QUALITY FUNDAMENTALS COURSE SYLLABUS

AABB

Quality Fundamentals Course

Syllabus

Table of Contents

Technical Requirements and Contact Information for Assistance

This course is offered online as independent, self-paced study through the AABB Education Platform located at http://education.aabb.org.

Technical Requirements - learners must:

- Have an internet connection to access the course
- Navigate and be able to use the features of the course content and Education Platform

The course can be viewed on a mobile device; however, a desktop or laptop computer is recommended. AABB recommends learners use either the Google Chrome, Safari, Microsoft Edge or Firefox browsers to access the course. Anyone using MAC or PC can download Google Chrome. Internet Explorer is not supported.

For questions related to the program submit an enquiry via email to the AABB eLearning team at eLearning@aabb.org. A response should be expected Monday – Friday during business hours (US Eastern Standard Time or EST) within 48 hours of request.

Course Overview

This course is developed for the early-career laboratory professional to provide a foundation in Quality Systems and Quality Management. It is comprised of six (6) modules covering key topic areas:

1. Quality System Basics
2. Organization, Facilities, Resources
3. Equipment and Suppliers
4. Process Control
5. Documents, Records and Nonconformances
6. Audits and Corrective/Preventive Action

The key topic areas cover elements relevant to developing an understanding of the fundamentals of a Quality program. Each module includes a video, additional supporting reading materials and knowledge checks. At the conclusion of each module, learners are provided three knowledge check questions designed to reinforce learning (two attempts on each knowledge check are provided). Although there is no required passing score, learners are encouraged to review the appropriate sections of the video or reading materials when questions are missed to ensure a better understanding of the content.

The course is expected to take approximately 2-3 hours to complete. The course can be taken asynchronously at the convenience of the learner; however, access to the course is available for one year from the date of registration.

Learning Objectives

Upon completion of this course, learners should be able to:

- Describe a Quality Management System and its elements.
- Apply elements of a Quality Management System within a laboratory setting.
- Identify resources for developing, defining and maintaining elements of the Quality Management System.

Course Outline

Module 1: Quality System Basics

Key points covered include the importance of Quality, and an overview of Quality Systems and Quality Management System. Module includes:

- Video (7:12 minutes)
- Reading: AABB *Technical Manual*, 20th Edition, Chapter 1 – Quality Management Systems: Principles and Practice

Module 2: Organization, Facilities, Resources

Key points covered include organization, executive management, and training and competence. Module includes:

- Video (13:14 minutes)
- Reading: US Code of Federal Regulations – 42 CFR 493 - Laboratory Requirements

Module 3: Equipment and Suppliers

Key points covered include equipment, suppliers and incoming supplies. Module includes:

- Video (7:52 minutes)
- Reading: US Code of Federal Regulations – 21 CFR 606.60 – Equipment

Module 4: Process Control

Key points covered include process control, validation, and change control. Module includes:

- Video (10:15 minutes)
- Reading: FDA General Process Validation – General Principles and Practices

Module 5: Documents, Records and Nonconformances

Key points covered include documents, document control, nonconformances and errors. Module includes:

- Video (11:25 minutes)
- Readings:
  - US Code of Federal Regulations – 21 CFR 606
  - Error reporting templates excepted from *Error Management: Turning a Negative Situation into a Positive One*, AABB Press, 2022

Module 6: Audits and Corrective/Preventive Action

Key points covered include audits, quality monitors, and corrective/preventative action. Module includes:

- Video (12:35 minutes)
- Readings: Root Cause Analysis Tools:
  - Five Whys Tool for Root Cause Analysis
  - How to Use the Fishbone Tool for Root Cause Analysis
  - Guidance for Performing Failure Mode and Effects Analysis with Performance Improvement Projects

Activities for Successful Completion of the Course

Watch the video for each module, review the additional reading materials, and complete the knowledge checks provided with each module. Learners can view the modules multiple times during their access period. After completing all the modules, a course evaluation is required before the course is marked as complete and continuing education credits are awarded. This is your opportunity to share with AABB your experiences and recommendations to further enhance the program.

Continuing Education Credits/Certificate of Completion

This course is eligible for three (3) continuing education credits/contact hours for General Participation, California Nurse, California Lab Personnel or Florida Lab Personnel. The number and type of credits awarded for this course was determined by the estimated program completion time. This course is not eligible for continuing medical education credit for physicians. For more information on each credit type please visit AABB's Continuing Education Credits webpage. A continuing education certificate of completion will be immediately provided upon reviewing all modules and completion of the course evaluation**.** Learners will also be able to access the continuing education certificate in the My Transcripts section of the AABB Education Platform.

References

These references are also recommended for additional reading as you expand your knowledge of Quality Management Systems (not provided with the course).

- Alsaqri, Faisal S., Chenoweth, A. Error Management: Turning a Negative Situation into a Positive One, AABB Press, 2022
- Arter, D. R. (2003). Quality Audits for Improved Performance. ASQ Quality Press 2003
- Association of the Advancement of Blood and Biotherapies (AABB). Standards for Blood Banks and Transfusion Services, 33rd ed, 2022
- Code of Federal Regulations, 42 CFR 493, 21 CFR 606
- Cohn, C. S., Delaney, M., Johnson, S. T., & Katz, L. M. Technical Manual. AABB 2020
- Grimes, Kevin G. ISO 9001:2000 A Practical Quality Manual Explained, ASQ 2003
- Nevalainen, D. Quality Systems in the Blood Bank Environment, 2nd ed., AABB Press 1998
- Walters, L. Introducing the Biq Q: A Practical Quality Primer, AABB Press 2004
- Westcott, Russell T. The Certified Manager of Quality/Organizational Excellence Handbook, 3rd ed, ASQ Quality Press 2006

Course Faculty

This course was developed and presented by **Holly M. Rapp, BS, MT(ASCP)SBB, CQA(ASQ), CMQ/OE**
After graduating from Alderson-Broaddus College in Philippi, WV with a degree in Medical Technology, Rapp spent more than two decades as a medical technologist with supervisory roles at various hospitals and blood centers across the United States. In 1999, she joined AABB as a lead assessor and was promoted to AABB's Director of Accreditation and Quality in 2002, a position she held until she retired in 2017. Rapp is recognized internationally as an expert in Quality in the blood and biotherapies field, and now helps facilities around the world develop and maintain quality assurance programs as an independent consultant. Rapp is based in Myrtle Beach, SC.

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