COBBLESTONE

COURSE ID 2578

The QbD Toolbox

Resources That Help New QbD Programs

DIRECTED BY

Ranjit Barshikar, CEO of QbD International, United Nations Adviser-Geneva

90 MINUTE

ACCREDITED COURSE

- Quality by Design step-by-step Implementation in Formulation Development
- Critical Quality Attributes (CQA)
- Critical Material Attributes (CMA)
- Critical Process Parameters (CPP)
- Quality Target Product Profile (QTPP)

about the course

If you are charged with exploring or implementing a QbD effort within your organization, where do you begin? Available guidance documents do not provide all of the information necessary to effectively implement such a program. Without proper understanding of how to establish QbD, your efforts may fail.

This 90-minute accredited training course presents methods that assist R&D - QbD team members and process operations personnel in understanding Product & Process. As a part of Risk Management, Risk Priority Number is an extremely useful metric for risk management only when its defining scales are appropriate. This course aids participants in establishing scales that make sense. The course includes basic simplified factorial analysis to reduce the sheer number of experiments, multivariate data analysis and software that will perform these experiments efficiently. At its conclusion, participants will have a toolbox of options for managing the details of a QbD program.

Live interaction with the instructor allows for dynamic discussions and clarifications.

For attendance verification and to maximize participation, participants attending the live training are required to use their webcam during the course. Microphones and speakers/headset are encouraged.

who should attend

This course is intended for professionals within the pharmaceutical industry. It will be especially valuable to personnel in the following areas: R&D, QA/QC, Regulatory, and Manufacturing.

Managers and supervisors of this personnel will also benefit from this training by learning the challenges faced by them.

learning objectives

Upon completion of this course, you will be able to:

- Improve process and product knowledge
- Classify ways to identify CQA, CMA & CPP
- Develop risk analysis and management metrics, including Risk Priority Number (RPN)
- Explain experimental design space that aid in Design of Experiments
- Examine multivariate data using, e.g., response surfaces
- Identify importance of control strategy

course outline

Review of Learning Objectives

Module 1:

- Why QbD
- Difference between Traditional vs. Enhanced understanding of Product & Process
- Customer Expectations -Quality Target Product Profile (QTPP)

Module 2:

- Identification of Critical Quality Attributes CQA by Risk Management
- Identification of CMA / CPP impact on CQA & Customers
- Ensuring effective Design Space of CPP

Module 3

- Design Space and Strategic Control Strategies
- Lifecycle Management

Question and Answer Session

Assessment Opportunity

course instructor

Ranjit Barshikar has 52 years of Pharmaceutical / Biotechnology Industry Experience in Quality, R&D, Mfg., and Regulatory. He is experienced in Quality Systems, Manufacturing Excellence, and the US and Foreign GMP Compliance. He being a QbD expert, has trained more than 1500 Scientists from Global Multinational & Generic Cos., on QbD implementation & ANDA filings for QbD elements. He has significant experience in Compliance and Quality Management, Validation, and GMP compliance auditing of manufacturing facilities for the production of sterile products by aseptic processing, solid dosage forms, etc. Additionally, Mr. Ranjit has high experience in ICH Q11-QbD implementation in API development, ICH Q14-Analytical Method Development by QbD & Validation, ICH Q12- Life Cycle Management. He has several articles published Globally on cGMP Compliances / QbD implementation. Mr. Ranjit is specialized in Process Analytical Technology (PAT) Process monitoring.

Accreditations

International Accreditors for Continuing Education and Training (IACET)

Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 1.5 contact hours, or.2 CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)

Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS- established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.