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.