

Practical Approach to Quality Culture

Overview

A good quality culture is established when all employees starting from CEO to shop floor workers are accountable for quality. The following attributes are important indicators for quality culture: management communication emphasizing that quality is everyone's responsibility, established quality improvement objectives, quality topics included in relevant meetings, and an implemented error prevention process. These quality attributes are related to management responsibility and are elements of the continuous improvement of the pharmaceutical quality system as mentioned in the ICH Q10 guideline. Quality culture is a key management element for success. However, quality culture does not establish itself but requires empowerment, communication and daily quality awareness.

Who Should Attend

Functions:

- Middle Management
- Managers with employee responsibility
- Group Leaders
- Department Heads
- Directors
- Executive Level

Departments:

- Quality Assurance
- Quality Control
- Production
- Purchasing
- Regulatory Affairs
- R&D
- Human Resources
- Controlling

Learning Objectives

This training course is interactive, hands-on, and will empower you to measure, develop and improve the quality culture of your company:

- Learn to measure quality attributes and quality behaviors
- Identify weaknesses and deficits in quality behavior
- Investigate root causes and define effective CAPAs for improvement
- Optimize your measures with respect to cost, time and quality

Faculty



Thomas Krieger, PhD, KU-Pharma Consulting

Thomas Krieger is founder and CEO of Krieger Unternehmensberatung - Pharma (KU-Pharma) since 2009. KU-Pharma is providing quality consulting in quality assurance, in value-based Quality Culture and support as a Qualified Person for the pharmaceutical industry. After the Ph.D. in Pharmacy, Thomas graduated as specialized pharmacist of Pharmaceutical Analysis. For 25 years he holds the legal qualification and has professional experience as a Qualified Person pursuant to Directive 2001/83/EC. For 20 years Thomas Krieger has held different legal functions according to the drug law and various senior management and leadership positions in quality control, quality assurance, regulatory affairs and scientific departments. He worked for several pharmaceutical companies, from Global Players with more than 50,000 employees to private owned companies with less than 100 employees.



Martin Haerer, Senior Director R&D/Qualified Person, Holopack Verpackungstechnik GmbH

After the Ph.D. in Pharmacy, Martin started his career at Holopack Verpackungstechnik in 1990. In the following years, he managed different projects in Production, Quality Control and Quality Assurance to improve the Quality System and Production. In 2006 he was appointed Production Manager and Qualified Person. Currently he is responsible for Business Development, Technology Transfer and Research, and still acting as Qualified Person with QA responsibilities. Martin was voted Member of the Board of the BFS-IOA Association as Regulatory Officer. He is member of the German QP Association and Board Member of Federal German Pharmacist Advanced Training Organisation (BAK).

Thursday, 28 June 2018 **9:00 – 17:45**

9:00	Welcome & Introduction
9:30	Lecture 1: What does Quality mean?
10:15	Lecture 2: Quality Behaviors
10:45	Coffee Break
11:15	Interactive Session 1: Bad and Good Behaviors
11:45	Interactive Session 2: Assessment Exercise
12:15	Lunch Break
13:15	Lecture 3: Investigation Principles
14:00	Interactive Session 3: Root Cause Investigation Exercise
14:45	Coffee Break
15:15	Interactive Session 3: Root Cause Investigation Exercise (continued)
17:00	Lecture 4: Correction, CAPAs, Effectiveness Check
17:30	Recap of Day 1, Forecast to Day 2
17:45	End of Day 1

Friday, 29 June 2018 **9:00 – 16:30**

9:00	Recap of Day 1, Forecast of Day 2
9:15	Lecture 5: Toolbox for Improvement of Quality Behaviors
10:00	Interactive Session 4: Toolbox Assessment
10:30	Interactive Session 5: Improvement of Quality Behaviors
11:00	Coffee Break
11:30	Interactive Session 5: Improvement of Quality Behaviors (continued)
12:00	Lecture 6: Cost-Time-Quality-Dilemma
12:30	Interactive Session 6: Optimized Quality Culture
13:00	Lunch Break
14:00	Interactive Session 6: Optimized Quality Culture (continued)
14:30	Lecture 7: Next steps for Improvement
15:20	Break
15:30	Exchange of experience with improvement of Quality Culture
16:00	Summary and Conclusion
16:15	Questions & Answers
16:30	End of Course