

Why Quality Culture?

More Success by Reducing Human Errors

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 Human Resources
- Controlling



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).

Wednesday, 22 May 2019 9:00 – 17:30

- 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

Thursday, 23 May 2019 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