

Tuesday, 15 October 2019

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, 16 October 2019

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**