Fax :	<input type="text"/>
E-Mail :	<input type="text"/>		

PARTICIPATION IN THE COST (INCLUDING LUNCH AND PRESENTATIONS ON USB STICK) :

Member of ISPE : 250 €
Non-Member of ISPE : 440 € (including 1 year ISPE membership valued 190 €)

I am an ISPE member and I pay 250 € for the participation
through Visa/Master Card n° Exp. date
 Amex Card n° Exp. date
ISPE membership number :

I am not yet an ISPE member and I pay 440 € for membership and participation
through Visa/Master Card n° Exp. date
 Amex Card n° Exp. date

Cardholder Name :

Date : Signature :

Subscribe now, because the number of participants is limited

- Ø ISPE reserves the right to delay the meeting and modify the program and the place, in case of force majeure.
- Ø Confirmation of subscription will be sent one week before the seminar date together with a road map
- Ø Any cancellation received later than one week before the event, will not be credited.