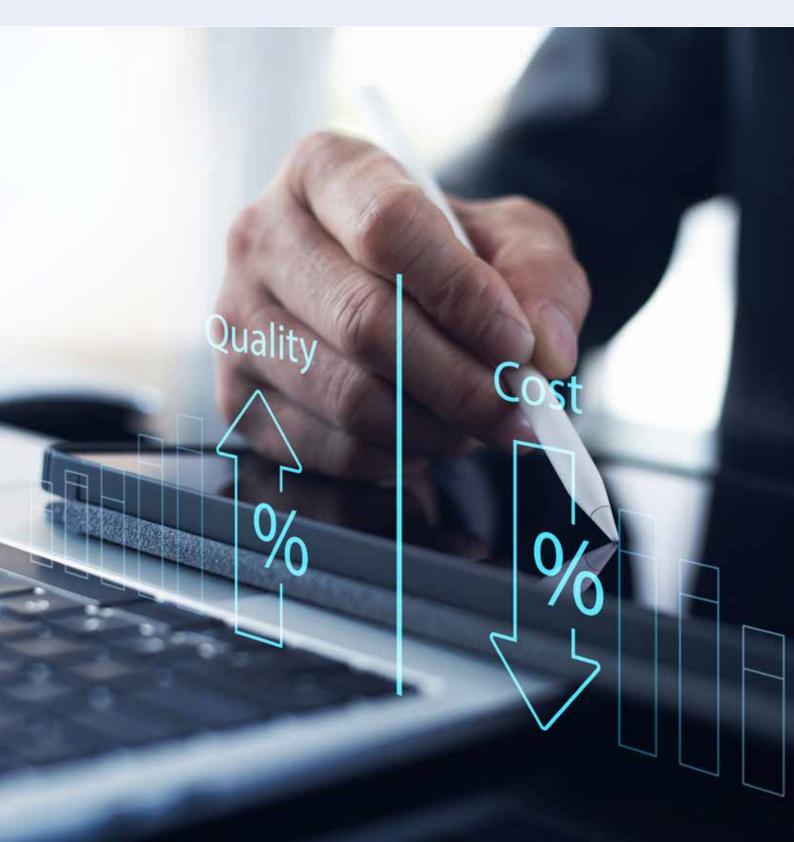


Cost of Quality

Understand, Measure and Optimise Cost of Quality

☑ Live Online Session on 19 September 2024



Objectives and Background

The primary goal of this live online training is to provide participants with a comprehensive understanding of Cost of Quality (CoQ) in the pharmaceutical industry and equip them with practical insights and strategies. The program will focus on key aspects such as understanding quality costs, determining the cost of poor quality, exploring CoQ in operations, and fostering a culture of quality improvement and innovation.

What Is "Cost of Quality" (CoQ)?

CoQ in pharmaceutical manufacturing refers to the total cost incurred by a company to ensure that its products meet the required quality standards, including GMP-compliant production, quality control, quality assurance and quality improvement activities. This includes the cost of all activities taken up proactively to prevent defects and failures and to deliver good quality. So overall, CoQ is the cost incurred to deliver a quality product to the client (patient).

In the dynamic and highly regulated pharmaceutical industry, maintaining and improving product quality is paramount. A CoQ framework offers a structured approach to assess the financial impact of quality-related activities. By understanding and effectively managing CoQ, pharmaceutical companies can enhance operational efficiency, ensure compliance with regulatory requirements, and ultimately deliver safer and more effective products to the market.

To achieve this, it is important to understand CoQ and setting clarity in expectations is very crucial. The challenge is to achieve the right balance between quality and cost and achieve what is best for the patient and required by the regulations.

All of this naturally leads to the question of how to measure CoQ and how to use this information to foster decisions.

Target Audience

Quality personal and professionals from pharmaceutical manufacturing and quality control who want to get a comprehensive understanding of the CoQ and its implications for the pharmaceutical industry.

Programme

Understanding Cost of Quality (what are Quality Costs and Costs of Non-Conformance?)

- Development of quality costs for drug production
 - Generic manufacturers and production costs
 - Manufacturer discount and cost pressure
 - Challenges and trends
- Cost driver quality costs
 - Explanation of CoQ methodology
 - Cost of poor quality (CoPQ)
 - Main categories within CoPQ

KPIs as a Tool for Measuring and Analysing CoQ

- Less is more: define reasonable KPI (for info or for action?)
- Generate understanding and buy in from team (department/site/ global)
- Feedback loop: Measure Analyse
 Improve Control
- "Saying No" and challenging status quo: discussions with team & management

CoQ in Operations: Benefits and Limitations

- How to ensure adherence to GMP and other quality requirements while minimizing CoQ
- The Link to Business Continuity
- Advantages of introducing CoQ
- Limitations of CoQ
- Quality Culture

Quality is all about Mindset!

- Understanding politics and stakeholders: influence of team dynamics
- Change management when setting CoQ initiatives
- Why quality professionals should use a bike often?

Benjamin Daum



Benjamin Daum is Site Head and Managing Director at Sandoz in Rudolstadt (Germany), Guest Lec-

turer for the Pharma Technology Master Course at Anhalt University of Applied Sciences, Köthen (Germany) and for the Maintenance and Operations Bachelor Course at University of Applied Sciences, Eisenach (Germany).



Prof Dr Florian Priese

Anhalt University of Applied Sciences

Florian Priese is Full Professor Pharmaceutical

Quality Management and Analytics, Anhalt University of Applied Sciences, Köthen (Germany) and consultant for Operational Excellence, Quality and Project Management with his own company cGMP-solutions. Before that he worked 15 years in several roles in the pharmaceutical industry (e.g. Novartis, Boehringer, IDT Biologika).



Dr Ramzan Tabasum

Ramzan Tabasum is Senior Director, Head of Biologics Quality Control at Lonza and a Visiting Pro-

fessor at the SBS Swiss Business School for Strategic Management and Leadership. He has almost 20 years of experience in a variety of roles in R&D, Operations and lately quality at GSK, CSL and Lonza.

Details

Date of the Live Online Training Thursday, 19 September 2024, 12.30 – 17.00 h CEST

Technical Requirements

We use Webex for our live online training courses and webinars.

Fees (per delegate plus VAT)

ECA Members EUR 590.-APIC Members EUR 640.-Non-ECA Members EUR 690.-EU GMP Inspectorates EUR 590.-The conference fee is payable in advance after receipt of invoice. The Registration does not include ECA Membership.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event. CONCEPT HEIDELBERG P.O. Box 10 17 64 | 69007 Heidelberg, Germany Phone +49(0)62 21/84 44-0 Fax +49(0)62 21/84 44 34 info@concept-heidelberg.de www.concept-heidelberg.de

For questions regarding content, contact:

Wolfgang Schmitt (Director Operations) at +49(0)62 21/84 44 39, or at w.schmitt@concept-heidelberg.de

For questions regarding organisation, contact:

Sonja Nemec (Organisation Manager) at +49(0)62 21/84 44 24 or at nemec@concept-heidelberg.de

All details and registration online at: www.gmp-compliance.org

CE/1604