

Competition Clause: We ask you for your understanding that participants of competing companies cannot take part in the training course.

Tuesday, 4 September 2018

9:00 – 18:30

09:00 Welcome and Theory 1

- Monitoring particles in air
- Cleanroom classes and classification
- Principles of ISO 14644 1 and 2

10:30 Coffee Break

11:00 Theory 2

- Microbiological classification & monitoring of air, surfaces & personnel
 - ▷ Theory
 - ▷ Methods
- Examples of devices

12:15 Lunch Break

13:15 Theory 3

- Regulations and guidelines
 - ▷ GMP & EP/USP

14:00 Theory 4

- Brief inside on EU GMP New Annex 1 with focus on EM

14:30 Coffee Break

15:00 Hands-on 1

- Cleanroom 1: Realtime EM, Gowning exercise, contact plates surfaces / personnel
- Cleanroom 2: Devices, software demonstration
- Calibration lab: Calibration of devices, wind tunnel

15:45 Workshop 1

- Risk analysis
- Design of EM
- Discussion of workshop results

18:00 End of Day 1

18:30 Networking Dinner

Wednesday, 5 September 2018

8:30 – 15:30

08:30 Hands-on 2

- Cleanroom 1: Realtime EM, Gowning exercise, contact plates surfaces / personnel
- Cleanroom 2: Devices, software demonstration
- Calibration lab: Calibration of devices, wind tunnel

10:00 Coffee Break

10:30 Theory 5

- Deviations / investigations
- Data trending
- Data integrity

12:30 Lunch Break

13:30 Workshop 2

- Case studies (Discussion of findings on aseptic handling, data integrity, data trending for EM)

15:00 Wrap-up, Q&A

15:30 End of Course