2019 PDA EUROPE TRAINING

Single-Use Systems – A New Age of Drug Making

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

26 - 27 NOVEMBER 2019
SARTORIUS STEDIM BIOTECH
GÖTTINGEN, GERMANY
FACILITY TOUR: 28 NOVEMBER

CONNECTING PEOPLE SCIENCE AND REGULATION®

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 container closure integrity testing 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.

Kai Touw, *Market Manager (Bio)Pharma, Sartorius Stedim Biotech*

Kai Touw works as Biopharma Market Manager at Sartorius Stedim Data Analytics. Within this function he works on the application of advanced data analytics in the biomanufacturing industry and how process data can be used for simulation and statistical modelling for process design and control. Before taking up this role Kai has been working on process intensification and next generation facility concepts as a Process Development Consultant at Sartorius Stedim Biotech. Furthermore, he has over 10 years of PD experience, working at Janssen Vaccines & Prevention (former Crucell) in Leiden (NL) on the development and scale-up of an intensified production platform for viral vectors. Kai holds an engineering degree from the technical university of Delft (NL).

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.

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).

30 Jul 2019

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**

HOTEL NEARBY

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

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**

VENUE

Sartorius Stedim Biotech
-Sartorius Campus-
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37079 Goettingen

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Education Program Inquiries
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For contact at PDA Europe
registration-europe@pda.org

3 WAYS TO REGISTER

1. **online: pda.org/EU/TC-SUS19**
2. **FAX: + 49 30 436 55 08-66**
3. **Email: registration-europe@pda.org**

This PDF-file provides an automatic fill-in function. Your signature, however, is needed in writing.

1 Your Contact Information

If this form is an update to a previously submitted form, please check here. ☐

☐ Mr. ☐ Ms. ☐ Dr. ☐ Nonmember ☐ **I want to become a PDA Member.**

☐ PDA Member ID Number

Name (Last, First, MI)

Job Title

Company Department

Mailing Address

City Postal Code

Country Email

Business Phone Fax

☐ Substituting for

(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the membership fee.)

3 Information about Visa Matters

- All registrations which will involve visa matters will have to be submitted to PDA EU four weeks prior to the start of the event at the latest. For later registrations, PDA Europe will be unable to assist participants in any visa affairs.
- All costs incurring in connection with visa affairs shall be borne by registrants. (This applies in particular to costs for submitting documents by courier.)
- Potential participants must be clients of UPS shipping agency and submit their UPS customer reference number to PDA EU (together with their registration).

3 Registration

All fees given in Euro, tax exempt in Germany

Training Course
(26 - 27 November 2019)
All Participants ☐ **1595**

Optional Facility Tour 28 November 2019 ☐

Your consent is important. We manage your personal data responsibly.
For more information, please visit pda.org/privacy-policy
RESPONSE REQUIRED – By checking the box(es) below, I consent to:

- ☐ My contact information (name, company, job title, city, state, country) being printed on the attendee list distributed at the event.
- ☐ PDA recording and/or photographing me and using those recordings and/or photographs in future PDA promotional and marketing materials.
- ☐ PDA sending me promotional information via email.
- ☐ PDA sending me promotional information via post

The fee includes course documentation as well as mid-session refreshments and lunch. Excellent networking opportunities with snacks and drinks will be given. The fee does not include the hotel accommodation. PDA Europe has secured a limited number of rooms at a special group rate.

4 Payment Options

☐ **By Credit Card**
☐ American Express ☐ MasterCard ☐ VISA

For your credit card information safety:
Please send your details by fax only (+ 49 30 436 55 08-66) or register online.

☐ **By Bank Transfer**
Beneficiary: PDA Europe gGmbH
IBAN: DE73 1007 0024 0922 8735 00
BIC (SWIFT-Code): DEUTDEDBBER
Bank Address: Deutsche Bank, Welfenallee 3-7, D-13465 Berlin, Germany

☐ **By Purchase Order** Purchase Order Number

PDA Europe VAT I.D.: DE254459362

Billing Address: ☐ Same as contact information address above. If not, please send your billing address to: **registration-europe@pda.org**

Your Company VAT I.D.:

This number starts by your country code with two characters
(example: PDA Europe's country code starts with: DE | followed by the number)

Date Mandatory Signature

CONFIRMATION: Transmitting your filled-in registration form constitutes a binding application for the specific event. PDA Europe will send you a confirmation including payment details. **A legally binding contract is concluded once PDA Europe has sent a written invoice by mail to you.** A letter of confirmation will be sent to you within one week once payment has been received. You must have this written confirmation to be considered enrolled for this PDA event. PDA Europe reserves the right to deny access to anyone unable to provide written confirmation that all dues have been fully settled. **SUBSTITUTIONS:** If you are unable to attend, substitutions are welcome and can be made at any time, including on site at the prevailing rate. If you are registering as a substitute attendee, please indicate this on the registration form. Changes are free of charge until 2 weeks prior to the start of the event. After this two-weeks period, there will be a charge of € 100 excl. VAT per name change. **REFUNDS: Refund requests must be sent to PDA Europe.** If your written request is received on or before **27 October 2019** you will receive a full refund minus a 150 € excl. VAT handling fee. After that time, no refund or credit requests will be approved. If you are an unpaid registrant and do not attend the event, you are responsible for paying the registration fee. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. PDA Europe works PCI-Compliant. **EVENT CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at **registration-europe@pda.org or fax to + 49 30 436 55 08-66.**

PDA EUROPE EVENTS

2019

2 September 2 September **3-4 September** 5 September	Interest Group Meeting Freeze Drying Interest Group Meeting Technology Transfer **BioManufacturing** Interest Group Meeting Vaccines	* **Munich, Germany**
2 September **5 September**	Interest Group Meeting Technology Transfer **Project Management in the Pharmaceutical Industry**	* **Munich, Germany**
24-25 September	**Pharmaceutical Freeze Drying Technology**	* **Berlin, Germany**
24-25 September	**Particles in Injectables**	* **Berlin, Germany**
 21 October 21 October 21 October **22-23 October**	Workshops: Innovating the Journey from Manufacturing to the Patient Innovative Drug Delivery Systems/Combination Products Impact of Pre-filled Syringe Components on Biopharmaceuticals **The Universe of Pre-filled Syringes and Injection Devices**	* **Gothenburg, Sweden**
12-13 November 14 November	**Pharma Logistics & Outsourced Operations** Interest Group Meeting Supply Chain Management	* **Lisbon, Portugal**

2020

25-26 February	**Parenteral Packaging**	* **Basel, Switzerland**
21-22 April	**Visual Inspection Forum**	* **Berlin, Germany**

Subject to change

For latest info: **europe.pda.org**

Shortlist 30 Jul 2019

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