



Speakers



Dr Stephanie Boggasch
Boehringer Ingelheim RCV, Austria



Arnoud Herremans
Y47 Consultancy, The Netherlands



Dr Thomas Krieger
KU-Pharma, Germany



Aidan Madden
FivePharma, Ireland



Francois Vandeweyer
VDWcGMP Consulting, Belgium

Quality Culture

People Empowerment in GMP

07/08 September 2022 | Vienna, Austria



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 Training Course 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

Programme

What is Quality Culture?

- 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?

- 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

- 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

- 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 Behaviour-Based Continuous Improvement Model

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

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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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.

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Reservation Form (Please complete in full)

Quality Culture, 07/08 September 2022 | Vienna, Austria

Title, first name, surname

Department

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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Date

Wednesday, 07 September 2022, 9.00h – 17.30h
(Registration and coffee 8.30 – 9.00 h)
Thursday, 08 September 2022, 8.00h – 15.30h

Venue

Radisson Blu Park Royal Palace Hotel
Schlossallee 8
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On site, we will implement the necessary and required hygiene measures in close co-operation with the hotel. If infection rates and/or travel restrictions generally do not permit an on site event, it will be conducted live online. In this case, you will be informed in due time.

Fees (per delegate, plus VAT)

ECA Members EUR 1.490€
APIC Members EUR 1.590€
Non-ECA Members EUR 1.690€
EU GMP Inspectorates EUR 845€
The conference fee is payable in advance after receipt of invoice and includes lunch on both days and all refreshments.
VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Conference language

The official conference language will be English.

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Organisation and Contact

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

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