COBBLESTONE

COURSE ID 0224

REVISED!

Quality Management and Compliance in the Pharmaceutical Industry

DIRECTED BY

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12 Hour

ACCREDITED COURSE

- Evolution of Global Regulations and GMPs (increase in ICH guidance exposure)
- Handling Regulatory Inspections
- Basic Quality Systems
- Facilities and Equipment
- Materials - Supplier/Vendor Management/External Manufacturing/Contract Requirements
- Production and Packaging (serialization)
- QC - Laboratory Controls/External Laboratories/Contract Requirements/Pharmacopoeia
- Key Quality Systems and their interdependence with other quality systems (deviation to CAPA or Change Control)

about the course

Under the global regulator-based inspection approach, the Quality system is one that is routinely audited. Quality issues are a huge factor in inspection observations leading to recalls for drugs, biologics, and medical devices. This indicates that not all companies are meeting current GMP expectations. Clearly a better understanding is needed to overcome this trend and ensure compliance for your company.

This intensive 12-hour, accredited training, provides the basic principles and practices of Quality Assurance, Quality Management, Quality Control, and use of robust Quality Systems in the pharmaceutical industry. The course is presented in an open, interactive manner, encouraging discussion throughout. The material also applies to the bio/pharmaceutical, diagnostic, and medical device industries.

This introductory course would be beneficial to excipient and API suppliers. Discussions will include the role of quality, major elements of pharmaceutical quality, the impact of management practices, the features of an effective quality organization, quality management throughout the product life cycle, and the role of corporate quality. This course discusses current quality issues including outsourcing, the evolution of global regulatory approaches, global standards, and the use of such techniques as Risk Management, Quality-by-Design and the Quality System approach.

who should attend

This introductory course will benefit those who need to understand the responsibilities and functions of the Quality Unit in a pharmaceutical firm. Participants will learn how the quality organization impacts all areas of operations and works as a team to help assure the quality of the products. In addition, the course highlights how to maintain compliance to regulations within the pharmaceutical manufacturing arenas and for supplier related materials or finished product. This course is particularly suitable for chemists, pharmacists, engineers, and administrators working in the following areas:

- Process Development
- Analytical Development
- Quality Assurance
- Quality Control
- Regulatory Affairs
- Plant Operations
- Engineering/Maintenance
- Corporate/Plant Management
- Contract (External) Manufacturing
- Supplier Quality
- Purchasing

learning objectives

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

- Explain how and why regulatory laws were enacted and how this evolved to global ICH guidance documents to define cGMPs expectations
- Identify what fundamental components are needed to implement robust quality systems and processes within the quality assurance and control functions as well as other departments in the pharmaceutical and medical device industries to assure compliance
- Discuss how and why Management Review and Quality Risk Assessments are instrumental to maintaining a compliant organization including contracted external manufacturers and laboratories.
- Analyze current agency inspection trends to help stay abreast of the focus of compliance failures

course outline

Review of Learning Objectives

Evolution of Global Regulators and GMPs

- GMPs - FDA, EMA, MHLW, NMPA, ANVISA, ICH etc.
- System Risk/Based Inspections
- The Role of QA & QC
- Handling Regulatory Inspections

Basic Quality Systems

- Documents
- Electronic Document Management
- SOPs & Training
- Records

Facilities and Equipment

- Equipment Qualification
- Computer Qualification
- CAPA Management
- Risk Management

- Management Review
- Water and Utilities (HVAC, Air)
- Facility Mapping
- Gowning/People Qualification
- Calibration

Materials - Supplier/Vendor Management

- Supplier Quality Oversight
- Supplier Audits

Production and Packaging

- Material Receipt, Inspection, Release
- Master Production Records
- Batch Production Record
- Batch Record Review & Disposition

Workshop on Change Controls

Questions & Answers

QC – Laboratory Controls

- Laboratory Operations
- R & D
- Commercial
- Method Development/Validation/
- Transfer/Verification
- Laboratory Records
- Role of Pharmacopoeia (USP, Ph. Eur., BP, JP, ChP, etc.)

Key Quality Systems

- Deviations
- Investigations
- Change Control
- Complaints, Field Alerts & Recalls

Question and Answer Session

Assessment Opportunity

course instructor

Joe Albanese is Owner and Managing Director of Albanese Consulting LLC, which he formed after more than 29 years' experience in the pharmaceutical industry. He recently retired from Janssen Pharmaceuticals (part of Johnson and Johnson) where he held positions in R&D, Supply Chain and Quality in both Small Molecule and Biotherapeutics development and manufacturing. Joe has held positions of Associate Director Quality Control in 2 plants (one for small molecule finished dosage production and one for biotherapeutics bulk API production). Joe was also an Associate Director of Lifecycle Management and Global Director of Quality Systems. His last role, as Director of Analytical Strategy and Regulatory Compliance, Joe was responsible to ensure emerging global regulations for CMC development were integrated into the R&D development processes to ensure timely filings in all markets. Additionally, Joe was responsible for the compendial vigilance process for all Janssen products ensuring compliance with all major global and national pharmacopoeias. He actively served in industry working groups such as the PhRMA Limited Duration Key Issues Team for compendial issues with USP, the EFPIA Biotherapeutics subteam for the elaboration of

biotherapeutic compendial standards and was a member of the USP General Notices Project Team. He is currently active in the industry trade organizations NJPQCA, Midwest Compendial Discussion group and PDA that influence global health and compendial authorities. Joe received a B.S degree. in Chemistry from Elizabethtown (PA) College and Ph.D. degree in Chemistry from the University of Delaware.

additional faculty

Beverly Barnwell is an independent consultant with over thirty-five years of experience, thirty-one of these years with the Johnson and Johnson family of companies. Bev began her career at McNeil Consumer Healthcare in the product stability group supporting both Developmental and Marketed Products for the McNeil portfolio. As she transitioned to the pharmaceutical sector (Janssen Pharmaceuticals), her responsibilities and experience grew as she moved into the Quality Assurance Function. This included creating uniformity in processes across the two quality assurance labs. She also worked as an auditor in the Supplier Quality Group before moving to the External Manufacturing group as a quality manager responsible for products manufactured for Janssen by third parties. From 2008 to 2012, Bev moved to a Supply Chain role at a small company in Philadelphia, Iroko Pharmaceuticals. Her role as Director of New Product Integration drove integration of new products and new active ingredient suppliers into Iroko's global supply base. She was responsible for all contractual agreements and liaising with the different functional areas to complete in-transfers on time. In 2012, she returned to McNeil Consumer Healthcare as platform lead (Director) in external manufacturing supporting the return of products to the market during while under a Consent Decree order. This included driving completion of the needed work plan for External Manufacturing, and qualification of third-party suppliers for the McNeil brands.

In 2016, Bev moved to DePuy-Synthes to support them in developing a more secure supply chain. She re- negotiated unfavorable contracts, brought reliability thinking and processes into the External Manufacturing space, and managed global projects to secure the supply of the medical device products for the future. Since retiring, Bev has consulted for a New Jersey based device company as they move toward approval of their first product. She also completed her Master Gardening certification through Cornell University and their cooperative extension network. She and her husband, Paul currently live in New York state on Keuka Lake.

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 X contact hours, or X 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.

The American Society for Quality (ASQ)

The American Society for Quality (ASQ)-Recertification Opportunities
ASQ offers 18 certification programs that recognize quality professionals who strive to maintain their competence through participation in continuing education and related professional development activities.
This and many other CfPA courses offer training that may be helpful in obtaining required ASQ's recertification education units. A list of recommended courses can be found on https://www.cfpa.com/Accreditation/AccreditionView/ASQ.
For more information, visit: www.asq.org