



## Speakers



Dr Stephanie Boggasch  
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Dr Thomas Krieger  
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# Quality Culture

## People Empowerment in GMP



Live Online Training on 09/10 September 2021



## Highlights

- What is Quality Culture?
- How to implement Quality Culture in Business
- Knowledge Management
- Error Culture and Human Behaviour
- Case Studies

## Objectives

This 2-day Live Online Training brings together well-experienced experts to explain and discuss the latest developments and expectations on Quality Culture and how Quality Culture is linked to human behaviour and continuous improvement. This will support you turning your company's quality excellence goals into reality.

## Background

**“Vision without execution is hallucination” – Thomas Edison**

More than ever, quality culture in pharmaceutical industry is coming to the fore. Industry leaders recognise that it is essential for ensuring high quality processes and products. Establishing and maintaining a good quality culture seems to be a key to continuous improvement and business continuity. Regulatory authorities also emphasise the importance of continuous improvement of processes and quality. A lived vital culture from the shop floor to upper management is indispensable here.

But it needs to be more than just a vision! A good quality culture is based on the behaviour of the individuals within the corporate quality strategy and the appropriate infrastructure of the company. It is important that everybody is aware of the importance of quality. Individuals need to transfer both knowledge and quality values. This vision must be executed. How this can be done will be presented and discussed in this Master Class.

## Target Audience

Managers and Executives from pharmaceutical Quality Assurance and Quality Management but also Business Executives and Production Managers and those involved in Quality Culture initiatives.

## Moderator

Wolfgang Schmitt  
CONCEPT Heidelberg (on behalf of ECA)

## Programme

### What is Quality Culture?

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- Why the focus on Quality Culture?
- Why is it important?
- Who creates culture and how?
- Core elements
  - Leadership at the top
  - Confidence in the part of all employees
  - Clear management visibility and leadership
  - Accountability at all levels
  - Sharing of knowledge and information
  - Best practices
- Before you improve the Quality Culture
  - Understand why changing culture is hard
  - What must be influenced to see desirable changes

### Developing a Quality Culture; why is EU GMP Volume 4 Chapters 1-9 the wrong Place to start?

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- How does EU-GMP promote a Quality Culture?
- What kind of Quality Culture does Chapter 1 promote?
- Where can we look to for better Quality Culture Guidance?
- Looking to the great Quality Culture proponents (ISO 9001, Deming, Motorola, Toyota) for inspiration

Case Studies:  
Which Quality Culture Options should be implemented in Business?

### Knowledge Management as part of Quality Culture

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- Principles – definition and segregation
- From content to knowledge: structuring of knowledge
- Relationship models and retrieval - how does knowledge become available
- How do I keep knowledge up-to-date? Knowledge Management Systems (KMS) vs. Data Warehouse

### Case Study: Boehringer Ingelheim's Quality Culture Initiative

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- Cultural enablement as a foundation for CQI und Business Continuity
- Quality Culture at BI: From initiative introduction to operationalisation
- Dimensions of cultural excellence framework
- Is Quality Culture measurable?

## Examples on: Quality Control Laboratory Production Environment

- Indicate/identify “bad” quality culture behaviours
- How to get to a better quality culture (how to create new behaviour)
- What will happen if we do not take the right action
- Set up appropriate KPIs

## Techniques to evaluate Quality Performance

- Process Analysis
- Root Cause Analysis
- Cause-and-Effect Diagrams
- Risk Assessment
- Quality Cockpit
- KPIs
- Tracking & Trending

## Error culture as part of Quality Culture

- Definitions
- How mistakes / errors become disasters
- Root Causes (Deep Dives) - symptoms and effects
- Good error culture: from error to success
- Errors and mistakes in the workspace: practical examples
- Role of the executive management - dealing with mistakes
- Tools from the OPEX toolbox
- Cooperation instead of confrontation
- The toddler rule: action must have consequences
- The team spirit

## A Behavior-Based Continuous Improvement Model

- Creating Quality Culture performance expectations
- Educating and training to influence behavior
- Communicating Quality Culture effectively
- Developing Quality Culture goals and measurements
- Using consequences to increase or decrease behaviors
- Encourage & energize the team

## GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.

## Speakers



**Dr Stephanie Boggasch**  
Boehringer Ingelheim RCV, Austria  
Head of Unit Manufacturing Compliance

Dr Stephanie Boggasch is Lead Biopharma Quality Culture Initiative and Head of Unit Manufacturing Compliance, Biopharma Austria – Focused Factory Microbial Upstream.



**Arnoud Herremans**  
Y47 Consultancy, The Netherlands  
Lean Kaizen Coach

Arnoud Herremans was Senior Scientist at Solvay Pharmaceuticals and Research Unit Manager at Abbott Healthcare. He has a psychological background (Behavioral Neuroscience at Utrecht University) and has been applying Lean - 6Sigma and Kaizen methods to the life sciences industry.



**Dr Thomas Krieger**  
KU-Pharma, Germany  
Quality Culture Consultant

Dr Thomas Krieger is Quality Culture Consultant and CEO of KU-Pharma, providing management consultancy for quality and efficiency in the pharmaceutical industry.



**Aidan Madden**  
FivePharma, Ireland  
CEO

Aidan Madden is CEO of FivePharma, a Quality Services Company founded in 2003. Aidan held senior quality positions in Wyeth Pharmaceuticals, Baxter Healthcare and Fort Dodge Laboratories.



**Francois Vandeweyer**  
VDWcGMP Consulting, Belgium  
Founder

Francois Vandeweyer started in 2019 with his own consultancy business. Before that he was Director Pharmaceutical Regulatory Compliance EMA/APAC at Janssen Pharmaceutica.

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Quality Culture, Live Online on 09/10 September 2021

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## Date of the Live Online Training

Thursday, 09 September 2021, 9.00h – 17.30h

Friday, 10 September 2021, 8.30h – 16.00h

All times mentioned are CEST.

## Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At <http://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation.

## Fees (per delegate, plus VAT)

ECA Members € 1,490

APIC Members € 1,590

Non-ECA Members € 1,690

EU GMP Inspectorates € 845

The conference fee is payable in advance after receipt of invoice.

## Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

## Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

## Conference language

The official conference language will be English.

## Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at <https://www.gmp-compliance.org/on-demand-online-training/recorded-online-training-webinars>. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

## Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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