2020 PDA EUROPE TRAINING

Single-Use Systems – A New Age of Drug Making

Using Single-Use Systems in GMP-Regulated Biomanufacturing – A Practical Approach

SARTORIUS STEDIM BIOTECH
GÖTTINGEN, GERMANY

OPTION 1: **26-27 MAY 2020**
FACILITY TOUR: 28 MAY

OPTION 2: **1-2 SEPTEMBER 2020**
FACILITY TOUR: 3 SEPTEMBER

OPTION 3: **24-25 NOVEMBER 2020**
FACILITY TOUR: 26 NOVEMBER

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In the biomanufacturing world, a huge diversification of products takes place with new therapeutic approaches rising up. Novartis e.g. recently released a new gene therapy drug for two Million Euros per dose, while other companies are still in the development phase for drugs targeting the same disease. Wouldn't it be great for them to have released these drugs faster to be the first one and to make two Million Euros per dose themselves? And what technologies might have helped to reach this goal?

One possibility to get drugs faster to the market is the use of single-use systems. But are they robust enough, when the product contact layer is made from polymers? And what will the authorities say? If the equation SUS plus GMP results in SOS to you, then you should sign up to this two-day course. Here you will learn and discuss with technical trainers and specialists for data handling and GMP regulations how to implement and operate single-use technologies in a GMP-controlled environment.

During an optional third day you can have a look into the manufacturing of single-use bioreactor bags and filters, followed by a visit in the Sartorius Application Center where you can see and test complete process solutions from molecule discovery to large scale biomanufacturing.

Who Should Attend

- Operators
- Manufacturing Supervisors
- QA Managers
- Manufacturing Managers
- QC Managers
- Auditors

Learning Objectives

Upon completion of the training course the participants

- have understood the regulations and relevant guidelines for single-use system (SUS) handling
- can explain basics in single-use processing, bag functionalities, connection-disconnection technologies
- can operate bags, tubings, filters and sensors
- have understood Data Integrity and Data Analysis / Monitoring for SUS handling
- have understood possible setups for filter and single-use system integrity in single-use assemblies

WELCOME TO SARTORIUS STEDIM BIOTECH

Ralf Schneider, *PhD, Application Center Manager, Sartorius Stedim Biotech*

Ralf Schneider studied Biotechnology at the University of Applied Sciences Weihenstephan, Freising (Germany) and received a PhD in Biochemistry from the University of Oxford (United Kingdom). After four years of academic research at the Max-Planck-Institute of Molecular Physiology, Dortmund (Germany) he established a new laboratory for customer trials on Sartorius systems for bioprocessing. With now more than six years of experience he is a technical expert to consult his visitors on complete single-use solutions for molecule & process development and large scale biomanufacturing. Ralf teaches in a training course on single-use process systems for several years.

Dominic Parry, *Managing Director, Inspired Pharma Training*

Dominic Parry has worked in the pharmaceutical industry since 1992 and is a leading pharmaceutical quality management specialist. He initially worked for Evans Medical Limited (now Novartis Vaccines) as a Production Development Scientist. He then moved to Hoechst Marion Roussel (now Patheon UK) where he worked as a Quality Assurance Officer and then Validation Manager for the sterile manufacturing operations. Over the past 15 years he has worked as a leading pharmaceutical trainer and Quality Management System specialist. He works closely with pharmaceutical companies and their suppliers on evaluating, developing and continually improving their quality systems so that they add real-value to organisations. Dominic is Managing Director of Inspired Pharma Training, a GXP and Quality Management training company.

Franziska Klingenberg, *Single-use Technologies Expert, Sartorius Stedim Biotech*

Franziska Klingenberg has worked since 2012 in various roles focussing on single-use technologies and their implementation within the biopharmaceutical industry. As Single Use Technologies Expert for Key Accounts, she works closely with the process experts and end users on designing and implementing a single-use strategy for their clinical and commercial operations.In her role she works closely with biopharmaceutical companies on evaluating, developing and continually improving their single-use technology footprint. Franziska holds a M.Sc. in Biotechnology of the University of Applied Sciences Koethen (Germany) as well as a B.B.A. in International Business Administration of the University of Applied Sciences Zeeland (Netherlands).

Timo Schmidberger, *Data Scientist, Sartorius Stedim Biotech*

Having been awarded his MSc in Bioprocess Analytics, Timo Schmidberger started his career at Sandoz, Austria as a Scientist. He was involved in the development, optimization and characterization of industrial cell culture processes. After receiving a PhD in Biotechnology in 2014 for his work in process analytical technology, he held several positions in development and quality control within Novartis. Currently Timo Schmidberger holds a position as Data Scientist at Sartorius Stedim Biotech.

Day 1 — 9:00 – 17:15

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

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

10:15 **Coffee Break**

10:30 **GMP Update on SUS (Part 1)**
- Current GMP regulation
- FDA requirements
- Technical guidelines
- Regulatory expectations

11:15 **Hands-on Exercise 1**
- Experiment on advantages of SUS

12:00 **Lunch Break**

13:00 **GMP Update on SUS (Part 2)**
- New Annex 1
- Cleanroom design

13:30 **Basics in Single-use Bioprocessing**
- Manufacturing of SU 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 **Evening Social Event**

Day 2 — 8:30 – 16:15

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

9:15 **Hand-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 meta data
- Data integrity strategies for compliance

11:30 **Filtration & Single-use Integrity**
- Filter integrity testing in SUS
- Bag Assembly Integrity Testing

12:15 **Lunch Break**

13:15 **Hands-on Exercise 4**
Filter integrity testing

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 & Viewing in SCADA**
- Using data from media prep experiment and filter IT hands-on

15:45 **Wrap-up**

16:15 **End of Training Course**

Day 3 — Optional Facility Tour

8:30 **Sartorius Site Visit Including Lunch**
Bag production
Filter production
Membrane production

14:00 **End of Facility Tour**

HOTEL NEARBY

PDA Europe recommends the reservation at the following hotel. The general terms of business are valid.

Best Western Hotel Am Papenberg
Hermann-Rein-Straße 2,
37075 Goettingen
Tel: +49 551 30550
https://bit.ly/2Kbhmsl

DIRECTIONS

© Google For directions click on the picture, scan the QR-code or go to **http://bit.ly/2K8QEAC**

TRAINING COURSE LOCATION

Sartorius Stedim Biotech
-Sartorius Campus-
Otto-Brenner Str. 20
37079 Goettingen

Registration Customer Care
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GENERAL ADDRESS

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PDA EUROPE EDUCATION PROGRAM

2020

18-20 February	Understanding Sterilization	TC	Albuzzano, Italy
27 February	Container Closure Development	TC	Basel, Switzerland
27-28 February	Extractables and Leachables	TC	Basel, Switzerland
27-28 February	Container Closure Integrity Testing – Basic Course	TC	Basel, Switzerland
27-28 February	CCIT for the Advanced User	TC	Wohlen, Switzerland
9-13 March	Freeze Drying in Practice	TC	Osterode am Harz, Germany
17-18 March	All About Virus Filtration	TC	Cologne, Germany
23-24 April	An Introduction to Visual Inspection	TC	Berlin, Germany
23-24 April	Mastering Automated Visual Inspection	TC	Berlin, Germany
26-27 May	Single-Use Systems – A New Age of Drug Making	TC	Göttingen, Germany
23 June	Practical Application of Risk-Based GMP and Quality Principles to Clinical Development of ATMPs	TC	Brussels, Belgium

Subject to change | For latest info: **europe.pda.org** | Shortlist 24 Jan 2020

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PDA EUROPE EVENTS

2020

25-26 February	Parenteral Packaging	*	Basel, Switzerland
21-22 April	Visual Inspection Forum	*	Berlin, Germany
9-10 June	Quality and Regulations Conference	*	Dublin, Ireland
22-23 June	Virus Forum	*	Brussels, Belgium
24-25 June	Advanced Therapy Medicinal Products	*	Brussels, Belgium
8-9 September	Medical Devices and Connected Health	*	Madrid, Spain
22-23 September	BioManufacturing	*	Dublin, Ireland
24-25 September	Pharmaceutical Freeze Drying Technology	*	Dublin, Ireland
20-21 October	Aseptic Animal Health	*	The Hague, The Netherlands

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