



**Belgium
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ENGINEERING
PHARMACEUTICAL
INNOVATION

**SEMINAR: HVAC AND CONTAINMENT SYSTEMS
IN PHARMA FACILITIES**

**VISIT: NEW DR. PAUL JANSSEN
RESEARCH CENTER**

19 DECEMBER 2006

Practical information on :

- Regulatory requirements for HVAC systems in pharma facilities
- Latest developments in design of HEPA/ULPA filters and in situ testing.
- Commissioning of HVAC installations and qualification of clean rooms.
- Risk based approach of HVAC qualification.
- Modular HVAC units for flexible operations.
- Containment and fume hood performances.

Location: Janssen Pharmaceutica
Turnhoutseweg 30
B 2340 BEERSE
Tel: 014/ 60 20 00



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- 8:30 - 9:00 Registration and coffee
- 9:00 - 9:10 ISPE Belgium welcome and introduction to the topic of the day.
(*ir. Jef De Clercq, Managing Director E.S.C. and President ISPE Belgium*)
- 9:10 - 9:50 Regulatory requirements of HVAC systems from design to maintenance.
(*Mr. B. Baghdikian, Managing Director Air Consult Engineering, Brussels-Belgium*)
- 9:50-10:30 Latest developments in HEPA/ULPA filters. In situ leak testing.
(*Mr. J.M. Van Hee, Product Manager Clean Process Camfil France*)
- 10:30-11:10 Risk based qualification of HVAC systems.
(*Mr. U. Janses, Engineering Manager Pfizer Manufacturing, Belgium*)
- 11:10-11:40 Coffee break and networking**
- 11:40-12:20 Flexibility and modularity of HVAC in modern laboratories.
(*Mr. P. Dockx, Business Unit Manager Technical Utilities Department Van Looy Group Belgium*)
- 12:20-13:00 Containment and fume hood performances.
(*Mr. M. Don Porto Carero, Senior Manager HVAC, Janssen Pharmaceutica Beerse, Belgium*)
- 13:00-14:15 Lunch**
- 14:15-15:00 State of the art research: Introduction to the Dr Paul Janssen research center.
(*Mr. V. Maes, Director Business Support R&D, Janssen Pharmaceutica Beerse, Belgium*
Mr. K. Verschraegen, Senior Project Manager Engineering, Janssen Pharmaceutica Beerse)
- 15:00-16:30 Visit of the new Dr. Paul Janssen Research Center Beerse
- 16:30-17:00 Q & A and technical issues
- 17:00-17:30 Conclusions of the day- Benchmarking-Closing drink.



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Regulatory requirements of HVAC systems from design to maintenance.(B. Baghdikian)

- Regulatory requirements and expectations along all V-model stages throughout the life cycle.
- Compliance through monitoring of maintenance and calibration, change control and annual review procedures.

Latest developments in HEPA/ULPA filters. In situ leak testing. (J.M. Van Hee)

- Filter certification according EN1822 and “bleed through” issue.
- Usage of thermal aerosol generators for in situ leak testing.
- Improved terminal housing design in order to match EUGMP/FDA requirements
- Testing of high temperature ceramic HEPA filters in tunnels and ovens.

Risk based qualification of HVAC systems. (U. Janses)

- The benefits of risk based approach .
- Commissioning versus qualification and boundary definitions.
- Key activities of HVAC commissioning and clean room qualification.

Flexibility and modularity of HVAC in modern laboratories. (P. Dockx)

- Ventilation in modern laboratories. Different options and solutions.
- Consequences of flexible lab usage on design and layout of HVAC installations.
- Follow up of important environmental control parameters.

Containment and fume hood performances.(M. Don Porto Carero)

- Critical parameters for fume cupboard containment performance.
- Computational fluid dynamics test methods.

Who should attend:

- Directors, managers and supervisors working in the engineering department or process development unit.
- Managers, engineers and supervisors who are responsible for aseptic processing, sterile manufacturing and environmental control.
- Maintenance management and supervision responsible for HVAC installations and equipment for clean room environments.
- QA/QC management and supervision responsible for environmental control specifications and deviations/ change control follow up and approval.
- Qualification and validation people responsible for engineering quality and technology development.



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REGISTRATION FORM SEMINAR 19 DECEMBER 2006
Please return before December 11, 2006 to Mrs. Edith Lauwers
by fax : +32 (0)14 60 61 02 or e-mail : Elauwer1@gpsbe.jnj.com

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