

## Tuesday, 26 November 2019 9:00 – 17:15

**9:00 Welcome & Introduction of Participants**

**9:30 Introduction to Single-use Bioprocessing**

**10:00 GMP Update on SUS (Part 1)**

- Current GMP regulation
- FDA requirements
- Technical guidelines
- Regulatory expectations

**10:45 Coffee Break**

**11:00 Hands-on Exercise 1**

- Gowning
- Experiment on advantages of SUS

**12:30 Lunch Break**

**13:30 GMP Update on SUS (Part 2)**

- New Annex 1 requirements

**14:00 Basics in Single-use Bioprocessing**

- Manufacturing of SU Consumables
- Different bag functionalities
- Connection/disconnection technologies

**14:45 Coffee Break**

**15:00 Hand-on Exercise 2 (Cleanroom)**

- Bag handling (Storage and mixing bags)
- Connection/Disconnection

**17:00 Wrap-up Day 1**

**17:15 End of Day 1**

**Evening Social Event**

## Wednesday, 27 November 2019 8:30 – 16:30

**8:30 Sensors and Automation in Single-use Systems**

- Overview and demonstration

**9:15 Data Integrity, Data Analysis and Monitoring**

- Regulatory requirements and guidelines
- ALCOA
- Data Integrity for computer, paper and hybrid systems
- Control of meta-data
- Data integrity strategies for compliance
- Checking for Data Integrity issues in practice
- Experimental approach

**10:15 Coffee Break**

**10:30 GMP View on Media Preparation**

- GMP requirements
- Best practice in equipment and facility design

**11:15 Filtration & CCIT**

- Filter integrity testing
- CCIT for SUS
- GMP considerations

**12:15 Lunch Break**

**13:15 Hand-on Exercise 3**

- Media preparation
- Filter Integrity testing

**14:45 Coffee Break**

**15:00 Data Recording & Evaluation**

- Data logging
- Batch monitoring

**15:30 Filter Integrity Testing Fault Handling – GMP View**

- GMP requirements
- Pre- and Post-use integrity testing
- Impact of new EU GMP Annex 1 requirements

**16:00 Wrap-up**

**16:30 End of Training Course**

## Thursday, 28 November 2019 Optional Facility Tour

**8:30 Insight Into the Production of Bag Assemblies**

- Injection molding of components (e.g. connectors, filter housings, etc.)
- Production of 50 and 200 L bags for SU bioreactors (STR)

**9:30 Insight Into the Production of Filters**

- Membrane production
- Cartridge, capsule and filter modules production

**11:00 Coffee Break**

**11:15 Overview on Complete Single-use Bioprocesses From Molecule Development to Final Filling**

- Tour through the Application Center
- With option for further hands-on tests

**13:00 Farewell Lunch**

**14:00 End of Facility Tour**