PORTLAND

BioPro Quality Assurance

Certificate

Curriculum Outline

- Overview of FDA
- Quality Systems Overview
- Preparing for Regulatory Inspections
- Current Good Manufacturing Practices (cGMP)
- Data Integrity
- Change Management
- Managing Deviations
- Risk-Based Approach to Manufacturing: ICH Q8, Q9, ISO14971
- Customer Complaints and Recalls
- Design Controls
- Root Cause Analysis and Corrective Action
- ISO13485:2016 Internal Auditor Training

Course Information

2020 Class Schedule
Location: Virtual
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Oregon Bioscience Association

www.oregonbio.org

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The BioPro Quality Assurance Certificate is a comprehensive 80-hour training series. With a formal steering committee of human resources representatives and industry experts, Oregon Bio selects courses and instructors that will have the most value to industry and their workforce development needs. From high level overview to technical details, this series is built to train current and future Quality Assurance professionals.

BioPro Training Program History

Since 2007 the Oregon Bioscience Association (Oregon Bio) has been offering a professional workforce training program (BioPro) designed to meet the needs of Oregon's growing bioscience industry. Since BioPro's inception, over 2,400 bioscience workers benefited from this program. Based on the guidance we receive from our Industry Steering Committee we have developed a robust catalog of industry specific classes taught by industry experts.

BioPro is built around the strength of our industry members and their direct input. In order to respond quickly to industry needs, the BioPro program is managed by the BioPro Industry Steering Committee. The committee develops new curriculum requests, evaluates actual course materials, and conducts mock classes to assess potential instructor and their teaching style.

Once selected, our current curriculum includes classes ranging from 1/2 day sessions addressing specialized topics to a sixteen week course for Six Sigma Black Belt certification.

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COURSE DESCRIPTIONS

OVERVIEW OF FDA (7/21/2020, 1 - 5 p.m.) This course is designed to provide participants with insight into what the regulations are, why they are there, where they fit together, when they apply, and how to interpret them. We will discuss Quality Systems and Good Manufacturing Practices, as well as submissions, registration, clinical trials, recalls, and adverse event reporting.

QUALITY SYSTEMS OVERVIEW (7/22/2020, 1 - 5 p.m.) This course focuses on medical device companies and how to create, implement, and improve QS that match your company. Both FDA QS and ISO QS will be discussed. We will also cover: how different departments are impacted by QS, the biggest pitfalls in establishing and maintaining QS, and how to critically evaluate your QS.

PREPARING FOR REGULATORY INSPECTIONS (7/23/2019, 1 - 5 p.m.) Many organizations, such as FDA, ISO, OSHA, and EPA, can conduct audits or inspections in a biotech company. We will focus on these preparatory techniques, for example, using internal auditing as a tool, developing an inspection procedure, educating employees, and conducting mock inspections. Participants will role-play being auditors and auditees.

CURRENT GOOD MANUFACTURING PRACTICES (cGMP) (7/27-28/20, 8 a.m. - 12 p.m.) Building upon Overview of FDA and Quality Systems Overview courses, this course goes beyond the basics and uses interactive exercises to understand and apply current Good Manufacturing Practice (cGMP) regulations for pharmaceutical, biopharmaceutical and medical device industries.

ISO 13485:2016 INTERNAL AUDITOR TRAINING (8/3-4/20, 8 a.m. - 12:30 p.m.) To successfully implement and maintain a quality management system a company must have an Internal Audit process and use trained auditors to perform the audits. Internal auditors are also a key element in quality system improvement. This new course teaches auditing to the ISO 13485:2016 standard and places a strong emphasis on promoting employee participation in the improvement process.

DATA INTEGRITY and GDP (8/13/20, 8 a.m. - 12 p.m.) Data integrity and good documentation are essential in providing evidence of a safe and effective product. Learn what the key elements of good documentation practices and data integrity are, how to apply them, and how to pro-actively ensure your system is compliant.

ROOT CAUSE ANALYSIS AND CORRECTIVE ACTION (8/17-18/20, 8 a.m. - 12:30 p.m.) This 1-day workshop will show how to use root cause analysis tools and methods to find the underlying causes of problems that impact an organizations operations and profitability. You will also learn the methodology to address corrective actions.

DESIGN CONTROL (8/26-27/20, 8 a.m. - 12 p.m.) In this "hands on" course participants will design a product utilizing regulations for design control and application of risk management. Participants will perform risk management, plan design activities, determine design inputs and outputs, verification, validation, how to handle design changes, and the contents and maintenance of a Design History File.

RISK-BASED APPROACH TO MANUFACTURING: ICH Q8, Q9, ISO14971 (One-Day) ICH Guidance documents Q8 (Pharmaceutical Development), Q9 (Quality Risk Management) and Q10 (Pharmaceutical Quality System) work in conjunction with one another to describe a science- and risk-based approach to pharmaceutical manufacturing and development. This course will explain the relationship between ICH Q8, Q9, and Q10, and describe regulatory expectations for risk-based management and programs.

CUSTOMER COMPLAINTS AND RECALLS (One-Day) Through interactive exercises of practical application and real life experiences, participants will learn why communication is key and how to apply governing regulations during the customer complaint and recall processes.

CHANGE MANAGEMENT (Half-Day) Through interactive examples, this course will teach the process by which change management should be used to identify, evaluate, document, approve, implement, and close changes made throughout the product life-cycle.

MANAGING DEVIATIONS (Half-Day) Departures from approved instruction or established manufacturing standards used in are considered a deviation and must be investigated and evaluated for impact to product quality. Participants in this course will use real world examples to learn the process of identifying, documenting, and evaluating deviations.