

# Measuring Quality Culture Maturity? Learn how!

## PDA Quality Culture Maturity Assessment Tool Training

### Overview

Is the PDA Quality Culture Maturity Assessment Tool something that may be of help to your company? There are many situations where you need to have an answer to the question how mature your quality system and quality culture in your company are. You may be engaged in a bidding contest or a preferred supplier selection process and the contract giver ask for a solid answer facing a customer audit and Quality Culture is already on the agenda scheduling an audit from an authority which is trained on the PDA tool (e.g. FDA and MHRA). With the PDA assessment tool, you can be sure to have the necessary answers!

Join your colleagues in industry for this active learning course to

- Learn why Quality Culture is important to patients and to your bottom line
- Understand how Regulators are using quality culture information
- Be informed on current quality culture research across industry
- Understand the linkage between mature quality attributes and culture behaviors
- Practice using the PDA tool to assess a manufacturing site through role-playing simulation

You will leave prepared to plan and execute an assessment at your own site!

### Who Should Attend

- QA Managers
- QA Leaders
- Business Developers
- Site Leads
- Executives of SME

### Learning Objectives

#### Upon completion of the course participants

- Have understood the value a good Quality Culture can bring to an organization
- Know how the PDA Quality Culture Maturity Assessment Tool is set up and how it can consistently measure Quality Culture Maturity
- Experienced the Quality Culture Maturity Assessment Tool hands-on in a safe practice environment
- Are prepared to deploy the Quality Culture Maturity Assessment to measure maturity levels across all your sites

### Faculty

Denyse Baker  
Alexander Yoon-Suk Chung



**Kerstin Wilken, PhD, Director Programs & Education, PDA Europe**

Kerstin Wilken holds a PhD in Microbiology and is a certified Project Manager (PMP). Before joining PDA Europe, she worked as Project Manager for a Contract Manufacturing Organization and as Head of Lab in a quality control service lab. Kerstin joined PDA Europe in July 2017 as Director Programs & Education. In her role, she develops and furthers PDA's training courses and event portfolios.

## Thursday, 24 October 2019 9:00 – 17:30

9:00 Welcome & Icebreaker

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9:30 Vision & Background

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10:00 Audit Logistics and Tools

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10:30 Coffee Break

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11:00 Characteristics of a Successful Assessor

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11:30 Intro to Case Study and Mock Assessment

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12:15 Lunch Break

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### Case Study Assessment

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13:15 **Employee Ownership and Engagement (4 metrics)**

- Understanding quality goals
- Staff Empowerment and Engagement

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14:15 **Leadership Commitment (4 metrics)**

- Commitment to Quality
- Enabling Resources

**Continuous Improvement (3 metrics)**

- CAPA Robustness
- Clear Quality Objectives

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15:15 Coffee Break

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15:45 **Technical Excellence (4 metrics)**

- Utilization of new technologies
- Maturity of systems

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17:30 End of Day 1

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## Friday, 25 October 2019 9:00 – 13:30

### Case Study Assessment Continues

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09:00 **Quality Communication and Collaboration (5 metrics)**

- Quality Communications
- Management Review and Metrics
- Internal Stakeholder Feedback
- Collaboration with Assessors (optional)

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10:30 Health Authority Engagement

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10:45 Coffee Break

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11:15 **Getting Site Management Involved and Setting Expectations**

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11:45 Wrap Up -- Feedback

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12:15 End of Course and Farewell Lunch

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