Quality Culture
People Empowerment in GMP

10/11 September 2020, Prague, Czech Republic

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

Speakers
- Stephan Dresen
  Corden Pharma, Germany
- Aidan Madden
  FivePharma, Ireland
- Dr Daniel Marquardt
  Boehringer Ingelheim, Germany
- Kristina Smith Hansen
  MilCor Consulting, Denmark
- Francois Vandeweyer
  VDWcGMP Consulting, Belgium
Objectives

This 2-day Master Class 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 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)

Social Event

In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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

Workshop: Which Quality Culture Options should be implemented in Business?

Knowledge Management and Knowledge Structuring

- Principles – definition and segregation
- Knowledge Management as part of Quality Culture
- From content to knowledge: structuring of knowledge
- Semantic Web: Ontology vs. Topic Map
- Relationship models and retrieval - how does knowledge become available
- Knowledge Management and Data Integrity
- How do I keep knowledge up-to-date? Knowledge Management Systems (KMS) vs. Data Warehouse
- Practice example: How can I store and preserve knowledge in a structured storage format?

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?
Interactive Sessions 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

Speakers

Stephan Dresen
Corden Pharma, Germany
Head of Quality & Compliance
Stephan Dresen has more than 16 years of experience in leading positions within the pharmaceutical industry. Before working for Corden Pharma, he was Director Quality at Warner Chilcott Deutschland GmbH (an Allergan affiliate).

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.

Dr Daniel Marquardt
Boehringer Ingelheim, Germany
Head of Focused Factory Respimat
Before his role as factory manager, Daniel Marquardt was Vice President Global Quality Services and Plant Manager at the Boehringer Ingelheim site in Sao Paulo, Brazil.

Kristina Smith Hansen
MilCor Consulting, Denmark
Founder
Kristina Smith Hansen is a certified quality auditor (GMP/GDP/ISO) consultant, helping industry get to the real root cause of their poor personnel related non-conformities by using behaviour science theories and tactics. She also gives courses, presentations, and lectures related to improving employee behaviour within the workplace.

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.
If the bill-to-address deviates from the specifications on the right, please fill out here:

__________________________________________________________________________________________

__________________________________________________________________________________________

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34
D-69007 Heidelberg
GERMANY

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
   - Cancellation until 2 weeks prior to the conference 10 %,
   - Cancellation until 1 week prior to the conference 50 %
   - Cancellation within 1 week prior to the conference 100 %.
CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for any airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-attendance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed) (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34
D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Quality Culture, 10/11 September 2020, Prague, Czech Republic

Title, first name, surname
Department
Company

Important: Please indicate your company’s VAT ID Number
Purchase Order Number, if applicable

City
ZIP Code
Country

Phone / Fax

E-Mail (Please fill in)

Reservations
Via the attached reservation form by e-mail or by fax. You will receive a room reservation form/PoG when you have registered for the course. Registration should be made directly with the hotel. Early registration is recommended.

Conference language
The official conference language will be English.

Certificate of Participation
Shortly after the event you will receive your certificate of participation by e-mail.

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

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a reservation form/PoG from us. The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch on the first day, lunch on both days, all refreshments, VAT is reclaimable.

Fees (per delegate, plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectors € 895

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Venue
Corinthia Hotel
Kongresova 1
14069 Prague 4, Czech Republic
Phone +49 (0) 420 261 191 111
Fax +49 (0) 420 261 191 111
E-Mail prague@corinthia.com

For questions regarding reservation hotel, organisation, etc., please contact: Ms. Julia Grimmer (Organisation Manager) at +49(0) 62 21/84 44 44, or per e-mail at grimmer@concept-heidelberg.de

For questions regarding reservation, hotel, organisation etc., please contact: Mr. Wolfgang Schmitt (Operations Director) at +49(0) 62 21/84 44 39, or per e-mail at w.schmitt@concept-heidelberg.de

For questions regarding content, organisation and contact: www.concept-heidelberg.com

For questions regarding content: www.gmp-compliance.org