COBBLESTONE

COURSE ID 1

GMP Laboratory Control Certification

A 10 Part Program

DIRECTED BY

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15
Hours

ACCREDITED COURSE

- 10 Courses
- 90-Minute each

about the course

"The pharmaceutical quality control laboratory serves one of the most important functions in pharmaceutical production and control," the FDA states in its own Guide to Inspecting Quality Control Laboratories. The quality control laboratory and product testing are covered by a significant portion of the CGMP regulations (21 CFR 211). " Accurate, reliable, and meaningful laboratory data is critical for the approval and use of raw materials, the release of commercial batches, and the support of a given product's shelf life."

Given the large number of FDA observations cited each year for laboratory operations, it is clear that industry is not fully complying with FDA requirements. Such flaws in laboratory operations can and do result in recalled batches, court injunctions, and even the forced discontinuation of commercial operations, all of which have a negative impact on company profitability. FDA-regulated organizations must ensure that their laboratories are fully compliant with GMPs.

Our GMP Laboratory Control Certification program teaches you the fundamental concepts and tools that a GMP Laboratory Control Professional must know. Its goal is to give rules, tools, and methods for managing GMP labs in a way that is effective and legal. This GMP Laboratory Control Certification Program gives professionals like you the training and skill development they need to earn

who should attend

The GMP Laboratory Control Certification will be valuable to all individuals working within or managing a GMP laboratory that supports either the R&D development of a new drug product or the testing and control of commercial drug product released to the market.

- Research and Development
- Quality Assurance
- Contract Laboratories
- Quality Control
- Technical Operations

Those who work in regulatory affairs or are in charge of reviewing or auditing lab data and reports should also think about how valuable this comprehensive certification is for their jobs.

learning objectives

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

- Operate as a laboratory analyst in full GMP compliance.
- Plan and manage laboratory control operations.
- Comply with all applicable regulatory requirements.
- Train and mentor staff.
- Develop SOPs and tools.
- Represent the organization in audits and regulatory investigations.
- Interact with management, regulators, and auditors.

certification outline

- Laboratory Controls Overview & Establishment of Specifications
- Analytical Methods Validation - 21CFR211.165(e)
- Stability Testing - 2 CFR 211.166 (a & b)
- IQ, OQ, and PQ for the Laboratory
- Good Documentation Practices for Laboratory Records
- How to Manage and Prepare for Pre-Approval Inspections (PAI)
- Managing Standard Operating Procedures (SOPs) in the FDA Regulated Environment
- Handling OOS Test Results and Completing Robust Investigations
- Laboratory Controls: Anticipate the Systems-Based FDA Inspection
- Data Integrity Practices for the Laboratory and Beyond

course instructor

Danielle DeLucy, is currently an Independent Consultant to the Biologics and Pharmaceutical Industries specializing in the areas of Quality Assurance and Quality Systems. Prior to this role, Danielle has been in the industry for 20 years serving in numerous Quality Management Roles, such as the Director of Product Quality, the oversight of Sterility Assurance practices and provided QA oversight of numerous filling and packaging operations. Danielle began her QA career as a Quality Control Pharmaceutical Microbiologist at a contract laboratory where she performed various tests for their clients. In the years after, she has held positions in the Quality management arena while increasing her responsibility. She has helped to lead many Regulatory Health Inspections and was instrumental in the coaching process of her peers prior to any inspection. Currently, Danielle assists companies who are faced with warning letters and consent decrees establish more robust quality systems so that the company can succeed.

Charlie Neal, Jr., Owner and Senior Consultant for Premier Quality Consulting, has been in the Pharmaceutical industry for over thirty-five years. He has a wealth of hands-on technical experience acquired from the chemical, drug, device, and pharmaceutical industries. He has experience in Research, Development, Process Engineering, Validation, Technical Transfers, Manufacturing, Quality, Compliance, Project Management, and Sales and Marketing.

He has written and presented numerous papers on Qualification and Validation and their requirements. He is a former member of the Institute of Validation Technology's Editorial Board. He has written and published articles on Technology Transfers and presented a paper on this topic in Tokyo, Japan. He has authored a chapter on Transdermal Process Validation that was published in the 3rd edition of "Pharmaceutical Process Validation". He has established and currently runs his own company, Premier Quality Consulting, which offers consulting expertise to the Pharmaceutical and Bio-Tech companies.

David E. Wiggins is an Analytical/Stability Consultant within the pharmaceutical industry with a focus on pre-market stability, analytical method validation and method transfer.

Mr. Wiggins was previously Sr. Associate Director of Analytical Development for Bayer Consumer Care. Prior to joining Bayer, Mr. Wiggins worked for Schering-Plough and Merck with responsibility for Method Optimization, Method Validation, Method Transfer and Stability (both pre- and post-market). These responsibilities have additionally included involvement with multiple NDA submissions, ANDA submissions and FDA general and PAI inspections.

Mr. Wiggins has over 35 years of experience in the pharmaceutical industry in both a QC and an R&D setting. During this time, he has been instrumental in establishing and updating stability and method validation policy to be consistent with the changing regulatory requirements.

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 the 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.