

The Parenteral Drug Association presents:

Mastering Environmental Monitoring



4-5 September 2018
Wattwil | Switzerland

Training & Education Program

europe.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.

Competition Clause: We ask you for your understanding that participants of competing companies cannot take part in the training course.

Tuesday, 4 September 2018

9:00 – 18:30

| | |
|---|--|
| <p>09:00</p> <p>Welcome and Theory 1</p> <ul style="list-style-type: none"> Monitoring particles in air Cleanroom classes and classification Principles of ISO 14644 1 and 2 | <p>15:00</p> <p>Hands-on 1</p> <ul style="list-style-type: none"> Cleanroom 1: Realtime EM, Gowning exercise, contact plates surfaces / personnel Cleanroom 2: Devices, software demonstration Calibration lab: Calibration of devices, wind tunnel |
| <p>10:30</p> <p>Coffee Break</p> | |
| <p>11:00</p> <p>Theory 2</p> <ul style="list-style-type: none"> Microbiological classification & monitoring of air, surfaces & personnel <ul style="list-style-type: none"> ▷ Theory ▷ Methods Examples of devices | <p>15:45</p> <p>Workshop 1</p> <ul style="list-style-type: none"> Risk analysis Design of EM Discussion of workshop results |
| <p>12:15</p> <p>Lunch Break</p> | <p>18:00</p> <p>End of Day 1</p> |
| <p>13:15</p> <p>Theory 3</p> <ul style="list-style-type: none"> Regulations and guidelines <ul style="list-style-type: none"> ▷ GMP & EP/USP | <p>18:30</p> <p>Networking Dinner</p> |
| <p>14:00</p> <p>Theory 4</p> <ul style="list-style-type: none"> Brief inside on EU GMP New Annex 1 with focus on EM | |
| <p>14:30</p> <p>Coffee Break</p> | |

Wednesday, 5 September 2018

8:30 – 15:30

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|--|--|
| <p>08:30</p> <p>Hands-on 2</p> <ul style="list-style-type: none"> Cleanroom 1: Realtime EM, Gowning exercise, contact plates surfaces / personnel Cleanroom 2: Devices, software demonstration Calibration lab: Calibration of devices, wind tunnel | <p>12:30</p> <p>Lunch Break</p> |
| <p>10:00</p> <p>Coffee Break</p> | <p>13:30</p> <p>Workshop 2</p> <ul style="list-style-type: none"> Case studies (Discussion of findings on aseptic handling, data integrity, data trending for EM) |
| <p>10:30</p> <p>Theory 5</p> <ul style="list-style-type: none"> Deviations / investigations Data trending Data integrity | <p>15:00</p> <p>Wrap-up, Q&A</p> |
| | <p>15:30</p> <p>End of Course</p> |

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

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VENUE

CAS AG

Reinluftweg 1

9630 Wattwil

Switzerland

RECOMMENDED HOTEL

PDA Europe recommends the reservation at the following hotel. A transfer during the event from the venue CAS Clean-Air-Service AG and to this hotel is guaranteed. The general terms of business are valid at the hotel.

Hotel-Restaurant Sternen

Hauptstrasse 289650 Nesslau

Switzerland

Tel: +41 71 994 19 13

<http://sternen-nesslau.ch/content/hotel/lang/en>

Special rates

PDA Europe has reserved a limited number of rooms until the 5th August 2018.

Book your room via E-Mail (sternen-nesslau@bluewin.ch) or by Phone for the PDA Group Rate: PDA/CASSingle Room 76.50 CHF per night*

*Rates include the following services and benefits free of charge: Buffet Breakfast in the restaurant, Wireless Internet Connection (Wi-Fi). Taxes and Service will apply

Parking

Free parking available on site.

3 WAYS TO REGISTER

- 1 ONLINE: pda.org/EU/EM2018
- 2 FAX: +49 30 4365508-66
- 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. 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.)

* This information will be published in the conference attendee list. Should you not wish us to publish these details, please contact us.

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 (4-5 September) Mastering Environmental Monitoring

All Participants **1595**

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.

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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): DEUTDE33
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 **5 August 2018** 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 4365508-66. **DOCUMENTATION:** With your signature you give complete picture usage right to PDA and allow to film your exhibition space and intervention in the event, including the recording of your presentation for video purposes (with your slides, voice and image). This right extends also to the use of the resulting images in film documentation for webinars and similar items produced by PDA.

2018 PDA EUROPE EVENTS

15-16 October **Pharmaceutical Microbiology** ★ Berlin, Germany

23-24 October **Visual Inspection Forum** ★ Berlin, Germany

6-7 November **Outsourcing & Supply Chain - A 360° View** ★ Seville, Spain

22 November **Project Management in the Pharmaceutical Industry – Challenges & Possibilities** ★ Berlin, Germany

27-28 November **Pharmaceutical Freeze Drying Technology** ★ Seville, Spain

27-28 November **11th Workshop on Monoclonal Antibodies** ★ Seville, Spain

2019 PDA EUROPE EVENTS

19-20 March **Parenteral Packaging** ★ Venice, Italy

Subject to change

For latest info: europe.pda.org

Shortlist 12 Jul 2018

★ Events with additional Education Program. More information – <http://t1p.de/7p9z>

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