The Parenteral Drug Association presents...

2013 PDA Europe Pharmaceutical Microbiology

Product Quality Microbiology – Keys for Successful Implementation

Register by 4 Jan 2013 and SAVE!

26-27 February 2013

Hotel Marriott
Berlin | Germany

CONFERENCE 26-27 Feb | **EXHIBITION** 26-27 Feb | **TRAINING COURSES** 28 Sep-1 Mar

https://europe.pda.org/Microbio2013

Letter from the Chairs

Dear Colleagues,

On behalf of the program planning committee, we are delighted to invite you to attend the **PDA Europe 4th Conference on Pharmaceutical Microbiology** which will take place in Berlin on 26-27 February 2013. Following the conference training courses covering Rapid Microbiological Methods, Biofilm and Contamination Control are offered.

The theme that we have chosen for this year conference is "Product Quality Microbiology – Keys for Successful Implementation" and a comprehensive program will include presentations from regulatory, industry and technology representatives from around the world.

Some of the highlights of the conference include:

- Rapid Microbiological Methods including validation of the methods
- Biofilms and water systems
- Environmental monitoring
- Contamination control
- Open panel discussion with regulators

Of equal importance to the content is to interact with the speakers and your fellow attendees. Morning and afternoon refreshment breaks will offer occasions to visit the exhibitors and to meet with other microbiologists. On-site lunch and evening receptions will also provide ample networking opportunities.

We look forward welcoming you to an informative and enjoyable conference.

Sincerely,

Michael Miller,
Co-Chair of Conference, Microbiology Consultants

Jette Christensen,
Co-Chair of Conference, Novo Nordisk

Scientific Planning Committee

Michael Miller, *Co-Chair, Microbiology Consultants*
Jette Christensen, *Co-Chair, Novo Nordisk*
Sandra Gay, *bioMérieux*
Subho Goswami, *BD Diagnostics*
Robert Mello, *FDA USA*
Barbara Gerten, *Merck*
Georg Roessling, *PDA Europe*
Bernd Krippner, *PDA Europe*

Who Should Attend

Departments
Microbiology, Compliance, Engineering, Manufacturing, QA/QC, CMC Documentation, Regulatory Affairs, Research and Development, Validation, QP
Level of Expertise
Senior Subject Matter Expert, Management, Scientists/ Technicians
Job Function
Supervisor, Researcher, Analyst, Operative Personnel

Venue

Berlin Marriott Hotel
Inge-Beisheim-Platz 1
10785 Berlin
Germany
Tel.: +49 30 22000-2090
Fax: +49 30 22000-2100
Email: berlin@marriotthotels.com
Website: www.marriotthotels.com

Special rates
Single Room: **€165***
Double room: **€185***
* Rates per room and night, breakfast included.

Room Reservations
PDA has secured a limited number of rooms at a special group rate until **25 January 2013, Code: PDA.**

Reservation link: **Marriott Hotel**

Housing at the selected hotel will be in high demand, so we strongly recommend making your reservations early.

Contacts

For additional conference information please contact:
PDA Europe gGmbH
Adalbertstr. 9
16548 Glienicke/ Berlin, Germany
Tel: +49 (0) 33056 - 23 77 10
Fax: +49 (0) 33056 - 23 77 77
info-europe@pda.org

To Exhibit:

Exhibition and Sponsorship Opportunities are available. PDA meetings and conferences are a great opportunity for your company to gain on-site exposure in front of highly-qualified, upper-level professionals in the pharmaceutical and biopharmaceutical industry. Exhibit at PDA events and let your company's products or services become a valuable tool or resource for our attendees.

For exhibition information please contact:
Creixell Espilla-Gilart
Exhibition & Sponsorship Manager PDA Europe
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Email: espilla@pda.org

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NOTE: Pop-ups must be enabled otherwise the booking platform window will not open.

These promotional fares are also available through your IATA / ARC travel agent. Travel agents can obtain ticketing instructions by sending an email to lufthansa.mobility@dlh.de and providing the access code as a reference.

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3. The data requested will be displayed on your screen

Agenda

Tuesday 26 February 2013

9:00	**Welcome and Introduction**	Jette Christensen, *Novo Nordisk* Michael Miller, *Microbiology Consultants*

Session 1 : Contamination Control Strategy in Sterile and Non-sterile Dosage Forms — *Moderator:* Subho Goswami, *BD*

Contamination control for sterile and non-sterile dosage forms is part art and part science. The best way to get better at this discipline is to learn from an assembly of noted industry experts. This session will kick-off with a talk on the use of new technologies for head-space analysis of sterile media fills. This will be followed by case studies that examine the robustness of microbial control strategies in bioprocessing, with a special emphasis on observed gaps and what could be done to mitigate these in the future. An overview of regulatory mandates and inspectional observations will then help industry to decide on what path to chart. The last presentation on objectionable organisms and identification of potentially susceptible dosage forms will also focus on case studies to present potential risk mitigation strategies.

9:15	**Using Laser-Based Headspace Analysis for Rapid Readout of Sterile Media Fills**	Derek Duncan, *Lighthouse Instruments*
9:45	**Microbial Control Strategies in Bioprocessing Falling Short of Assuring Product Quality and Satisfying Regulatory Expectations**	Anastasia Lolas, *Visionary Pharma Consulting*
10:15	Coffee Break & Exhibition	
10:45	**Regulatory Aspects of Contamination Control – Observations from FDA Regulatory Submissions and Inspectional Observations**	Robert Mello, *FDA*
11:15	**The Role of Product Formulation, Manufacturing and Testing in the Exclusion of Objectionable Microorganisms from Non-sterile Pharmaceutical Drug Products**	Tony Cundell, *Merck Research Laboratories*
11:45	**Q & A, Discussion**	
12:15	Lunch Break & Exhibition	

Session 2: Environmental and Process Water Monitoring — *Moderator:* Robert Mello, *FDA*

One key to a successful product quality microbiology program is a robust, viable environmental monitoring program. There is general agreement as to the content of such a program – bio burden in air, water, bulk solutions, APIs, excipients and on components, personnel and facility surfaces. However, the diversity of medical products and their manufacturing facilities can present significant methodological challenges to the site's microbiology group. This session will address issues affecting some existing methods as well as introduce newer, more cutting edge methodologies for monitoring WFI and aseptic environments.

13:15	**Development of a Rapid and Highly Sensitive Detection System for Bacterial Monitoring in Pharmaceutical Manufacturing**	Shuichi Mori, *Hitachi Plant Technologies*
13:45	**Microbiological Monitoring of Clean Rooms: Qualification of Media with Neutralizers for Clean Room Monitoring – a Case Study**	Frank van der Zanden, *Bactimm*
14:15	**Alternative Methods Used to Enumerate and Identify Organisms of Interest in WIFI Water**	Adrienne Pryor, *Medtronic*
14:45	**Q & A, Discussion**	
15:00	Coffee Break & Exhibition	

Session 3:	Water Systems and Biofilm Control	*Moderator:*	Barbara Gerten, *Merck*

Control of water systems is an everyday challenge in pharmaceutical production. This session will provide an overview of the topics of biofilms, regulations of drinking water and control of water systems. Background of biofilm formation and also the remediation from water systems will be deeply discussed. Most incoming water to pharmaceutical plants is handled and controlled according to drinking (potable) water standards – for these standards, latest news from regulations and standardization will be presented. Furthermore, production of High Purified Water (HPW) and control of water systems will be highlighted.

15:30	**Biofilms: Bacteria Resist!**	Romain Briandet, *INRA*
16:00	**Actual Regulations and Standards in European Microbiological Drinking Water Analysis and its Impact on Pharmaceutical Companies**	Barbara Gerten, *Merck*
16:30	**Remediating Pharmaceutical Water System Biofilm – What To Do After It Gets Ahead of You**	T.C. Soli, *Soli Pharma Solutions*
17:00	**HPW Production and Water System Control**	Michael Clever, Peter Kreutzenbeck, *F. Hoffmann-La Roche*
17:30	**Q & A, Discussion**	
18:00	**End of Day 1**	
	Networking Reception	

Wednesday, 27 February 2013

Session 4:	New Technologies	*Moderator*	Sandra Gay, *bioMérieux*

This session will present the vendors' latest technologies and products for microbial detection and integrity test models.

8:00	**RMM – An Alternative Method Validation with a New Light on Statistical Tools**	Vincent Beguin, *Merck Millipore*
8:20	**CCIT: Rumors and Reality Essential Updates**	Ralf Holzinger, *Confarma*
8:40	**The Response of Organisms to Stress and Injury: Exploring the Dynamics of Recovery using a Rapid Micro Method**	Andrew Sage, *Rapid Micro Biosystems*

Session 5:	Rapid Micro Methods	*Moderator:*	Jette Christensen, *Novo Nordisk*

RMMs have been available for several years and more and more companies are investigating the possibility of implementing or already do implement these methods. Firstly, the regulatory perspective of implementing RMMs will be addressed. This will be followed by a presentation on validation and implementation of a RMM for identification and presentation on bio burden/sterility testing for release of a virus vaccine product. Furthermore, there will be a talk about the use of Solid Phase Cytometry including the story of submission file. Finally, issues from the updated PDA Technical Report No. 33, RMM Validation, that is close to being finalized, will be presented.

9:00	**RMM Issues from a Regulatory Perspective**	Andrew Hopkins, *MHRA (invited)*
9:30	**Implementation of the MALDI Biotyper for Microbial Identifications in a QC Microbiology Laboratory**	Amy McDaniel, *Pfizer*

10:00	**Application of Rapid Microbiology Techniques to Release a Virus Vaccine: A Case Study**	Daniel Galbraith, *BioOutsource*
10:30	Coffee Break & Exhibition	
11:00	**Rapid Microbiological Methods (RMM) – A "Stunning" Advance in the Microbiological Field, but a "Slow" Implementation in the Pharma industry**	Fulvio Tavellini, *Baxter*
11:30	**About RMM Validation/Technical Report No. 33**	Michael Miller, *Microbiology Consultants*
12:00	**Q & A, Discussion**	
12:30	Lunch Break & Exhibition	

Session 6: Hot Topics in Microbiology — *Moderator:* Michael Miller, *Microbiology Consultants*

This last session will cover a number of hot topics associated with microbial control, monitoring, method transfer and expert opinion. First, we will review the current technical and quality expectations when transferring validated microbiological methods from one laboratory to the next. Second, we will explore the methods needed to fully understand the relationship between temperature and the reduction of bioindicator counts. Third, a review of the recent changes to USP's aseptic monitoring chapter ‹1116› will be provided by a member of the USP Expert Committee. Finally, we will invite industry and regulatory experts to join the podium to answer your most important questions.

13:30	**Transfer of Microbiological Methods**	Timo Krebsbach, *L&S Labor*
14:00	**Validation of High Temperature Sterilization Processes with Accurate Bioindicators: Comparing Calculations between Temperature Data and Bioindicator Reduction Data**	Gunnel Lundahl, *AstraZeneca*
14:30	**USP 1116 and its Potential Impact to the Industry and Regulators**	Scott Sutton, *Microbiology Network*
15:00	**Q & A, Discussion**	
15:15	Coffee Break & Exhibition	
15:45	**Panel Discussion: "Ask the Experts!"**	Moderator: Michael Miller, *Microbiology Consultants*
16:15	Closing Comments & End of Conference	

28 February 2013 8:30 - 17:00 | 1 March 2013 8:30 - 15:30

The A to Z's of Biofilm Control, Monitoring, Validation, and Excursion Investigations of Pharmaceutical Water Systems

Presented by Teri C. ("T.C.") Soli, PhD
President and Principal Consultant, Soli Pharma Solutions, Inc.

USP Expert Committee Member since 2000
(Various USP Expert Committees responsible for Pharmaceutical Water)

Abstract

All pharmaceutical, biologics, and medical device facilities are likely to have high purity water systems. The chemical purification processes are well understood and relatively easily achieved. However, the microbiological purity of the finished water and the impact and control of biofilm on the purification train is NOT widely understood, sometimes even by the site's microbiologists or QA, let alone by the engineers and other utilities maintenance personnel tasked with maintaining microbial control.

In order to understand the microbiology of a water system, one has to understand biofilms since that is the mode of microbial growth in a water system. There is much hype and fear about water systems biofilms by users and regulators alike who do not understand how they grow, how to effectively control that growth, or even how to monitor their presence. This course will help you understand how microorganisms respond to our efforts (or lack of effort) to control their numbers and even to how we try to count them.

This course is designed to provide a microbiology-focused education in language understandable by all personnel, microbiologist and non-microbiologist alike who have any involvement with water systems. The instructor can provide the necessary background needed to understand this very important subject matter. This understanding is essential to the proper design, validation, operation, monitoring, maintenance, and investigations of a high purity water system. Without this understanding, water system control consists of a set of rules that often do not work and can cause very costly system downtime or even product recalls.

More Course Details

Key Topics:

- The "real" story behind some common water system design and control myths
- Biofilm properties, resistances, susceptibilities and examples
- Water system sanitization to control biofilm
- Water system microbial enumeration issues
  - USP's view on sampling and microbial enumeration
  - Microbial enumeration options/advantages/ disadvantages
  - How to chose the best microbial enumeration method and "validate" it
- Water System Validation and Change Control
- Improving outcomes and reducing the frequency of excursion investigations
- How to perform successful Water System excursion investigations
- What USP actually says about all this

Learning Objectives:

At the completion of the course, attendees will be able to:

- Understand the role of system design, maintenance and sanitization in controlling microbial levels in pharmaceutical water systems
- Develop regulatorily sound and completely reproducible sampling procedures
- Successfully troubleshoot problems resulting from poor design/maintenance versus sampling or testing problems
- Devise water system validation protocols that truly validate microbial control
- Optimize, validate, and defend your water microbial test method to regulators
- Develop sound Alert and Action Levels that preclude making poor water quality

Course Modules and Content Details

1 Basics of Water System Biofilm Control by Design & Operation

- Microbial control – where and why it matters
- Biofilm basics and how it develops
- Biofilm impact on "active" surfaces
- Environmental resistances of biofilm
- Biofilm impact on purification unit operations and how to control it
- Good design practices to control biofilm
- Good maintenance practices to control biofilm

2 Successful Water System Sanitization

- Material and construction limitations
- Continuous vs intermittent sanitization
- The importance of biofilm removal
- How sanitants work (or don't work)
- When to sanitize
- Common causes for sanitization failures and trouble-shooting sanitization problems

3 Water System Validation by Logic Instead of Tradition

- Why validate a water system?
- Basic ground rules for water systems before you validate them
- Minimum validation expectations
- How to figure out what you should validate
- What happens after the honeymoon is over
- Is validation ever really over?
- Special considerations for lab water systems
- Are packaged waters a viable option?

4 Implementing Changes to a Validated System

- Purpose of a Change Control program – a help, not a hindrance
- When is a change major vs minor, requiring full vs limited re-qualification?
- What about water use during re-qualifications?
- FDA validation expectations
- Reliance on logic and common sense and the disservice of precedent and paradigms
- Additional useful tips

5 Reducing Water Microbial Excursions & Improving Investigations

- What are excursions?
- Water system dilemma: process control or quality control (utility or raw material), or both
- Intended roles of Alert/Action Levels and Specifications
- Investigation, necessary and often fruitless
- Excursion responses and impact
- Criticality of valves, hoses, & outlet flushing
- Diagnosing the source of the problem

Minimizing unnecessary excursion responses through best practices

6 Understanding and Controlling Endotoxin

- Where does endotoxin come from?
- What are the properties of endotoxin?
- How do you get rid of it?
- How do you detect it?
- What assay controls are used?
- What are the endotoxin specs for water?
- How do you control it?

7 Harmonizing vs Optimizing Water Microbial Testing for System Quality Control

- Water harmonization that has occurred
- Water Micro TM "Dis-Harmonization"
- Biofilm diversity in water systems
- The good and bad of Micro harmonization
- Where RMMs can fit in

8 Microbial Enumeration Issues with High Purity Water Systems

- Biofilm enumeration issues (planktonic vs surface)
- Purpose of sampling and testing (PC vs QC)
- Traditional cultivative approach issues
- Validation of your test method
- Alternative RMM choices (advantages/disadvantages)
- Significance of water isolates

9 Water System Investigation "How-To's" and Example Case Studies

- Gathering and using existing information/opinions
- Investigation approach: what stones to turn over
- Discovering a root cause and mitigation strategy
- Water system contamination case studies

10 What USP Does and Doesn't Say about PW, WFI, Pure Steam and Micro Issues

- PW, WFI, Pure Steam micro specifications?
- Starting water issues
- Misunderstood issues clarified
- Microbiological test issues clarified
- Suggested micro test method
- Micro Specifications
- Alert and Action Levels and max's
- Recent/Upcoming USP water changes
- Discrepancies between pharmacopeias
- New water initiatives – need your input/feedback

Key Resources

The instructor for this course has authored a number of chapters in authoritative publications that are key resources for this course and, in general, for understanding high purity water system microbial control:

1. *USP 35, Chapter ‹1231› "Water for Pharmaceutical Purposes"*
2. *ISPE Baseline Guide for Water and Steam Systems, 2nd Edition, Chapter 13 – "Microbiological Considerations for Pharmaceutical Water Systems"*
3. *ISPE Good Practice Guide for Ozone Sanitization of Pharmaceutical Water Systems – Numerous chapters and appendices, including Chapter 4 – "Ozone Characteristics", Chapter 5 – "Effectiveness of Ozone for Microbial Control", and Chapter 13 – Ozone and Chemical Sanitization Comparison"*
4. *Microbiology in Pharmaceutical Manufacturing, ed. Richard Prince (a PDA publication), Chapter 14 – "Pharmaceutical Water"*
5. *Biofilms: Preventing and Controlling Microbial Contamination in Pharmaceutical Production, eds. Lucia Clontz and Carmen Wagner (a PDA publication), Chapter 6 – "Prevention and Control of Biofilms in Pharmaceutical Water Systems", Chapter 8 – "Biofilm Detection", Chapter 10 – "Sanitization Approaches for Biofilm Control"*

Who Should Attend

This two-day course is particularly relevant to managers, supervisors, and operatives taking on new responsibilities related to water, but also for experienced water personnel to learn the "true" whys behind what they do and perhaps better ways of doing things. Specific positions that would benefit are:

- Microbiology Laboratory supervisors and analysts responsible for water sampling and testing
- Quality Assurance personnel responsible for water system deviation management and change control
- Regulatory and Compliance professionals responsible for FDA interactions
- Process and Utility Engineers responsible for water system maintenance, troubleshooting, and excursion mitigation
- Facility Engineers responsible for water system design or renovation
- Validation personnel for water system qualification– Good maintenance practices to control biofilm

About the Course Director

T.C. Soli has over 33 years of combined pharmaceutical experience as a consultant. He is President of Soli Pharma Solutions. Dr. Soli's career-long experience with water systems and product and process contamination troubleshooting, coupled with USP, ISPE, and PDA committee involvements, afford him this practical knowledge and troubleshooting skill.

The Parenteral Drug Association presents...

2013 PDA Europe Workshop on Single Use Systems for Pharmaceutical Applications

The workshop addresses the importance of Single Use Systems (SUS) in pharmaceutical development and manufacturing. Based on the Technical Report, you will hear about advantages, disadvantages and how you can make best use of SUS. Benefit from case studies, discussions with regulators and industry experts. Get in direct contact with the different suppliers of SUS technology.

15-16 January
Milano | Italy

Benefit from your early Booking!

WORKSHOP 15-16 January | **EXHIBITION** 15-16 January

https://europe.pda.org/SingleUse2013

28 February 2013 8:30 - 17:00 | 1 March 2013 8:30 - 15:30

Rapid Microbiological Methods

Presented by Michael Miller, PhD
Microbiology Consultants, LLC .

Background

Effective monitoring of our manufacturing processes can help to ensure that a state of control is maintained, areas for continual improvement are identified, process and product understanding is enhanced, and manufacturing agility and efficiencies are realized. From a microbiology perspective, we can design processes to prevent contamination, investigate ways to correct a contamination event, and assess the potential impact of failing results on the patient. Unfortunately, our microbiology procedures are trapped in the 19th Century, using conventional methods that have not changed since the discovery of the agar plate! Therefore, the modern microbiological laboratory should look toward developing innovative approaches to the detection, quantification and identification of microorganisms in our products, processes and manufacturing environments, and recent advances in rapid microbiological methods (RMMs) now provide the analytical tools necessary to accomplish these tasks.

This comprehensive course is designed to provide an introductory review of currently available rapid microbiological method (RMM) technologies, validation strategies, applications, regulatory expectations, financial justification models and implementation plans. Taught by one of the industry's global leaders in rapid methods, the attendee will be immersed in discussions that will provide a meaningful and understandable roadmap for how to evaluate RMMs and employ them in their own laboratory and manufacturing areas.

Syllabus

Introduction

- History of microbiology methods and the need for change
- RMM technical benefits as compared with traditional methods
- Opportunities for use and areas of application including microbial detection, quantification and identification
- Understanding of how to match the right RMM with the intended application

Technology Review

- Growth-based technologies that rely on the measurement of biochemical or physiological parameters that reflect the replication and proliferation of microorganisms
- Viability-based systems that utilize viability stains and/or cellular markers for the detection and quantification of microorganisms without the need for cellular growth
- Artifact-based technologies that rely on the analysis of cellular components or the use of probes that are specific for microbial target sites of interest
- Nucleic acid RMMs including PCR-DNA amplification, RNA-based transcription-mediated amplification, 16S rRNA typing and gene sequencing
- Spectroscopic methods that use of light scattering and other optical techniques to detect, enumerate and identify microorganisms
- Introduction to Micro-Electro-Mechanical Systems (MEMS), such as microarrays, biosensors and Lab-On-A-Chip technologies

Validation Strategies

- Guidance from USP ‹1223›, Ph. Eur. 5.1.6 and PDA Technical Report #33
- Insights on how to develop a meaningful DQ, IQ, OQ and PQ program
- Software and hardware qualification
- Validation and acceptance criteria
- Use of statistics
- Vendor expectations

Regulatory Perspectives

- US FDA expectations
- EMA expectations
- Submission strategies
- Comparability protocols
- Research exemptions
- Changing acceptance levels and specifications
- The role of process analytical technology initiatives (PAT)

Developing a Business Case for RMMs

- The need for creating a business case to economically justify RMM implementation
- Understand how to develop return on investment (ROI) and payback period models
- Review an actual RMM ROI case study

Review of RMM References

- Regulatory
- Pharmacopoeia
- Journals and books
- Professional meetings
- Online references

About the Lecturer

Dr. Michael J. Miller is an internationally recognized microbiologist and subject matter expert in the due diligence, validation, registration and implementation of rapid microbiological methods, pharmaceutical microbiology, Process Analytical Technology (PAT) and isolator design and qualification. Currently, Dr. Miller is the President of Microbiology Consultants, LLC. In this position, he is responsible for providing microbiology, regulatory and quality solutions for the pharmaceutical, biopharmaceutical and medical device industries.

2013 PDA Europe Conference, Exhibition

Pharmaceutical Microbiology

26 February - 1 March 2013 | Berlin | Germany

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4 WAYS TO REGISTER

1. **ONLINE: https://europe.pda.org/Microbio2013**
2. **FAX: +49 33056 23 77 77**
3. **EMAIL: petzholdt@pda.org**
4. **MAIL: PDA Europe, Adalbertstr. 9, 16548 Glienicke/Berlin, Germany**

Your Contact Person is Antje Petzholdt at PDA Europe

1 Your Contact Information

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

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☐ 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 Conference Registration

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

Conference (26-27 February)	**By** 4 Jan 2013	**After** 4 Jan 2013
PDA Member	☐ 1345	☐ 1495
Nonmember	☐ 1595*	☐ 1745*
Govern./Health Authority/Academic	☐ 670*	☐ 750*

Two-Day Training Course (28 February-1 March)
The A to Z's of Biofilm Control, Monitoring, Validation, and Excursion Investigations of ...
All Participants ☐ 1495

Two-Day Training Course (28 February-1 March)
Microbiology - Rapid Microbiological Methods
All Participants ☐ 1495

Conference + Two-Day Training Course (26 February-1 March) The A to Z's of Biofilm Control, Monitoring, Validation, and Excursion Investigations of ...		
PDA Member	☐ 2395	☐ 2645
Nonmember	☐ 2645*	☐ 2895*

Conference + Two-Day Training Course (26 February-1 March) Microbiology - Rapid Microbiological Methods		
PDA Member	☐ 2395	☐ 2645
Nonmember	☐ 2645*	☐ 2895*

Should you wish to participate for one day only please contact us (above) for prices and conditions.

Group Registration Discount Register 4 people from the same site as a group (at the same time) for this event and receive the **5th registration FREE.** Special rates are available for multiple attendees from the same organization. For more information on group discounts please contact Antje Petzholdt at petzholdt@pda.org. Other discounts cannot be applied.

☐ **Discount for Exhibiting Companies**
Please mark here if your company is an exhibitor to this event and you will receive the conference ticket at the special price of **995 Euro per ticket.** No further discounts are applicable with this option (as PDA Membership Discount or Group Ticket discount). This special rate does not include one-year PDA membership.

*Registration fee includes a one-year PDA membership if no further special discount is granted (except discount for exhibit companies). If you do not wish to join PDA and receive the benefits of membership, please check here (same rate applies). ☐

3 Payment Options

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Your VAT I.D.:

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 once payment is received. You must have this written confirmation to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. If you have received an invoice please be advised that you are not a fully confirmed registrant. Payment must be received or guaranteed by Purchase Order or credit card details on 1st day of event, at the very latest. **SUBSTITUTIONS:** If you are unable to attend, substitutions can be made at any time, including on site at the prevailing rate. If a participant is unable to attend, substitutions are welcome. If you are pre-registering as a substitute attendee, please indicate this on the registration form. Changes are free of charge until 3 weeks prior to the start of the event. After this date, there will be a charge of € 50 per name change. **REFUNDS: Refund requests must be in writing and faxed to PDA at +49 (33056) 23 77 77** (emails are not accepted). If your written request is received on or before **1 February 2013,** 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 if your cancellation has not been received in writing on or before **8 February 2013.** On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. To process refunds PDA Europe's suppliers for credit card transactions save the provided credit card details (credit card holder, credit card number, expiration date) for a period of 12 months. **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 **info-europe@pda.org or fax to +49 (33056) 23 77 77. 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.

MAKING IT EASIER FOR BOTH OF US

1 Please include your member ID number on registration form if available/known

If uncertain about your member ID number and/or your membership status, call or email Ms. Antje Petzholdt.
+49 (0)33056 2377-10 **petzholdt@pda.org**

2 Do not send money in advance

Please wait until we send our invoice to you.
It is helpful to reference our invoice number in your bank transfer details.

3 Complete and sign the event registration form

Please note the registration and cancellation policies at the bottom of the form.

4 Purchase Orders

Registration cannot be completed by sending Purchase Order alone. A Purchase Order is only accepted if a complete registration form is enclosed or follows very soon.

5 Please state VAT ID number if European-based Company

This number starts by your country code
(example: PDA Europe's VAT ID number = DE254459362)

6 Please state the correct billing address on the registration form

This is particularly important if billing address and site address are different. Contact your accounting department for correct address and company name. There could be special requirements for accounting. Changes in the billing address (if induced by participating company) will be charged 25,- € if imposed 3 weeks prior to the start of the event.

7 Confirmation of your registration

Credit card charges are confirmed immediately if successfully approved.
Bank transfers are confirmed upon receipt of full payment.

8 Refund/Credit Notes

Refunds to credit card can be done immediately if payment had been done by credit card and details are available. Refunds to bank accounts can be done if payment had been done by bank transfer and the following details are provided: **a) Name of your bank** **b) IBAN number** **c) Swift/BIC code**

9 Substitutions

If an participant is unable to attend, substitutions are welcome at any time. Changes are free of charge until 3 weeks prior to the start of the event. After this date, there will be a charge of € 50 per name change.

10 For assistance contact: Antje Petzholdt, PDA Europe

Tel: +49 (0)33056 2377-10 **Email: petzholdt@pda.org**

THANK YOU FOR YOUR COOPERATION!