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ENGINEERING  
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## **BEST PRACTICES FOR RABS & ISOLATOR TECHNOLOGY WITH TABLE TOP EXHIBITION**

### **Practical information on :**

- Draft guidelines on RABS and Annex 1 for aseptic filling.
- Advancements and trends in aseptic processing manufacturing.
- Comparative investments study for isolators-RABS-LAF filling.
- Barrier systems for filling machines.
- Risk analysis and reduction of contamination risk.
- Two case studies Pfizer of implementation of isolators and RABS.
- Table top exhibition with presentation of newest materials and equipment.
- Case study Thissen of adaptation of an existing filling line with RABS

**22 MAY 2008**

(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



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## **BEST PRACTICES IN RABS AND ISOLATOR TECHNOLOGY PROGRAM**

8:30 - 9:00 Registration and coffee—Table Top Exhibition

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 - 9:35 Keynote session: Advancements and trends in aseptic manufacturing  
( *Mr Jack.Lysfjord, Principal Consultant LLC, former Vice President Bosch company, USA* )

9:35-10:15 Case study 1: Investment comparison for an isolator,RABS & LAF.  
( *Mr Pascal François, Project Leader Pfizer Manufacturing, Puurs-Belgium* )

### **10:15-10:45 Coffee break with table top and networking**

10:45-11:25 Case study 2: Plastic Vial filling line under isolator or RABS ?  
( *Mr Alain Deprez, Technical Improvement & Automation Mgr, Pfizer AH, Louvain-la-Neuve* )

11:25-12:05 Case study 3: Reduction of pinholes in lyophilization filling lines.  
( *Mr Guido Cammarota, Staff process Engineer GPSG-EMEA, Janssen,Beerse-Belgium* )

### **12:05-14:00 Lunch with table top and networking**

14:00-14:40 Things to do to reduce contamination risk  
( *Mr Jack.Lysfjord, Principal Consultant LLC, former Vice President Bosch company, USA* )

14:40-15:20 Adaptation of existing filling line for toxic products with barriers  
( *Mr Dominique Lammerant, Production Director Thissen Laboratories, Braine L'Alleud,Belgium* )

### **15:20-15:40 Coffee break with table top and networking**

15:40-16:20 Barrier systems for filling machines, aspects and examples.  
( *Mr Dieter Paschenda, Global Key Account Manager R. Bosch Company, Crailsheim-Germany* )

16:20-16:50 RABS and Isolator Technologies; an engineering evaluation.  
( *Mr Julien Filou, Manager Pharma Equipment , Jacobs Engineering, Paris-France* )

16:50-17:10 Communities of Practice –Isolator and RABS COP ISPE Belgium.  
( *Mr Geoffrey Folie, senior manager projects engineering GSKBiologicals, Wavre-Belgium*  
*Mr. Pol Van de Perre, Vice-President Operations ISPE Europe, Brussels-Belgium* )

17:10-17:30 Q & A and Closure of the day  
Drink and networking



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## **BEST PRACTICES FOR RABS AND ISOLATOR TECHNOLOGY TOPICS TO BE DISCUSSED.**

### Advancements and trends in aseptic processing manufacturing ( J. Lysfjord )

- Historical evolution in aseptic processing
- Current choices: Cleanroom-RABS-Isolator. Containment of potent drugs
- Sterility assurance levels ( SAL )
- Why continuous improvement
- Capital and operational cost issues for the different containment methods.
- Future trends.

### Comparative investment study for Isolator-RABS-LAF and case study ( P. François )

- General differences in various solutions ( ease of use-validation-sterility assurance )
- Environmental data comparison
- Cost comparison

### Plastic vials filling line under isolator or RABS ( A. Deprez )

- Pro's and con's for isolators versus RABS technology for a vial filling line
- Financial implications

### Reduction of pinholes in lyophilization filling lines ( G. Cammarota )

- Case study on the occurrence of pinholes in isolator gloves of 2 filling lines
- Definition of root causes
- Improvement steps and reduction of pinhole occurrence

### Things to do to reduce contamination risk ( J. Lysfjord )

- Analysis of major risk factors for contamination
- Practical tips how to reduce and minimize the risk for contamination
- Application based single-use technology risk analysis



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### Adaptation of existing filling line for toxic products with barriers ( D. Lammerant)

- Existing filling line for toxic products needed output increase and adaptation to future GMP operation.
- Design and implementation aspects of new closed barrier system.
- Time constraint: installation and validation within one month.

### Barrier systems for filling machines: aspects and examples ( D. Paschenda )

- Barrier isolation system on a complex high speed aseptic filling line
- Case study of practical implementation

### RABS and isolator technologies: an engineering evaluation ( J. Filou )

- Different types of RABS ( passive-active-closed )
- Benefits of RABS ( drivers-limitations )
- RABS versus isolator technology comparison ( capital-operational-facility )
- Future trends and perspectives

### ISPE community of practice re isolators and RABS ( G. Folie - P. Van de Perre )

- Access and usage of ISPE communities of practice. Demonstration via the ISPE website.
- Benefits to ISPE members and non-members
- International and Belgian COP on Isolators and RABS.

### **Who should attend:**

- Directors, managers and supervisors working in the engineering department or secondary equipment development.
- Managers, engineers and supervisors who are responsible for aseptic filling.
- Directors, managers and supervisors responsible for secondary manufacturing and aseptic filling operations.
- Maintenance management and supervision.
- QA/QC/QP management and supervision responsible for validation of aseptic filling operations .
- Qualification and validation responsible for engineering quality and technology development.



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**BEST PRACTICES FOR RABS AND ISOLATOR TECHNOLOGY**  
22 May 2008

**REGISTRATION FORM**

Please return before May 10, to Mrs. Emilie Niset  
by fax : +32 (0)10 85 90 40  
or e-mail : [emilie.niset@gskbio.com](mailto:emilie.niset@gskbio.com)

**PARTICIPANT :**

Last name :  First name :

Title :

Company :

Street :

City :  ZIP Code :

Tel. :  Fax :

E-Mail :

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

Member of ISPE : 250 €  
Non-Member of ISPE : 450 € (including 1 year ISPE membership valued 190 €)

I am an ISPE member and I pay 250 € for the participation  
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- Confirmation of subscription will be sent one week before the seminar date together with a road map
- Any cancellation received later than one week before the event, will not be credited.