

2017 PDA Europe Conference, Exhibition

Pharmaceutical Microbiology



16-17 February

Rapid Microbiological Methods

16-17 February

Practical Guide for Root Cause Investigations
– Methodology & Tool Kit

Register by
14 Jan 2017
and SAVE!

14-15 February 2017

Hotel Porto Palácio
Porto | Portugal

LETTER FROM THE CHAIR

Dear Colleagues,

On behalf of the program planning committee, we are delighted to invite you to attend the **PDA Europe 8th Conference on Pharmaceutical Microbiology**, to take place in **Porto, Portugal on 14-15 February 2017**.

The 2017 conference theme will be “Microbiology in Pharmaceutical Manufacturing” and a comprehensive scientific program will include presentations from regulatory, industry and technology representatives from around the world.

The conference program is tailored to address the current issues and opportunities our industry faces every day. For example, topics of interest can include how to maintain process water systems, how to validate new technologies and microbiological methods, how to prevent contamination in sterile and non-sterile products and of course, new trends in endotoxin testing.

In addition, the following new sessions will be included to provide even more opportunity for addressing key issues on a face-to-face basis:

- **PDA Challenge Summit:** Where two speakers team up to present an industry challenge and their jointly developed solutions.

- **PDA Interactive:** Where you will engage with industry experts in controversial topics of interest.

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 industry and regulatory microbiologists. On-site luncheons and an evening reception in Porto will provide ample networking and discussion opportunities.

The planning committee has been working diligently to make this conference relevant to the most important microbiological challenges our industry is facing today.

We look forward to welcoming you to an informative, engaging, thought-provoking and enjoyable conference.

Come join us in a new and exciting location, Porto, Portugal!



Michael J. Miller, PhD, Microbiology Consultants, Conference Co-Chair



SCIENTIFIC PROGRAM PLANNING COMMITTEE

1 Michael J. Miller, Microbiology Consultants, Chair

2 Heike Merget-Millitzer, Janssen, Pharmaceutical Companies of J&J

3 Johannes Reich, Microcoat

4 Marsha Stabler-Hardiman, ValSource

5 Anil Sawant, Merck & Co.

6 Falk Klar, PDA Europe

WHO SHOULD ATTEND

A wide-angle night photograph of a city skyline, likely Porto, Portugal. The image shows a bridge with many lights, buildings on a hillside, and a river in the foreground with boats and reflections of the city lights.

Departments

Microbiology,
Compliance, Engineering,
Manufacturing, QA/QC,
CMC Documentation,
Regulatory Affairs,
Research and Development,
Validation, QP

Job Function

Supervisor,
Researcher, Analyst,
Operative
Personnel

Level of Expertise

Senior Subject Matter
Expert,
Management,
Scientists/Technicians

Tuesday, 14 February 2017

9:00 Welcome and Introduction

Falk Klar, *PDA Europe*
Michael J. Miller, *Conference Chair*

Session 1: Current Regulatory Perspectives

*Moderator: Anil Sawant,
Merck & Co*

Regulatory Perspectives on the current and future state of Pharmaceutical Microbiology will be provided, highlighting practical examples of how to achieve regulatory compliance.

9:10 **CDER Case Study: A Microbial Investigation of Contamination by Burkholderia Multivorans**

John Metcalfe,
US FDA

9:45 **Microbiological Quality Considerations in Non-sterile Pharmaceutical Product Manufacturing**

Lynne Ensor,
US FDA

10:15 **Coffee Break, Poster Session & Exhibition**

10:45 **Data Integrity: Overview & PDA Technical Report**

Anil Sawant,
Merck & Co.

11:15 **Risk Management in the Age of EU Annex 15: Implementation and Case-Study**

Ana Henriques,
4Tune Engineering

11:45 **Additional Points to Consider in Aseptic Processing for Achieving Product Safety and Regulatory Compliance**

Günther Gapp,
Gapp Quality

12:15 **Q & A, Panel Discussion**

13.00 **Lunch Break, Poster Session & Exhibition**

Session 2: PDA Challenge Summit Joint Presentations of Innovation and Cooperation

*Moderators: Heike Merget-Millitzer,
Janssen J&J*

Engaging talks of co-speaking teams will cover microbiological challenges that made it necessary to reach out to other industry experts and jointly develop technologies that result in easy to implement solutions. These teams will share insights into their development process and how a mutually beneficial cooperation could be established.

14:00 **Lessons Learned from Microbial Contamination in Pharmaceutical Manufacturing**

Walid El Azab, *Steris*
& Olivier Chancel, *Merial*

14:30 **The Case for Recombinant Factor C - Primed for the Big Time**

Jay Bolden, *Eli Lilly*
& Elena Gustchina, *LONZA*

15:00 **Coffee Break, Poster Session & Exhibition**

15:30 **Case Study: Equivalence Studies & the Use of Statistic**

Michael J. Miller,
Microbiology Consultants,
Andrew Sage,
Rapid Micro Biosystems

16:00 **Rapid Detection Methods**

Ulrich Herber, *Charles River Labs*
Neil Lewis, *Procter & Gamble*

16:30 **Q & A, Discussion**

16:45 **Transition Break**

Session 3 Environmental Monitoring & Testing

*Moderator: Johannes Reich,
Microcoat*

Approaches to environmental monitoring, objectionable organisms and testing will be addressed and discussed in this session.

17:00	Environmental Monitoring Program: Hot Topics in Microbiology and Best Practices	Benoit Ramond, Sanofi
17:30	Low Endotoxin Recovery – A Laboratory Case Study	Kris de Smet, Genzyme
18:00	Q&A, Discussion	
18:30	End of Day 1 & Networking Reception	

THE PARENTERAL DRUG ASSOCIATION IS PROUD TO INVITE YOU TO A VERY SPECIAL

Networking Event



This is a great opportunity to meet your colleagues and peers. Refreshments and dinner will be served.

Full details of the event will be published soon.

CONFERENCE AGENDA

Wednesday, 15 February 2017

Session 4: International Perspectives on Practical Microbiology

*Moderator: Michael J. Miller,
Microbiology Consultants*

Common laboratory practices will be highlighted here along with technical innovations and case studies providing valuable insights for translation into practice.

8:30	Current State of the Low Endotoxin Recovery Task Force	Friedrich von Wintzingerode, <i>Roche</i>
9:00	Implementation of Rapid Microbiological Methods: Benefits, Challenges and Application	Inge Van der Schoot, <i>Janssen J&J</i>
9:30	Validation of an Amplified ATP Bioluminescence Method for Rapid Sterility Testing of Large Volume Parenterals	Terezinha de Jesus Andreoli Pinto, <i>São Paulo University</i>
10:00	Coffee Break, Poster Session & Exhibition	
10:30	Reliable Water for Injection Generation with Reverse Osmosis	Shlomo Sackstein, <i>Biopuremax</i>
11:00	Sterile Filtration of Liposomes and Related Fluids	Martha Folmsbee, <i>PALL</i>
11:30	Achieving High Reactivity and Sensitivity with the Monocyte Activation Test (MAT)	Shabnam Solati, <i>MAT Research</i>
12:00	Q & A, Discussion	
12:30	Lunch Break, Poster Session & Exhibition	



**Session 5: PDA Interactive:
Knowledge Meets Discussion**

*Moderators: Falk Klar, PDA Europe
All Committee Members*

Committee members and selected speakers will facilitate lively discussions and exchange around a choice of controversial key issues. Results will be collected and presented as a summary at the end of the day.

13:30 Roundtable Discussions:

- **Participants will rotate every 30min.**
- Each moderator will prepare a short summary of the discussions and present it to the audience

RAPID MICROBIOLOGY METHODS	ENDOTOXINS	ENVIRONMENTAL MONITORING
Will your regulators accept rapid microbiology methods as alternatives for traditional, compendial methods?	Why is Low Endotoxin Recovery (LER) a problem, and how does your company address it?	How are you handling any EM results that are >1 CFU recovered in the Grade A area (active air, settle plates, surface samples and glove samples)?

Moderator:
Michael J. Miller,
Microbiology Consultants

Moderator:
Johannes Reich,
Microcoat

Moderator:
Anil Sawant,
Merck & Co

13:35



14:05



14:10

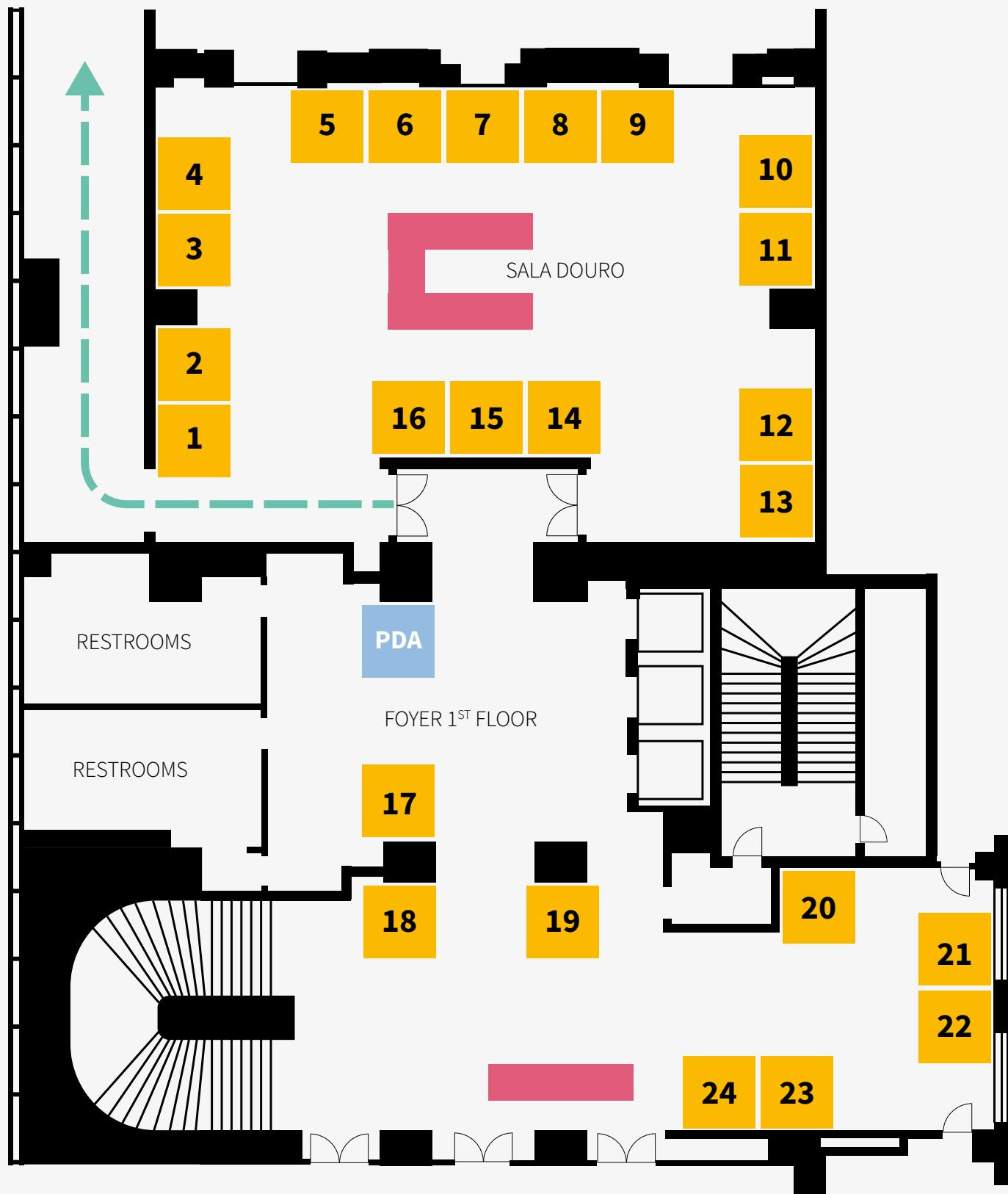


14:40

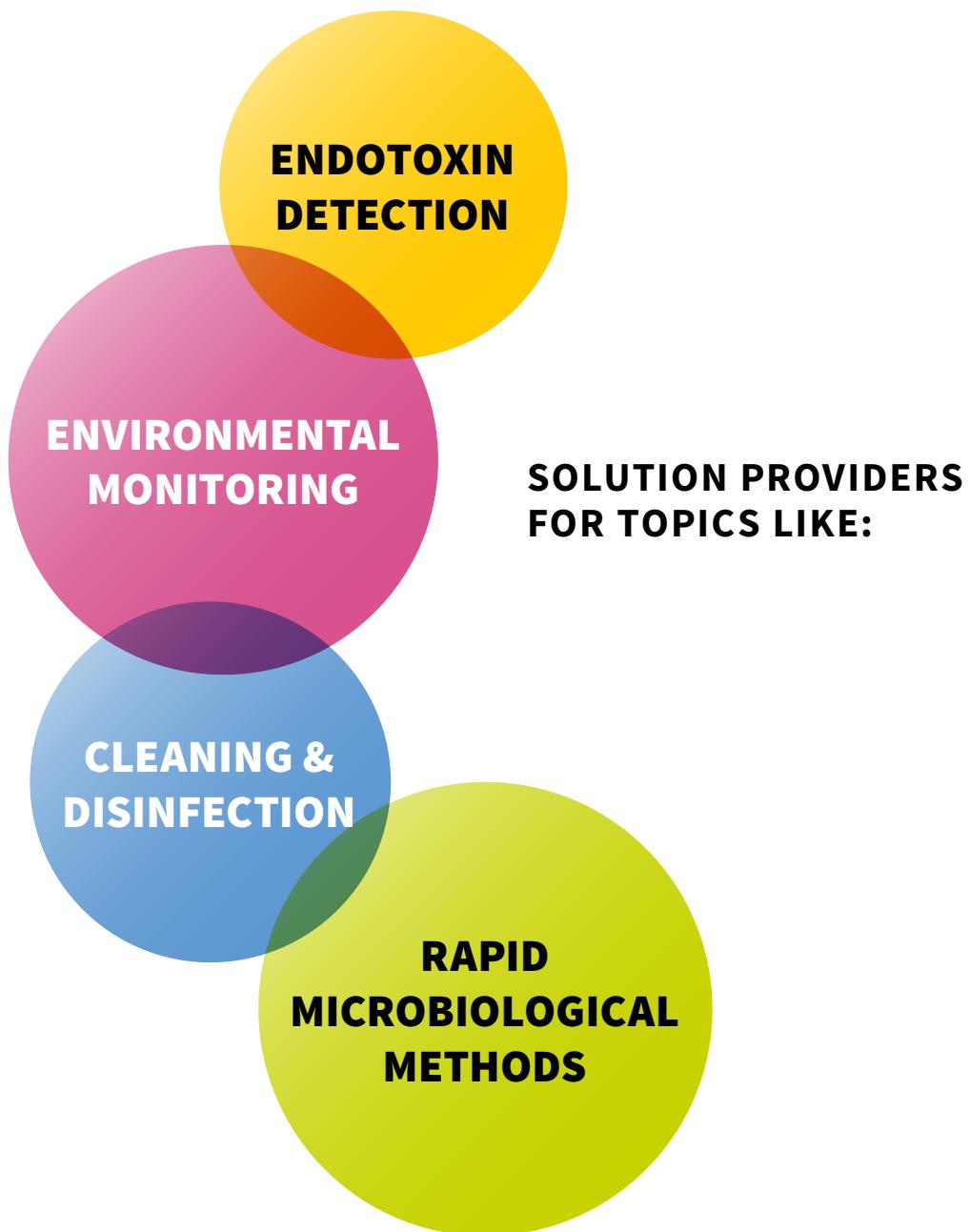
15:15 Coffee Break, Poster Session & Exhibition

15:45 Summary Presentations of Results, Panel Discussion	Committee Members and Facilitators
16:15 Closing Comments & Farewell	Falk Klar, PDA Europe

FLOOR PLAN



- Yellow box: Table Top
- Blue box: PDA Registration
- Pink box: Coffee Station
- Green dashed line: Conference Room Acess



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.

A basic exhibition package for this event is priced **1.895 Euro net (table-top)**. Sponsorship Packages are available, for more information please contact **expo-europe@pda.org**

Training & Education Program



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

Facts that Make a Difference

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

16-17 February 2017
Rapid Microbiological Methods
Two-Day Training Course

16-17 February 2017
Practical Guide for
Root Cause Investigations
Two-Day Training Course

Rapid Microbiological Methods

Overview

This comprehensive course is designed to provide an intensive 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.

Who Should Attend:

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

Learning Objectives:

- Discuss the benefits of alternative and RMM technologies as compared with classical microbiological methods
- Describe the scientific basis for a variety of technologies that may be qualified as alternative methods to classical microbiology procedures; explore case studies and actual workflows for dozens of commercially-available technologies
- Explain the regulatory environment, guidance, policies and expectations for validation, submissions and implementation from FDA, EMA, TGA, PMDA, ISO and WHO; understand when and how to change acceptance levels
- Develop business plans and return on investment justifications, follow an actual case study in significant cost savings and cost avoidances by implementing a RMM for environmental monitoring
- Apply industry best practices for validating these new technologies in order to demonstrate that the methods are acceptable for their intended use via IQ, OQ and PQ qualification strategies; understand the differences between PDA TR 33, the new USP 1223 chapter and the proposed Ph. Eur. Chapter 5.1.6



Michael J. Miller, PhD, President, Microbiology Consultants, President

Dr. Michael J. Miller is an internationally recognized microbiologist and subject matter expert in pharmaceutical microbiology and the design, validation and implementation of rapid microbiological methods. He is currently the President of Microbiology Consultants, LLC. In this role, he is responsible for providing scientific, quality, regulatory and business solutions for the pharmaceutical industry and suppliers of new microbiology technologies. Michael currently serves on a number of PDA's program and publication committees and advisory boards, and is co-chairing the revision of PDA Technical Report #33: Evaluation, Validation and Implementation of New Microbiological Testing Methods. Dr. Miller holds a PhD in Microbiology and Biochemistry from Georgia State University (GSU), a BA in Anthropology and Sociology from Hobart College, and is currently an adjunct professor at GSU.

Thursday, 16 February 2017**9:00 – 18:00****9:00** **Welcome****9:15** **Introduction to RMMs, Applications, Implementation Strategies, Opportunities****Growth-based RMMs; Scientific Principles, Applications and Case Studies****10:30** **Coffee Break****11:00** **Regulatory Policies and Expectations: FDA, EMA, TGA, PMDA, ISO and WHO****12:30** **Lunch Break****13:30** **Cellular-component Based RMMs; Scientific Principles, Applications and Case Studies****Viability-based RMMs; Scientific Principles, Applications and Case Studies****15:30** **Coffee Break****16:00** **Spectroscopic-based RMMs; Scientific Principles, Applications and Case Studies****Genetic and Gene Amplification-based RMMs Part 1; Scientific Principles, Applications and Case Studies****18:00** **End of Day 1****Friday, 17 February 2017****9:00 – 16:30****9:00** **Genetic and Gene Amplification-based RMMs Part 2; Scientific Principles, Applications and Case Studies****10:30** **Coffee Break****11:00** **MEM-based RMMs; The Future of Alternative Technologies****Validation of RMMs Part 1; Due Diligence Activities, Vendor Expectations, IQ, OQ and PQ Strategies, Validation Acceptance Criteria, Use of Statistics****12:30** **Lunch Break****13:30** **Validation of RMMs Part 2; Equivalence, Method Suitability, Comparison of PDA TR33, the New USP 1223 and the Proposed Ph. Eur. 5.1.6****A Case Study on Conducting Economic Assessments and Return-on-Investment (ROI) Calculations****15:00** **Coffee Break****15:30** **References, On-line Resources and Final Remarks****16:30** **End of Training Course**

Practical Guide for Root Cause Investigations

Methodology & Tool Kit

Overview

This engaging two-day workshop teaches a step by step, proven process ideal for researching any change/decline in the performance of a product or work process/system, whether it be physical or virtual. It is appropriate for individuals new to this discipline, as well as those who are seasoned veterans looking to improve/refresh their skills, regardless of industry or function within the organization. Simply put, this is one of the most practical and applicable trainings available!

On day one, the participants are introduced to the seven step methodology. A Roadmap is provided to guide the participants through the steps and suggest appropriate tools to ensure the right questions are being asked, the right data is being collected, and the right documentation is being made. After each step is presented leveraging an instructor case study, the participants immediately apply the learning on their own case study (which is based upon a real life investigation).

On day two, several hours are devoted to strengthening the participants' skills leveraging the methodology through practice on another, more complex, real life case study. As the participants work on this case study they will compare their work with that of the investigation conducted by the real team.

Participants will be emailed a set of electronic templates. These templates, plus the Roadmap, guide the investigator through the methodology and provide the basis for documentation.

Who Should Attend:

Alumni of this program typically (though not exclusively) have a background in:

- Quality
- Risk management
- Regulatory affairs
- Compliance
- Manufacturing
- Product development
- CAPA
- Supply chain & purchasing
- Production
- Engineering
- Project management
- R&D
- Fraud management
- and more

Learning Objectives:

Upon completion of the workshop, participants will be able to immediately, effectively, and efficiently apply the methodology to:

- Identify the technical root cause(s), that is, the change(s) that occurred.
- Identify systemic root cause(s), that is, any underlining breakdown in the organization's broader systems that allowed the change(s) to occur.
- Implement a comprehensive corrective and/or preventive action plan to restore performance.
- Implement a control plan to minimize and/or prevent recurrence.



Rob Weaver, President of Weaver Consulting

Founded in 2003, Weaver Consulting is a two-person enterprise comprised of Tom Weaver and Rob Weaver. They are quality and operations improvement consultants who focus their business exclusively on root cause analysis. With a combined 40+ years' experience and a client base that expands worldwide, they have helped organizations across a multitude of highly regulated industries, including pharmaceutical, medical device, aerospace, defense, financial services, food & beverage, consumer products, automotive, telecommunications, semiconductors, and many more, successfully implement their premier root cause analysis methodology, Root Cause Investigation for CAPA. Both Tom and Rob held titles of Vice President in their respective careers before joining the firm, Tom with Baxter Healthcare and Rob with Wells Fargo & Company.

Thursday, 16 Feb 2017 9:00 – 18:00**9:00 Welcome & Introduction**

- Define technical CAPA problem
- Common investigation mistakes
- Investigation Roadmap template
- Introduce 1st participant real life case study

10:00 Step 1: Define the Performance Problem

- Introduce instructor case study
- Problem statement
- Problem description

10:30 Coffee Break**11:00 Step 1: Continued**

- Problem description continued
- Workshop
- Flow chart process(es) being investigated & identify key inputs
- Workshop
- Time of events
- Team charter including performance & cost savings goals

12:00 Lunch Break**13:00 Step 2: Collect Data**

- Determine data needed
- Data collection tools & techniques
- Data measurement plan
- Workshop

15:00 Coffee Break**15:30 Step 3: Identify Possible Causes**

- Time of changes
- Differences between Is & Is Not facts
- Workshop
- Changes associated with identified differences
- Review risk analysis
- Brainstorming techniques
- Workshop

16:30 Step 4: Test Possible Causes

- Test possible causes against facts
- Summarize testing leveraging contradiction matrix
- Historical perspective of investigations
- Workshop

17:30 Step 5:**Identify Technical & Systemic Root Causes**

- Verify assumptions
- Conduct studies/experiments
- Identify technical root cause(s)

18:00 End of Day 1**Friday, 17 Feb 2017 9:00 – 16:30****9:00 Step 5: Continued**

- Identify systemic root causes

9:30 Step 6:**Determine Corrective/Preventive Actions**

- Mistake proofing techniques
- Variation reduction & optimization techniques
- Corrective/preventive actions
- Acceptance criteria

10:30 Coffee Break**11:00 Step 6: Continued**

- Risk mitigation
- Control plan
- Workshop

11:45 Step 7: Verify Corrective/Preventive Actions

- Implement & measure corrective/preventive actions
- Evaluate control plan
- Determine additional preventive actions

12:00 Lunch Break**13:00 Second Participant Real Life Case Study**

- Introduction
- Workshop to develop problem statement, problem description, identify possible causes
- Workshop to collect data
- Workshop to test possible causes

15:00 Coffee Break**15:30 Second Participant Real Life Case Study Continued**

- Workshop to determine corrective/preventive actions including risk mitigation, control plan, acceptance criteria

16:00 Closing Remarks

- Compare/contrast this investigation methodology with traditional approach
- Shortcuts
- Simple investigations
- Difficult investigations
- Investigation report
- Return on investment
- References

16:30 End of Course

INFORMATION

VENUE

Hotel Porto Palácio

Av. da Boavista 1269
4100-130 Porto
Portugal
Tel +351 226 086 600
Fax +351 226 091 467
www.hotelportopalacio.com/en

Special Rates

Single Room 110 € per room and night

Double Room 125 € per room and night

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

DIRECTIONS

© Google For directions click on the picture, scan the QR-code or go to <https://goo.gl/maps/cGhz8qWmxZ62>

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CONFERENCE REGISTRATION HOURS

Tuesday, 14 February: 8:00 - 12:00

Wednesday, 15 February: 8:00 - 10:00

COURSE REGISTRATION HOURS

Thursday, 16 February: 8:00 - 12:00

Friday, 17 February: 8:00 - 10:00

SPECIAL REQUIREMENTS

 If you require special accommodations to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to registration-europe@pda.org



Join us in Spain for these

13 March
PDA IG Meeting
Pre-filled Syringes
2017



PDA Europe Conference, Exhibition, Education

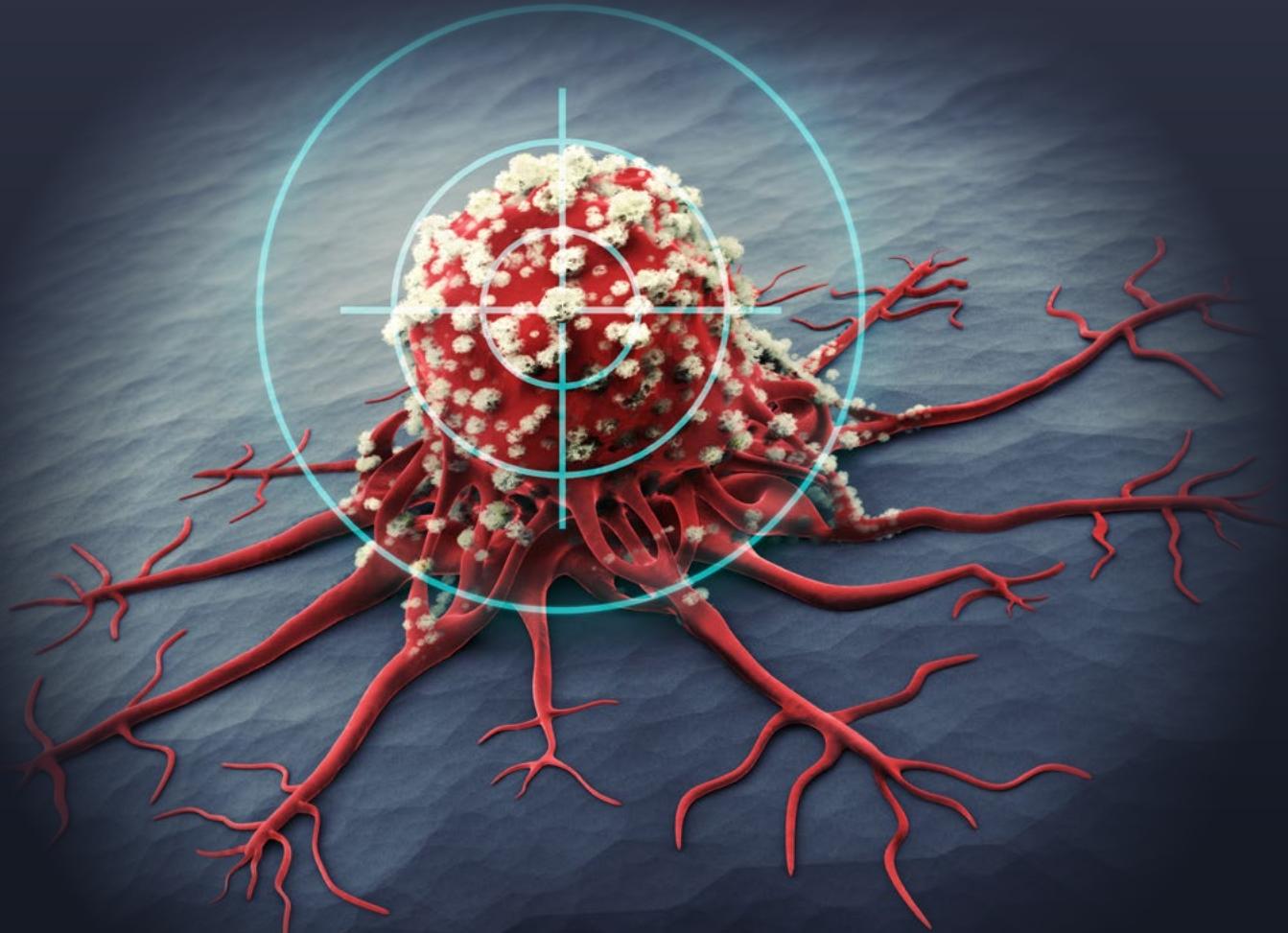
Parenteral Packaging

14-15 March 2017

Hotel Porta Fira
Barcelona | Spain

Register by
14 Feb 2017
and **SAVE!**

conferences:



PDA Europe Conference, Exhibition

Advanced Therapy Medicinal Products

27-28 June 2017
Valencia | Spain

Register by
27 May 2017
and SAVE!

2017 PDA EUROPE CONFERENCES

14 – 15 February	Pharmaceutical Microbiology	★ Porto, Portugal
14 – 15 March	Parenteral Packaging	★ Barcelona, Spain
26 – 27 April	Current Trends in Aseptic Fill & Finish of Prefilled Syringes	★ Lindau, Germany
30 May – 1 June	Virus & TSE Safety Forum	★ Dubrovnik, Croatia
13 – 14 June	2 nd PDA Europe Annual Meeting	★ Berlin, Germany
27 – 28 June	Advanced Therapy Medicinal Products	★ Valencia, Spain
19 – 20 September	Pharmaceutical Freeze Drying Technology	★ Cologne, Germany
26 – 27 September	10 th Workshop on Monoclonal Antibodies	★ Berlin, Germany
10 – 11 October	Pharmaceutical Cold & Supply Chain Logistics	★ Prague, Czech Republic
7 – 8 November	The Universe of Pre-filled Syringes and Injection Devices	★ Vienna, Austria
21 – 22 November	Outsourcing & Contract Manufacturing	★ Munich, Germany

Subject to change

For latest info: pda.org/pda-europe

Shortlist 17 Jan 2017

★ Events with additional Education Program. More information – www.pda.org/pda-europe

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www.pda.org/pda-europe