COBBLESTONE

COURSE ID 3

GMP Professional Certification

A 10- Part Program

DIRECTED BY

Louis Angelucci — Consultant for the Pharmaceutical Industry

15
Hours

ACCREDITED COURSE

- 10 Courses
- 90 Minutes each

about the course

The GMP Professional Certification Program will provide the necessary orientation and understanding of the USA FDA's Current Good Manufacturing Practice for pharmaceutical products.

The certification program will cover techniques and practices to ensure compliance with these regulations including manufacturing, packaging, holding, distribution and the laboratory. It will provide a practical application of the cGMP on the operating level.

who should attend

The Certified GMP Professional is an individual trained in the understanding and interpretation of the FD&C Act, the cGMPs, the FDA Guidance Documents, and FDA's recent Observations issue in FD 483's to Pharmaceutical firms.

learning objectives

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

- Demonstrate a good working knowledge of Good Manufacturing Practices (GMP's) for drugs and international standards and regulatory requirements – as applicable.

certification outline

- Scope of the FDA – History and FDA Regulations
- 21 CFR 211 Subparts A & B: Quality and Personnel
- 21 CFR 211 Subparts C & D: Facility and Equipment
- 21 CFR 211 Subparts E & F: Control of Components and Production/Process Control
- 21 CFR 211 Subparts G & H: Packaging, Labeling and Distribution
- 21 CFR 211 Subparts I: Laboratory Controls
- 21 CFR 211 Subparts J &K: Records and Salvaged Drug Product
- FDA Quality Systems Guideline
- cGMP Compliance and non-compliance
- cGMP Compliance - Process Validation

course instructor

Louis Angelucci, is a Consultant for the Pharmaceutical Industry as a pharmaceutical professional with over 30 years' experience in Quality Assurance, Quality Control, Regulatory Affairs, Validation, consent decree remediation as well as cGMP Compliance in the Medical Device and Pharmaceutical industries.

He has worked for several well-known companies including Johnson & Johnson, Bristol-Meyer Squibb, Pfizer, Schering Plough, and Merck. His experience has been either as a direct employee or as a contracting consultant while employed at Foster Wheeler and Aker Kvaerner. As a consultant, Mr. Angelucci has worked at various project locations domestically and in Europe and Asia. With these firms he has been involved with auditing, GMP training, Bio-tech consulting as well as FDA audit and PAI readiness training and participation.

Mr. Angelucci is a degreed engineer with two master's degrees in engineering, holds industry certifications with ASQ as a CQE, CQA, and CPGP. Previously, he was the ASQ Philadelphia chapter Education Chair. In addition, he holds a PMP certification through the Project Management Institute. He has published numerous articles on the subjects of Validation and compliance and has been a speaker to industry groups such as ISPE, IVT, DIA, PDA, ASQ, and Cobblestone.

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 15 contact hours, or 1.5 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.