Training Course Agenda

PDA EU00161 Single-Use-Systems – A New Age of Drug Making
CEST

Day 1, 13 June 2022	
13:00	**Arrival & Lunch**
14:00	**Campus tour**
18:30	**Dinner**

Day 2, 14 June 2022	
8:30	**Introduction of Participants, Safety Briefing**
9:00	**Introduction to Single-Use Bioprocessing**
9:45	**GMP Update on SUS (part 1)** • Current GMP Regulation • FDA Requirements • Technicalal Guidelines • Regulatory Expectations
10:30	*Coffee Break*
10:45	**GMP Update on SUS (part 2)** • **New Annex 1**
11:15	**Hands-on Exercise 1 (Cleanroom) (incl. 5 min lecture)** • Experiment on Advantages of SUS • Gowning
12:15	*Lunch Break*
13:15	**Basics in Single-Use Bioprocessing** • Manufacturing of Single-use Consumables • Different Bag Functionalities • Connection/Disconnection Technologies
14:15	*Coffee Break*
14:30	**Hand-on Exercise 2 (Cleanroom)** • Bag Handling (Storage and Mixing Bags) • Connection/Disconnection
16:30	**Wrap-up Day 1**
17:00	*End of Day 1*
18:30	*Dinner*

Day 3, 15 June 2022

8:30	**Sensors and Automation in Single-Use-Systems: Overview and Demonstration**
9:15	**Hands-on Exercise 3** • Media Preparation with Automated Sterile Filtration
10:15	*Coffee Break*
10:30	**Data Integrity, Data Analysis, and Monitoring** • Regulatory Requirements and Guidelines • ALCOA • Data Integrity for Computer, Paper, and Hybrid Systems • Control of Metadata • Data Integrity Strategies for Compliance • Checking for Data Integrity Issues in Practice • Experimental Approach
11:30	**Filtration & CCT** • Filter Integrity Testing in SUS • Bag Assembly Integrity Testing
12:15	*Lunch Break*
13:15	**Hand-on Exercise 4 (Cleanroom)**
14:00	**GMP Practical Session** • Failed Filter IT – what to do under GMP? • What are the Differences between Media Preparation and Final Filtration of a Drug Product prior Filling? • 'Bioburden Reduction' vs. 'Sterile Filtration'
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 GMP Annex 1 Requirements
16:00	**Wrap-up**
16:30	*End of Training Course*