



## Module 3: Sterile manufacturing: a thorough discussion on sterility assurance challenges

**PROGRAM**  
7 – 9 October 2019  
Hotel Bergse Bossen, Driebergen,  
the Netherlands

### Monday, 7 October 2019

**Theme: Microbiology and design for sterility Environmental monitoring and utilities**

- 09.30: Welcome and outline of the course  
Jos Mathôt
- 09.45: Biology of microorganisms  
Implications for pharmaceutical  
production and quality control  
Vincent Hamers
- 10.45: Sterile manufacturing:  
a philosophy on design and  
control  
Jos Mathôt
- 12.30: Lunch
- 13.30: Environmental monitoring  
Marco Rijnbeek
- 15.00: Case study Environmental  
Monitoring  
Marco Rijnbeek
- 16.00: Pharmaceutical water systems  
and utilities  
Peter Vleugel
- 17.30: The gowning procedure  
Harm de Beer
- 18.30: Dinner

### Tuesday, 8 October 2019

**Themes: Sterilisation and disinfection  
Sterility assurance in practice**

- 08.30: Environmental monitoring: water  
monitoring  
Marco Rijnbeek
- 09.30: Sterilization methods: steam, dry  
heat  
Exercises for steam  
Wim van der Boon
- 10.30: Cleaning and disinfection  
Marco Rijnbeek
- 11.30: Sterilization methods: Filtration  
and alternative methods  
Wim van der Boon
- 12.30: Lunch
- 13.30: Case studies: Sterility Assurance  
in practice  
Jos Mathôt
- 15.45: Lean: application in sterility  
Assurance  
Marc Stegeman
- 18.00: Dinner

### Wednesday, 9 October 2019

**Themes: Validation and qualification  
The role of the QP**

- 09.00: Validation of aseptic processes  
Jos van der Lubbe
- 11.30: Validation of analytical methods  
Jos van der Lubbe
- 12.15: Operator Qualification, incl. case  
studies  
Jos van der Lubbe
- 13.00: Lunch
- 14.00: Workshop: the role of the QP in  
assuring the quality of sterile  
pharmaceuticals  
René Maassen
- 16.00: Evaluation of the course  
Jos Mathôt
- 16.30: Close



# PAOFarmacie

Netherlands Centre for Post Academic Education in Pharmacy

## Sterile manufacturing: a thorough discussion on sterility assurance challenges Faculty

### COURSE LEADER

Drs. J.H.A. (Jos) Mathôt

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### LECTURERS

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*ProPharma Group, Leiden, The Netherlands*

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*Vleugel Engineering, Anna Paulowna, the Netherlands*

### GENERAL INFORMATION

See last page for information on registration, dates and costs is available on the website of [www.paofarmacie.nl](http://www.paofarmacie.nl)

Select course **Quality Management**

For more information contact Hans Noordhuis, email address [h.noordhuis@paofarmacie.nl](mailto:h.noordhuis@paofarmacie.nl)

Netherlands Centre for Post-Academic Education in Pharmacy

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