PORTLAND

BioPro
Medical Device Foundations

Certificate

CURRICULUM Outline

- Design of Experiments
- High Performance Teamwork
- Impromptu Presenting
- Failure Mode and Effects Analysis
- Preparing for Regulatory Inspections
- Project Management
- Overview of FDA
- Quality Systems Overview
- Statistical Process Control

Course Information

Location: Virtual
Inquiries: julie@oregonbio.org

Oregon Bioscience Association

www.oregonbio.org

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The BioPro Medical Device Foundations Passport is a comprehensive 10-day 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 business topics including project management and impromptu presenting to technical topics including quality, design and control, this series is built to train current and future medical device 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.

www.oregonbio.org/biopro

COURSE DESCRIPTIONS

OVERVIEW OF FDA (7/21/20, 1 - 5 p.m.)
This course is designed to provide participants with insight into what the FDA regulations are, why they exist, how they fit together, when they apply, and how to interpret them. We will not just discuss Quality Systems and Good Manufacturing Practices, but also submissions, registration, clinical trials, recalls, and adverse event reporting. Each participant will develop a better understanding of the environment in which their company exists and how they can help their company thrive.

QUALITY SYSTEMS OVERVIEW (7/22/20, 1 - 5 p.m.) This course focuses on medical device companies and how to create, implement, and improve Quality Systems (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. There will be group exercises and lots of interaction among participants to provide multiple options. In QS, it is definitely true that one size does not fit all!

PREPARING FOR REGULATORY INSPECTIONS (7/23/20, 1 - 5 p.m.)
Many organizations, such as FDA, ISO, OSHA, and EPA, can conduct audits or inspections in a biotech company. Most people view these events as scary, but there are ways to make them less difficult. The first method is compliance with the applicable rules. After that, preparation is the key. We will focus on these preparatory techniques, using internal auditing as a tool, developing an inspection procedure, educating employees, and conducting mock inspections. Participants will roll-play being auditors and auditees.

FAILURE MODE AND EFFECTS ANALYSIS DESIGN OR PROCESS (8/24-25/20, 8 a.m. - 12:30 p.m.)
This course provides a structured guide to the process of performing an effective Failure Mode and Effects Analysis for Design and Development (DFMEA). DFMEA can be performed during design and development on products to minimize risks and future costs of new products. It is also a highly effective technique to use in planning under any quality management system standard, such as ISO 9001 and ISO 13485.

HIGH PERFORMANCE TEAMWORK (9/10-11/20, 8 a.m. - 12:30 p.m.) This course provides a structured guide to the process of performing an effective Failure Mode and Effects Analysis for Design and Development (DFMEA). DFMEA can be performed during design and development on products to minimize risks and future costs of new products. It is also a highly effective technique to use in planning under any quality management system standard, such as ISO 9001 and ISO 13485.

PROJECT MANAGEMENT (9/21, 22, 28, 29/20, 8 a.m. - 12:30 p.m.)
This course introduces students to the foundations of successful project management, especially in a technology environment. Students will learn key project management concepts, then immediately apply them in a hands-on team simulation. This course approaches project management from the standpoint of managing a single, stand-alone project that is small to medium in size. The class takes students through the project life cycle in the same sequence they would face when managing a real project in the workplace.

DESIGN OF EXPERIMENTS (10/19, 20, 26, 27/20, 8 a.m. - 12:30 p.m.) Today's highly competitive environment leaves no time for trial and error. The Design of Experiments (DOE) course provides a structured method for determining the relationship between factors affecting a process and the output of that process. With this information, you can quickly develop the optimum balance between factors leading to dramatic improvements in quality, cost, and productivity. Participants in this 16 hour course will gain a firm understanding of the statistical concepts and basic principles underlying Design of Experiments.

STATISTICAL PROCESS CONTROL (11/2, 3, 9, 10/20, 8 a.m. - 12:30 p.m.) The key to improving process performance is to understand, control and reduce variation. In this workshop, participants will learn how the monitoring and analysis tools of SPC can be used to achieve that goal. Going beyond the mere mechanics of SPC, this workshop will also guide participants through the steps needed to define a process and determine proper measurement techniques so that the right control chart is used in the right place at the right time.

IMPROMPTU PRESENTING (Half-Day) You have less than 8 hours to pull together a last minute presentation to upper level management. Making your argument clear, concise, and coherent is critical. Here are some topics this class will address:

- What is your presentation goal?
- How do you decide what information to present and its prioritization?
- Who is your audience?
- How do you prepare for Q&A?
- What visuals are needed, if any?