

Training Course Agenda

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

CEST

| Day 1, 30 September 2024 | |
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| 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, 1 October 2024 | |
| 8:30 | Introduction of Participants, Safety Briefing |
| 9:00 | Introduction to Single-Use Bioprocessing |
| 9:45 | GMP Update on SUS (part 1) <ul style="list-style-type: none"> • Current GMP Regulation • FDA Requirements • Technical Guidelines • Regulatory Expectations |
| 10:30 | <i>Coffee Break</i> |
| 10:45 | GMP Update on SUS (part 2) <ul style="list-style-type: none"> • New Annex 1 |
| 11:15 | Hands-on Exercise 1 (Cleanroom) (incl. 5 min lecture) <ul style="list-style-type: none"> • Experiment on Advantages of SUS • Gowning |
| 12:15 | <i>Lunch Break</i> |
| 13:15 | Basics in Single-Use Bioprocessing Focus on Bags <ul style="list-style-type: none"> • Manufacturing of Single-use Consumables • Different Bag Functionalities |
| 14:15 | <i>Coffee Break</i> |
| 14:30 | Hands-on Exercise 2 (Cleanroom) <ul style="list-style-type: none"> • Connect Opta/AQ and Welding • Disconnect Clipster and Sealer • Connection/Disconnection |
| 16:30 | Wrap-up Day 1 |
| 17:00 | OPTIONAL: Virtual Reality Demo: Operator Training - BioWelder or Mixing Demo |
| 18:00 | <i>End of Day 1</i> |

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| 19:00 | Dinner at Restaurant Kartoffelhaus Goetheallee 8 37073 Göttingen |
| Day 3, 2 October 2024 | |
| 8:30 | Sensors and Automation in Single-Use-Systems: Overview and Demonstration |
| 9:15 | Hands-on Exercise 3 <ul style="list-style-type: none"> • Overview Bag Types |
| 10:15 | Coffee Break |
| 10:30 | Data Integrity, Data Analysis, and Monitoring <ul style="list-style-type: none"> • 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 | Data Recording & Evaluation <ul style="list-style-type: none"> • Data Logging • Batch Monitoring |
| 12:00 | Lunch Break |
| 13:00 | Filtration & CCT Hands-on Exercise 4 (Cleanroom) <ul style="list-style-type: none"> • Filter Integrity Testing in SUS • Bag Assembly Integrity Testing • Transferset for Final Filling & PUPSIT |
| 14:30 | Coffee Break |
| 14:45 | Filter Integrity Testing fault handling – GMP View <ul style="list-style-type: none"> • GMP Requirements • Pre- and Post-use integrity testing • Impact of new EU GMP Annex 1 requirements |
| 15:15 | GMP Practical Session <ul style="list-style-type: none"> • 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’ |
| 16:00 | Wrap-up |
| 16:30 | End of Training Course |