PDA Europe Workshop

The Parenteral Drug Association presents:

Quality Culture Transformation Resources

Register by 16 Feb 2018 and SAVE € 1300!

17-18 April 2018

FAVORITE Parkhotel Mainz

Mainz | Germany

Be Transformed!

Overview

What are most important positive quality culture behaviors that impact product quality?

Can you identify which mature quality attributes have the biggest impact on quality culture behavior?

Would you like to quantify the strengths and weaknesses of quality culture maturity at your plant site?

Take the first step on a journey to transform your Quality Culture with resources developed by PDA volunteers specifically for pharmaceutical manufacturing sites.

THIS IS THE BEST PDA COURSE I HAVE EVER TAKEN!
Stephan Krause, PDA Member

Following a successful pilot conducted over the last 18 months, PDA is pleased to launch the **Quality Culture Transformation Resources** to the industry.

When you enroll in this new program, PDA will train your assessors, teach you how to use the Maturity Model, offer an anonymous survey to your site staff and give you access to PDA's composite benchmarking results so you know where you stand with your peers.

Your site leadership will be able to gauge employees' views of quality culture and have a better understanding of where to take action, how to track progress, and which decisions to take to improve the site culture.

YOUR REGISTRATION FEE INCLUDES:

1. **COURSE:** TWO participants in hands-on active learning in a two-day course on "Quality Culture Transformation"
2. **TOOL:** Quantitative assessment of current quality culture at TWO manufacturing sites
3. **SURVEY:** Blinded, direct employee feedback on aspects of your Quality Culture at TWO sites
4. **BENCHMARK:** Compare your results against more than 40 sites from 24 companies in North America, Europe, and Asia that have already completed Quality Culture Assessments.

Who Should Attend

This program will benefit pharmaceutical and biopharmaceutical manufacturing leaders who want to measure quality culture maturity at their plant sites and identify areas for improvement.

It will also prepare your assessors to conduct site evaluations in a consistent and verifiable manner using the PDA Model and Tools.

Faculty

Denyse Baker, *PDA Director of Science and Regulatory Affairs*

Denyse Baker is the Director of Scientific and Regulatory Affairs at PDA. She has 30 years of pharmaceutical industry and regulatory authority experience. Denyse holds the RAC designation in both US and European regulatory affairs and is a registered professional engineer. She is a leader in PDA's pharmaceutical quality and culture metrics programs, contributor to the PDA Letter and PDA Journal, as well as the coordinator for PDA regulatory commenting globally and PDA taskforces working on data integrity and post approval change concerns within the pharmaceutical industry

Cylia Chen-Ooi, *Senior Manager Amgen Operations Intelligence Program, Amgen.*

Cylia leads the Amgen Operations Intelligence Program which keep abreast with worldwide GMP/GDP regulatory requirements, inspectional and industry trends. In her current role, she also develops the external engagement strategy for Amgen and is actively engaged with several industry associations. She is currently the leader of PDA Quality Culture Task Force Team and have led a panel of experts from industry and regulators to develop tools to help industry advance understanding and maturity of quality culture at their companies. Prior to her current role, she led several initiatives for Amgen's international expansion plan and she has extensive experience in fill finish process development. She holds a Master's degree in Regulatory Science and B.S. degree in Biomedical Engineering from University of Southern California.

Tuesday, 17 April 2018	9:00 – 17:00
9:00	**Welcome and Introduction**
9:30	**Vision & Background**
10:00	**Coffee Break**
10:30	**Behaviors vs. Attributes**
11:30	**Audit Logistics & Tools**
12:00	**Lunch Break**
13:00	**Intro to the Case Study & Exercise**
13:30	**MOCK ASSESSMENT** **Employee Empowerment** • Understanding quality goals • Staff empowerment and engagement
15:00	**Coffee Break**
15:30	**Continuous Improvement** • CAPA robustness • Management review and metrics • Clear quality objectives • Internal stakeholder feedback
17:00	**End of Day 1**

Wednesday, 18 April 2018	9:00 – 15:30
8:30	**MOCK ASSESSMENT** *CONTINUES* **Technical Excellence** • Utilization of new technologies • Maturity of systems (QMS, QRM, DI)
10:00	**Coffee Break**
10:30	**Leadership Commitment to Quality** • Accountability and quality planning • Enabling qualified resources
	Quality Communication and Collaboration • Quality communications • Communication and collaboration
12:00	**Lunch Break**
13:00	**Characteristics of a Successful Assessor**
13:30	**Learning from Previous Site Participants – Understanding Scores**
14:30	**Getting Site Management Involved and Setting Expectations**
15:00	**Wrap Up, Feedback**
15:30	**End of Program**

Steven Mendivil, *Senior Advisor, Amgen*

Steven Mendivil is currently a Senior Advisor to Amgen Quality leadership. He had been with Amgen for 19 years and was Executive Director of International Quality, External Affairs. He managed a group responsible for identifying and reviewing new or revised GMP & GDP documents for impact as well as managing Amgen external activities related to GMP & GDPs. Previously, Steve held positions as the Head of Corporate Quality GMP & EHS Compliance and Amgen Global Operation Leader managing various biotech products from preclinical through commercial development. Steve is currently PDA's Quality Metric Task Force leader. Prior to Amgen, Steve worked for 5 years at Genentech in Quality and 10 years at Syntex and Syva in Regulatory Affairs, Quality and Manufacturing encompassing both the pharmaceutical and medical device industries. Steve holds a BS from University of California at Davis and is Regulatory Affairs Certified (RAC) by the Regulatory Affairs Professional Society.

Brianna Peterson, *Compliance Expert, Boehringer Ingelheim*

Brianna Peterson is an experienced quality professional, serving within the pharmaceutical industry for 15 years. She is currently serving as a compliance expert in Athens, Greece for Boehringer Ingelheim. Recently, with a global role, Brianna partnered with sites within Asia, Europe, and the Americas to strengthen their Quality Culture. Previously, Brianna worked within US pharma for 10 years within Quality Assurance/Systems, Quality Control, and Development functions. Brianna has been an active member of the PDA Quality Culture team since 2015.

VENUE

FAVORITE Parkhotel Mainz
Karl-Weiser Str. 1
55131 Mainz
Germany
Tel: +49 6131 / 80 15 0
www.favorite-mainz.de/en/

Special rates
PDA Europe has reserved a limited number of bedrooms. Book your group rate for PDA.
Single Room 108 €per room and night
Rates are per room and night, including the following services and benefits free of charge: Buffet Breakfast in the restaurant, Wireless Internet Connection (WI-FI),VAT, Taxes and Service Charge will apply.
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/LumQ4fnZDDS2**

CONTACT INFORMATION

Registration Customer Care
Tel: +49 30 4365508-10
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Education Program Inquiries
Elke von Laufenberg
training-europe@pda.org

GENERAL ADDRESS

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13507 Berlin, Germany
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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.

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

3 WAYS TO REGISTER

1. **ONLINE: pda.org/EU/Eventname2017**
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 subsription 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

EARLY BIRD DISCOUNT ☐ **Book by 16 Feb 2018 to receive € 1300 off the course fee only**

Course, Tool, Survey, Benchmarking

TWO course seats * and quantitative assessment at TWO manufacturing sites	☐ **8100**
Per Extra Attendee Enrolled	☐ **3400**
Per Extra Site Participating	☐ **1300**

*** Please send contact data of the second and any additional participant to registration-europe@pda.org**

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.

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): 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 **19 March 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

26 February	Interest Group Meeting Pre-filled Syringes	IG	
26 February	Interest Group Meeting Packaging Science	IG	
27-28 February	**Parenteral Packaging**	*	**Rome, Italy**
13 April	Interest Group Meeting Visual Inspection	IG	**Berlin, Germany**
24-25 April	**Vaccines**		**Málaga, Spain**
7 May	Interest Group Meeting Advanced Virus Detection Technologies	IG	
8-9 May	**Virus Forum**	*	**Florence, Italy**
29-30 May	**Pharmacopoeia Conference**		**Vienna, Austria**
5-6 June	**Advanced Therapy Medicinal Products**	*	**Amsterdam, The Netherlands**
25 June	Interest Group Meeting Quality Systems	IG	
25 June	Interest Group Meeting Freeze Drying	IG	
26-27 June	**3rd PDA Europe Annual Meeting**	*	**Berlin, Germany**
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**
27-28 November	**Pharmaceutical Freeze Drying Technology**	*	**Seville, Spain**
27-28 November	**11th Workshop on Monoclonal Antibodies**	*	**Seville, Spain**

Subject to change | For latest info: **europe.pda.org** | Shortlist 5 Feb 2018

*** Events with additional Education Program. More information – europe.pda.org**

PDA Parenteral Drug Association

Connecting People, Science and Regulation®

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