Training Course Quality Management in Pharma and Biotech

M3: Sterile manufacturing: a thorough discussion on sterility assurance challenges.

PROGRAM 2019 - draft

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 **Social drink and dinner**

Tuesday, 8 October 2019

Themes: Sterilsation and desinfection
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 desinfection**
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 **Social drink and 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**