

2019 PDA EUROPE TRAINING

# Mastering Environmental Monitoring



**15-16 OCTOBER 2019**  
**WATTWIL, SWITZERLAND**

# Training & Education Program

europa.pda.org



**PDA** Education offers courses that are developed and taught by experts. They are uniquely targeted to professionals involved in the development and manufacturing of quality pharmaceutical and biopharmaceutical products.

## Facts that Make a Difference

-  Up-to date training courses and workshops taught by internationally renowned experts
-  Wide range of training courses with hands-on experience to drive expertise, awareness, and innovation
-  Customized in-house training courses and workshops available



# Welcome to Switzerland



# Mastering Environmental Monitoring

## A Hands-on Training Course

### Overview

Environmental Monitoring (EM) is one of the key pillars to ensure aseptic manufacturing. It covers particle measurement and hygiene monitoring (air and surface sampling). This two-day course is set up as a highly interactive event with hands-on lab training sessions and workshop sessions on risk analysis and design of Environmental Monitoring. The lecture part will cover current regulations, methods and devices. All participants are invited to bring their own case studies or audit findings and questions to be discussed in the group. The group has the unique opportunity to visit the calibration lab of CAS to see calibration of devices in action.

### Who Should Attend

This course is designed for

- Lab Staff
- Lab Supervisors
- Manufacturing Supervisors
- QC Managers
- QA Managers
- Manufacturing Managers
- Auditors and Regulators

### Learning Objectives

Upon completion of this course the participants

- have understood the principles of EM
- can explain different methods of EM (microbial, particles), standard and advanced methods
- have understood basic designs of EM program in facility or clean room
- are able to give input to / perform a risk analysis
- have understood impact of operator behaviour in cleanroom on EM
- can operate EM devices
- have understood principles of data trending and integrity
- have understood current guidelines and regulations (including Annex 1 revision)

### Faculty



**Frank Panofen, PhD, Senior Consultant, Particle Measuring System**

Over the last 15 years with Merck, Frank Panofen gained proven expertise in traditional microbiological topics like sterility testing and bioburden analytics and a long experience on the implementation and development of new rapid technologies for the pharmaceutical industry. Today, Frank is the Product Line Manager for Sterility Assurance/Microbiology products at Particle Measuring Systems, globally responsible for all products related to industrial microbiological testing, with a strong focus on environmental monitoring. He is certified Microbiological Laboratory Manager from ECA. Frank gained a Diploma in Chemistry from the University of Bielefeld and a PhD in molecular and cell biology from the University of Osnabrück.



**Gilberto Dalmaso, PhD, Global Pharma Customer Advisory Team Manager, Particle Measuring Systems**

Gilberto Dalmaso has over 25 years' experience in pharmaceutical microbiology and sterility assurance, primarily with GlaxoSmithKline (GSK) where he started in 1984. Over his last five years with GSK, Gilberto led a series of initiatives implementing Process Analytical Technologies (PAT) and Rapid Microbial Methods (RMM). Today Gilberto is the Senior Advisor and Global Pharma Customer Advisory Team Manager for Particle Measuring Systems. In this role and with his team of subject matters experts, he collaborates and consults with pharmaceutical companies to develop and implement science-based strategies and processes that utilize Quality by Design (QbD) principles to monitor, control, and improve the chemical, physical, and microbiological state of various production processes.



**Marcel Goverde, PhD, Managing Director, MGP Consulting**

Marcel Goverde gathered first work experience as scientific collaborator in the agro biological section of Novartis. From 2002-2010 he led several QC labs for microbiology at F. Hoffmann-La Roche Ltd. From 2010-2011 Marcel worked as a QC expert for microbiology at Novartis Pharma Ltd. Since 2011 he leads his own business for consulting, training, project and deviation management named MGP Consulting GmbH. Marcel is a regular speaker at different institutions and has written several scientific papers. He is the Swiss expert in the EDQM group for modern microbiological methods since 2003. Marcel studied biology at the University of Basel, where he gained his PhD in 2001.

**Tuesday, 15 October 2019**

**9:00 – 18:30**

- 09:00 Welcome and Theory 1**
- Monitoring particles in air
  - Cleanroom classes and classification
  - Principles of ISO 14644 1 and 2

**10:30 Coffee Break**

- 11:00 Theory 2**
- Microbiological classification & monitoring of air, surfaces & personnel
    - ▷ Theory
    - ▷ Methods
  - Examples of devices

**12:15 Lunch Break**

- 13:15 Theory 3**
- Regulations and guidelines
    - ▷ GMP & EP/USP

- 14:00 Theory 4**
- Brief inside on EU GMP New Annex 1 with focus on EM

**14:30 Coffee Break**

- 15:00 Hands-on 1**
- Cleanroom 1: Realtime EM, Gowning exercise, contact plates surfaces / personnel
  - Cleanroom 2: Devices, software demonstration
  - Calibration lab: Calibration of devices, wind tunnel

- 15:45 Workshop 1**
- Risk analysis
  - Design of EM
  - Discussion of workshop results

**18:00 End of Day 1**

**18:30 Networking Dinner**

**Wednesday, 16 October 2019**

**8:30 – 15:30**

- 08:30 Hands-on 2**
- Cleanroom 1: Realtime EM, Gowning exercise, contact plates surfaces / personnel
  - Cleanroom 2: Devices, software demonstration
  - Calibration lab: Calibration of devices, wind tunnel

**10:00 Coffee Break**

- 10:30 Theory 5**
- Deviations / investigations
  - Data trending
  - Data integrity

**12:30 Lunch Break**

- 13:30 Workshop 2**
- Case studies (Discussion of findings on aseptic handling, data integrity, data trending for EM)

**15:00 Wrap-up, Q&A**

**15:30 End of Course**

## TRAINER

### Frank Panofen,

*PhD, Senior Consultant, Particle Measuring System*

### Gilberto Dalmaso,

*PhD, Global Pharma Customer Advisory Team Manager,  
Particle Measuring Systems*

### Marcel Goverde,

*PhD, Managing Director, MGP Consulting*

## CONTACT INFORMATION

### Registration Customer Care

Tel: +49 30 436 55 08-10

[registration-europe@pda.org](mailto:registration-europe@pda.org)

### Education Program Inquiries

#### **Elke von Laufenberg**

[training-europe@pda.org](mailto:training-europe@pda.org)

## GENERAL ADDRESS

PDA Europe gGmbH

Am Borsigturm 60

13507 Berlin, Germany

Tel: +49 30 436 55 08-0

Fax: +49 30 436 55 08-66

## VENUE

### CAS AG

Reinluftweg 1

9630 Wattwil

Switzerland

## HOTEL NEARBY

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

### Hotel-Restaurant Sternen

Hauptstrasse 289650 Nesslau

Switzerland

Tel: +41 71 994 19 13

[sternen-nesslau.ch/content/hotel/lang/en](http://sternen-nesslau.ch/content/hotel/lang/en)

Located in the village of Nesslau, Hotel-Restaurant Sternen serves traditional Swiss cuisine and features a modern bowling alley and private fishing waters on the nearby Thur River.

All rooms have a balcony with mountain and river views, a seating area with a flat-screen satellite TV, and a bathroom.



## 3 WAYS TO REGISTER

- 1 online: [pda.org/EU/EM2019](http://pda.org/EU/EM2019)
- 2 FAX: + 49 30 436 55 08-66
- 3 Email: [registration-europe@pda.org](mailto:registration-europe@pda.org)

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

GENERAL ADDRESS:

PDA Europe gGmbH | Am Borsigturm 60 | 13507 Berlin, Germany | Tel: + 49 30 436 55 08-0 | Fax: + 49 30 436 55 08-66

### 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. Please send me a subscription form  
 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.)

### 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).

### 2 Registration

All fees given in Euro and excluding VAT (7,7 %)

#### Two-Day Training Course (15-16 October 2019)

Mastering Environmental Monitoring

1695

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.

#### Your consent is important. We manage your personal data responsibly.

For more information, please visit [pda.org/privacy-policy](http://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

### 3 Payment Options

#### By Credit Card

American Express     MasterCard     VISA

#### For your credit card information safety:

Please send your details by fax only (+49 30 4365508-66) or register online.

#### By Bank Transfer

**Beneficiary:** PDA Europe gGmbH

**IBAN:** DE73 1007 0024 0922 8735 00

**BIC (SWIFT-Code):** DEUTDE33HAN

**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](mailto: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 **15 September 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](mailto:registration-europe@pda.org) or fax to + 49 30 436 55 08-66.

# PDA EUROPE EVENTS



## 2019

16-17 May	<b>Pharmacopoeia</b>	★ Geneva, Switzerland
22-24 May 24 May	<b>Visual Inspection Week</b> Interest Group Meeting Visual Inspection	★ Berlin, Germany
4-5 June	<b>Advanced Therapy Medicinal Products</b>	★ Vilnius, Lithuania
24 June 24 June 25-26 June	Workshop: The Digital Robot Pharma Fab Interest Group Meeting Quality Systems <b>4<sup>th</sup> PDA Europe Annual Meeting</b>	<b>Amsterdam, The Netherlands</b>
2 September <b>3-4 September</b> 5 September	Interest Group Meeting Freeze Drying <b>BioManufacturing</b> Interest Group Meeting Vaccines	★ Munich, Germany
2 September <b>5 September</b>	Interest Group Meeting Technology Transfer <b>Project Management in the Pharmaceutical Industry</b>	★ Munich, Germany
<b>24-25 September</b>	<b>Pharmaceutical Freeze Drying Technology</b>	★ Berlin, Germany
<b>24-25 September</b>	<b>Particles in Injectables</b>	★ Berlin, Germany
21 October 21 October 21 October <b>22-23 October</b>	Workshops: Impact of Pre-filled Syringe Components on Biopharmaceuticals Innovating the Journey from Manufacturing to the Patient Innovative Drug Delivery Systems/Combination Products <b>The Universe of Pre-filled Syringes and Injection Devices</b>	★ Gothenburg, Sweden
<b>12-13 November</b>	<b>Pharma Logistics &amp; Outsourced Operations</b>	★ Lisbon, Portugal

Subject to change

For latest info: [europe.pda.org](http://europe.pda.org)

Shortlist 17 Apr 2019