Training Course Agenda

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

CEST

Day 1, 09 May 2023	
13:00	**Arrival & Lunch**
14:00	**Campus and Application Center Tour**
19:00	**Dinner at Restaurant Mazzoni Cucina e Vino** **Hermann-Rein-Str. 2** **37075 Göttingen**
Day 2, 10 May 2023	
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 Focus on Bags** • Manufacturing of Single-use Consumables • Different Bag Functionalities
14:15	***Coffee Break***
14:30	**Hands-on Exercise 2 (Cleanroom)** • Connect Opta/AQ and Welding • Disconnect Clipster and Sealer • Connection/Disconnection
16:30	**Wrap-up Day 1**
17:00	***End of Day 1***

19:00	***Dinner at Restaurant Bullerjahn*** ***im Ratskeller Göttingen*** ***Markt 9*** ***37073 Göttingen***
Day 3, 11 May 2023	
8:30	**Sensors and Automation in Single-Use-Systems: Overview and Demonstration**
9:15	**Hands-on Exercise 3** • Overview Bag Types
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 Meta data • Data Integrity Strategies for Compliance • Checking for Data Integrity Issues in Practice • Experimental Approach
11:30	***Lunch Break***
12:15	**Filtration & CCT** • Filter Integrity Testing in SUS • Bag Assembly Integrity Testing
13:15	**Hand-on Exercise 4 (Cleanroom)** • Filter Integrity Testing
14:00	***Coffee Break***
14:15	**Filter Integrity Testing fault handling – GMP view** • **GMP requirements** • **Pre- and Post-use integrity testing** • **Impact of new EU GMP Annex 1 requirements**
14:45	**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'
15:30	**Data Recording & Evaluation** • Data Logging • Batch Monitoring
16:00	**Wrap-up**
16:30	***End of Training Course***