BioCatalyst

Professional Certificate Program

Medical Device Foundations

CURRICULUM OUTLINE

- Design of Experiments
- Project Management
- Overview of FDA
- Business Communication Fundamentals
- Design Controls for Medical Devices
- Statistical Process Control
- Failure Mode and Effective Analysis
- Impromptu Presenting

business oregon

Oregon Bioscience Association

Course Information

Dates: October 2 - 17, 2014
Location: TDB
Applications /Inquiries:
biocatalyst@oregonbio.org

Employer Information: www.oregonbio.org

In 2014 Business Oregon, in partner ship with Oregon Bio received funding from the legislature to offer bioscience specific professional training (BioCatalyst) to under/unemployed Oregonians hoping launch their careers in the bioscience industry. The objective is to prepare qualified, mid-career candidates to earn sector specific bioscience industry certificates to facilitate this employment transition.

Offered at no cost to qualified candidates, Oregon Bio will launch this sophisticated certificate program in conjunction interested employers in August of 2014. Potential applicants should contact Oregon Bio and submit their application (website).

BioCatalyst History

For over five years 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 1,600 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.

The BioCatalyst program is a natural outgrowth of our existing program and lverages this deep pool of training expertise. Built around the strength of our industry members and their direct input, the BioCatalyst program is managed by the BioPro Industry Steering Committee of industry/human resource experts. These programs are specifically designed by industry leaders and embody their commitment to industry driven training, their years of expertise and desire to hire locally when possible.

About BioCatalyst Partners

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The BioCatalyst program would also not be possible without the financial support of the Oregon legislature and our deployment partner Business Oregon. Together we lead the way in establishing this unique public/private, industry-based bioscience training program.

COURSE DESCRIPTIONS: Medical Device Foundation Certificate

PROJECT MANAGEMENT (Two-Day)
Overview: 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.

FAILURE MODE AND EFFECTS ANALYSIS - PROCESS (One-Day)
Overview: 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.

OVERVIEW OF FDA (Half-Day, 8-12)
Overview: The FDA has more power to affect regulated companies than almost any other organization, yet many people don't understand it. Many others ignore it as much as possible. But the FDA affects the job of every person in a medical device or drug company. This course is designed to provide participants with insight into what the 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.

DESIGN CONTROLS FOR MEDICAL DEVICES (Half-Day 1-5)
Overview: Design Controls have been an FDA requirement for most medical device manufacturers since June 1998, but many still struggle with effective compliance. Design Control is the FDA term for how a medical device manufacturer controls the design, development, and manufacturing of its products. ISO 13485 uses the term "product realization" to describe these activities. In addition to the design and testing of devices, engineers must also focus on ensuring that all of the necessary documentation is in place to demonstrate compliance with Design Controls. This documentation can amount to several hundred pages or more for a single product launch.

DESIGN OF EXPERIMENTS (Three-Day)
Overview: 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 twenty four hour course will gain a firm understanding of the statistical concepts and basic principles underlying Design of Experiments.

BUSINESS COMMUNICATION FUNDAMENTALS (Half-Day, 8-12)
Overview: Whether communicating with your co-workers, your boss, or upper level management, get your message heard in a clear, concise and compelling manner. In this four-hour interactive business communication course, we will provide you necessary verbal, non-verbal and written tools to help you to communicate more effectively, and promote a respectful working environment.

IMPROMPTU PRESENTING (Half-Day 8-12)
Overview: 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. Your team is counting on you, and your reputation is at stake. 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?

STATISTICAL PROCESS CONTROL (Two-Day)
Overview: 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.

BioCatalyst

Professional Certificate Program

Medical Device Foundations

CURRICULUM OUTLINE

- Practical Data Analysis
- Project Management
- Overview of FDA
- Business Communication Fundamentals
- Design Controls for Medical Devices
- Statistical Process Control
- Failure Mode and Effective Analysis
- Impromptu Presenting
- Quality Systems Overview
- Preparing for Regulatory Inspections

business oregon

Oregon Bioscience Association

Course Information

Dates: November 6 - 21, 2014

Applications /Inquiries:
biocatalyst@oregonbio.org

Employer Information: www.oregonbio.org

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COURSE DESCRIPTIONS: Medical Device Foundation Certificate

PROJECT MANAGEMENT (Two-Day)
Overview: 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.

FAILURE MODE AND EFFECTS ANALYSIS - PROCESS (One-Day)
Overview: 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.

OVERVIEW OF FDA (Half-Day, 8-12)
Overview: The FDA affects the job of every person in a medical device or drug company. This course is designed to provide participants with insight into what the 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.

DESIGN CONTROLS FOR MEDICAL DEVICES (Half-Day 1-5)
Overview: Design Controls have been an FDA requirement for most medical device manufacturers since June 1998, but many still struggle with effective compliance. Design Control is the FDA term for how a medical device manufacturer controls the design, development, and manufacturing of its products. ISO 13485 uses the term "product realization" to describe these activities.
In addition to the design and testing of devices, engineers must also focus on ensuring that all of the necessary documentation is in place to demonstrate compliance with Design Controls. This documentation can amount to several hundred pages or more for a single product launch.

BUSINESS COMMUNICATION FUNDAMENTALS (Half-Day, 8-12)
Overview: Whether communicating with your co-workers, your boss, or upper level management, get your message heard in a clear, concise and compelling manner. In this four-hour interactive business communication course, we will provide you necessary verbal, non-verbal and written tools to help you to communicate more effectively, and promote a respectful working environment.

IMPROMPTU PRESENTING (Half-Day 8-12)
Overview: 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?

STATISTICAL PROCESS CONTROL (Two-Day)
Overview: 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.

PRACTICAL DATA ANALYSIS (Two-Day)Overview:
This 16-hour course provides an introduction to analyzing common business and industrial data. By the end of the course, you will be able to: analyze data using the most appropriate statistical methods and interpret the results, use statistical graphics to display data and the results of data analysis., distinguish between comparison and correlation hypotheses, apply the most appropriate statistical methods to test comparison and correlation hypotheses, and use a leading PC-based statistical software program.

QUALITY SYSTEMS OVERVIEW (Half-Day, 8-12)
Overview: Quality Systems (QS) are sometimes viewed as a necessary evil or belonging only to production and quality assurance personnel. However, effective QS can help a business not only comply, but excel. 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. 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 (Half-Day, 1-5)
Overview: 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, for example, using internal auditing as a tool, developing an inspection procedure, educating employees, and conducting mock inspections. Participants will roll-play being auditors and auditees.

BioCatalyst

Professional Certificate Program

Quality Assurance

CURRICULUM OUTLINE

- Business Communication Fundamentals
- Impromptu Presenting
- Principles of Lean Manufacturing
- Measurement Systems Analysis
- Overview of FDA
- Design Controls for Medical Devices
- Quality Systems Overview
- Preparing for Inspections in Regulated Industries
- ISO 9001/ISO 13485 Internal Auditor Training
- Financial Skills for Non-Finance People
- Problem Solving for Corrective and Preventive Action (CAPA)

business oregon

Oregon Bioscience Association

Course Information

Location: Welch Allyn
Dates: January 6 - 28, 2015
Applications /Inquiries:
julie@oregonbio.org

Employer Information: www.oregonbio.org

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COURSE DESCRIPTIONS: Medical Device Nontechnical Certificate

BUSINESS COMMUNICATION FUNDAMENTALS
Dates: Half-Day, *Jan. 6 (8:00-12:00 p.m.)*

Overview: Whether communicating with your co-workers, your boss, or upper level management, get your message heard in a clear, concise and compelling manner. In this four-hour interactive business communication course, we will provide you necessary verbal, non-verbal and written tools to help you to communicate more effectively, and promote a respectful working environment.

IMPROMPTU PRESENTING
Dates: Half-Day, *Jan. 7 (8:00-12:00 p.m.)*

Overview: 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?

PRINCIPLES OF LEAN MANUFACTURING
Dates: One-Day, *Jan. 8 (8:30-5:00 p.m.)*

This one-day highly interactive course provides an overview of the principles of Lean Manufacturing. Participants review the history of lean manufacturing and learn how lean manufacturing tools and programs apply in today's manufacturing environment. The course combines lecture and simulation that affords participants an immediate opportunity to apply the principles learned in the class. The results of the first simulation round provide the setting for continuous improvement. Lean principles incorporated over subsequent rounds allow participants to transform a chaotic, inefficient process to a highly productive and efficient production process

MEASUREMENT SYSTEMS ANALYSIS
Dates: One-Day, *Jan. 14 (8:30-5:00 p.m.)*

Overview: This one day course demonstrates the need for measurement systems analysis. For quantitative measurement systems, it covers repeatability, reproducibility, linearity, stability, precision, and accuracy. For attribute measurement systems, it covers appraiser self-agreement, appraiser cross-agreement, and agreement with standard.

OVERVIEW OF FDA
Dates: Half-Day, *Jan. 15 (8:00-12:00 p.m.)*

Overview: The FDA affects the job of every person in a medical device or drug company. This course is designed to provide participants with insight into what the 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.

DESIGN CONTROL FOR MEDICAL DEVICES
Dates: Half-Day, *Jan. 15 (1:00-5:00 p.m.)*

Overview: Design Controls have been an FDA requirement for most medical device manufacturers since June 1998, but many still struggle with effective compliance. Design Control is the FDA term for how a medical device manufacturer controls the design, development, and manufacturing of its products. ISO 13485 uses the term "product realization" to describe these activities.

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In addition to the design and testing of devices, engineers must also focus on ensuring that all of the necessary documentation is in place to demonstrate compliance with Design Controls. This documentation can amount to several hundred pages or more for a single product launch.

QUALITY SYSTEMS OVERVIEW
Dates: Half-Day, *Jan. 16 (8:00-12:00 p.m.)*

Overview: Quality Systems (QS) are sometimes viewed as a necessary evil or belonging only to production and quality assurance personnel. However, effective QS can help a business not only comply, but excel. 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. 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 INSPECTIONS IN REGULATED INDUSTRIES
Dates: Half-Day, *Jan. 16 (1:00-5:00 p.m.)*

Overview: 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, for example, using internal auditing as a tool, developing an inspection procedure, educating employees, and conducting mock inspections. Participants will roll-play being auditors and auditees.

ISO 9001/ISO 13485 INTERNAL AUDITOR TRAINING
Dates: Two-Day, *Jan. 20-21 (8:30-5:00 p.m.)*

Overview: 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 course teaches auditing to the ISO 9001/ISO 13485 standards and places a strong emphasis on promoting employee participation in the improvement process.

FINANCIAL SKILLS FOR NON-FINANCE PEOPLE
Dates: Two-Day, *Jan. 22-23 (8:30-5:00 p.m.)*

Overview: This two-day intensive workshop is specially developed to provide a solid foundation in financial analysis and decision-making, both from the perspective of the company and specific projects.

Financial Skills for Non-Finance People is an interactive workshop format including exercise, case studies, and real world projects to improve participants understanding and application of:

1.Financial analysis tools and how to apply them to value new products and programs

2.Basic and advanced techniques to make tradeoff and a portfolio decisions for product investments

3.Financial techniques to communicate and sell advanced R&D, platform and architecture programs

PROBLEM SOLVING FOR CORRECTIVE AND PREVENTIVE ACTION
Dates: One-Day, *Jan. 28 (8:30-5:00 p.m.)*

Overview: Two key goals of a quality management system are to find the root causes of actual and/or potential problems and to develop permanent solutions. In this one day workshop you will learn how to use tools and methods of problem solving in order to develop and implement solutions that are accepted, efficient, and effective. This workshop will also examine best practice CAPA systems to provide thoughts and ideas on how to improve the performance of your current system. This workshop is perfect for the novice or for those desiring an invigorating refresher.

BioCatalyst

Professional Certificate Program

Medical Device Foundations

business oregon

Oregon Bioscience Association

CURRICULUM OUTLINE

- Failure Mode and Effects Analysis
- Business Communication Fundamentals
- Impromptu Presenting
- Overview of FDA
- Design Controls for Medical Devices
- Quality Systems Overview
- Preparing for Inspections in Regulated Industries
- Practical Data Analysis
- Statistical Process Control
- Project Management

Course Information

Location: Welch Allyn
Applications /Inquiries:
julie@oregonbio.org

Employer Information: www.oregonbio.org

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COURSE DESCRIPTIONS: Medical Device Option Two

FAILURE MODE AND EFFECTS ANALYSIS
Dates: One-Day, *Jan. 5, 2015, (8:30-5:00)*
Overview: 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.

BUSINESS COMMUNICATION FUNDAMENTALS
Dates: Half-Day, *Jan. 6, (8:00 to 12:00 p.m.)*
Overview: Whether communicating with your co-workers, your boss, or upper level management, get your message heard in a clear, concise and compelling manner. In this four-hour interactive business communication course, we will provide you necessary verbal, non-verbal and written tools to help you to communicate more effectively, and promote a respectful working environment.

IMPROMPTU PRESENTING
Dates: Half-Day, *Jan. 7, (8:00 to 12:00 p.m.)*
Overview: 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. Topics covered include: your presentation goal, how you decide what information to present and its prioritization, profiling your audience, preparing for Q&A and deciding what visuals are needed, if any.

OVERVIEW OF FDA
Dates: Half-Day, *Jan. 15, (8:00 to 12:00 p.m.)*
Overview: The FDA affects the job of every person in a medical device or drug company. This course provides participants insights into 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.

DESIGN CONTROLS FOR MEDICAL DEVICES
Dates: Half Day, *Jan. 15, (1:00 to 5:00 p.m.)*
Overview: Design Controls have been an FDA requirement for most medical device manufacturers since June 1998, but many still struggle with effective compliance. Design Control is the FDA term for how a medical device manufacturer controls the design, development, and manufacturing of its products. ISO 13485 uses the term "product realization" to describe these activities. In addition to the design and testing of devices, engineers must also focus on ensuring that all of the necessary documentation is in place to demonstrate compliance with Design Controls. This documentation can represent several hundred pages or more for a single product launch.

QUALITY SYSTEMS OVERVIEW
Dates: Half-Day, *Jan. 16, (8:00 to 12:00 p.m.)*
Overview: Quality Systems (QS) are sometimes viewed as a necessary evil or belonging only to production and quality assurance personnel. However, effective QS can help a business not only comply, but excel. 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. 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 INSPECTIONS IN REGULATED INDUSTRIES
Dates: Half-Day, *Jan. 16, (1:00 to 5:00 p.m.)*
Overview: 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, for example, using internal auditing as a tool, developing an inspection procedure, educating employees, and conducting mock inspections. Participants will role-play being auditors/auditees.

PRACTICAL DATA ANALYSIS
Dates: Two-Day, *Jan. 26-27, (8:30 to 5:00 p.m.)*
Overview: This sixteen-hour course provides an introduction to analyzing common business and industrial data. By the end of the course, you will be able to: analyze data using the most appropriate statistical methods and interpret the results, use statistical graphics to display data and the results of data analysis, distinguish between comparison and correlation hypotheses, apply the most appropriate statistical methods to test comparison and correlation hypotheses, and use a leading PC-based statistical software program.

STATISTICAL PROCESS CONTROL
Dates: Two-Day, *Jan. 29-30, (8:30 to 5:00 p.m.)*
Overview: 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.

PROJECT MANAGEMENT (Two-Day)
Dates: *Feb. 9-10, Jun. 1-2*
Overview: 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.

BioCatalyst

Professional Certificate Program

Quality Assurance

business oregon

Oregon Bioscience Association

CURRICULUM OUTLINE

- Overview of FDA Requirements for Regulated Industries
- Quality Systems Overview , Implementation and Improvement
- Preparing for Regulatory Inspections
- Protecting Workers Through Effective Hazard Communication
- Current Good Manufacturing Practices (cGMP)
- Problem Solving for Corrective and Preventive Action (CAPA)
- Business Communication Fundamentals
- Managing Deviations
- Risk-Based Approach to Manufacturing: ICH Q8, Q9, Q10
- Impromptu Presenting
- Change Management
- ISO9001/ISO13485 Internal Auditor Training

Course Information

Dates: April 27 - May 12, 2015
Applications /Inquiries:
julie@oregonbio.org

Employer Information: www.oregonbio.org

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COURSE DESCRIPTIONS

OVERVIEW OF FDA REQUIREMENTS FOR REGULATED INDUSTRIES

Dates: Half-Day

Overview: The FDA affects the job of every person in a medical device or drug company. This course is designed to provide participants with insight into what the 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, IMPLEMENTATION AND IMPROVEMENT

Dates: Half-Day

Overview: Quality Systems (QS) are sometimes viewed as a necessary evil or belonging only to production and quality assurance personnel. However, effective QS can help a business not only comply, but excel. 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. 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 INSPECTIONS IN REGULATED INDUSTRIES

Dates: Half-Day

Overview: 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, for example, using internal auditing as a tool, developing an inspection procedure, educating employees, and conducting mock inspections. Participants will roll-play being auditors and auditees.

PROTECTING WORKERS THROUGH EFFECTIVE HAZARD COMMUNICATION

Dates: Half-Day

Hazard Communication training is required for all employees that work around or can be exposed to hazardous substances.

CURRENT GOOD MANUFACTURING PRACTICES (cGMPs)

Dates: Two Days

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. This course will dive into the details of 21 CFR Parts 210, 211, & 820, ICHQ7, and the EU GMP guidelines.

PROBLEM SOLVING FOR CORRECTIVE AND PREVENTIVE ACTION (CAPA)

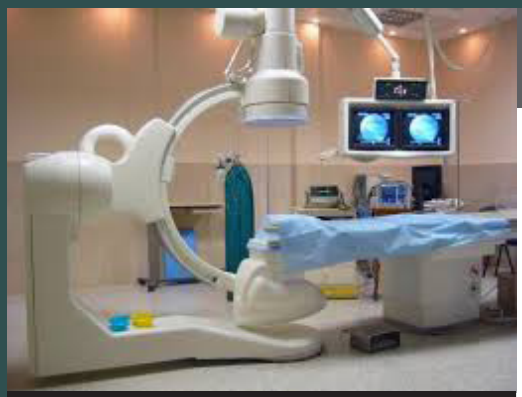
Dates: One-Day

Overview: Two key goals of a quality management system are to find the root causes of actual and/or potential problems and to develop permanent solutions. In this one day workshop you will learn how to use tools and methods of problem solving in order to develop and implement solutions that are accepted, efficient, and effective. This workshop will also examine best practice CAPA systems to provide thoughts and ideas on how to improve the performance of your current system. This workshop is perfect for the novice or for those desiring an invigorating refresher.

BUSINESS COMMUNICATION FUNDAMENTALS

Dates: Half-Day

Overview: Whether communicating with your co-workers, your boss, or upper level management, get your message heard in a clear, concise and compelling manner. In this four-hour interactive business communication course, we will provide you necessary verbal, non-verbal and written tools to help you to communicate more effectively, and promote a respectful working environment.



BioCatalyst History

For over five years 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 1,600 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.

The BioCatalyst program is a natural outgrowth of our existing program and leverages this deep pool of training expertise. Built around the strength of our industry members and their direct input, the BioCatalyst program is managed by the BioPro Industry Steering Committee of industry/human resource experts. These programs are specifically designed by industry leaders and embody their commitment to industry driven training, their years of expertise and desire to hire locally when possible.

Descriptions continued . . .

MANAGING DEVIATIONS
Dates: Half-Day

Overview: Any departure from an approved instruction or established standard used in the manufacturing process, including data or results outside of the expected range, is considered a deviation and must be investigated and evaluated for impact to product quality. Other terms are used for deviations in regulations and guidance, including "non-conformances" and "discrepancies". Whichever terminology is used, deviations are a normal part of any manufacturing process, but how they are handled is a matter defined in the law

RISK-BASED APPROACH TO MANUFACTURING ICH Q8, Q9, Q10
Dates: One-Day

Overview: The International Conference on Harmonisation (ICH) was established in 1990 with the goal of achieving greater synchronization in the interpretation and application of regulatory requirements of Europe, Japan and the United States for pharmaceutical product registration. 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.

IMPROMPTU PRESENTING
Dates: Half-Day

Overview: 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?

CHANGE MANAGEMENT
Dates: Half-Day

Overview: The idea of change management is addressed throughout the cGMP regulations, such as when encountering issues and focusing on process improvements with the design of the manufacturing facility (§ 211.42), the design of the manufacturing equipment (§ 211.63), the design of the production and control procedures (§ 211.100), or the design of laboratory controls (§ 211.160). The current standards require that a risk-based approach utilizing scientific knowledge is used when implementing a change.

ISO 9001/ISO 13485 INTERNAL AUDITOR TRAINING
Dates: Two-Day

Overview: 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 course teaches auditing to the ISO 9001/ISO 13485 standards and places a strong emphasis on promoting employee participation in the improvement process.

business oregon

Oregon Bioscience Association

BioCatalyst

Professional Certificate Program

Cloud computing in Biomedicine

CURRICULUM OUTLINE

- Use, benefits and challenges of big data and the cloud.
- Cloud services, providers, and security
- Cloud monitoring and alert management
- Cloud implementation strategies
- Security and compliance for healthcare data in the cloud
- Big data and the cloud: transforming healthcare

Course Information

Date: June 2015

Inquiries:

https://www.oregonbio.org/biopro/biocatalyst

Employer Information: www.oregonbio.org

In 2014 Business Oregon, in partner ship with Oregon Bio received funding from the legislature to offer bioscience specific professional training (BioCatalyst) to under/unemployed Oregonians hoping launch their careers in the bioscience industry. The objective is to prepare qualified, mid-career candidates to earn sector specific bioscience industry certificates to facilitate this employment transition.

Offered at no cost to qualified candidates, Oregon Bio will launch this sophisticated certificate program in conjunction interested employers in August of 2014. Potential applicants should contact Oregon Bio and submit their application (website).

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About BioCatalyst Partners

Oregon Bio would like to acknowledge the support our programs have received from our training partner at Worksystems Inc. Together we have developed a successful professional training program that is highly respected and actively supported by our industry members.

The BioCatalyst program would also not be possible without the financial support of the Oregon legislature and our deployment partner Business Oregon. Together we lead the way in establishing this unique public/private, industry-based bioscience training program.

COURSE DESCRIPTIONS

PROJECT MANAGEMENT
Date: *June 1-2 (8:30 a.m.-5:00 p.m.)*
Overview: 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 hand-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. It takes students through the project life cycle in the same sequence they would face when managing a real project in the workplace.

WELCOME TO CLOUD ARCHITECTURE, PART I AND II
Christopher Aedo, Product Architect
Date: *June 3-4 (9:00 a.m.-6:00 p.m., 8:00 a.m.-5:00 p.m.)*
Overview: Welcome to cloud architecture will cover all the components and technologies that comprise modern cloud computing, and how all these disparate bits evolved into the clouds we use today. This includes virtualization, hypervisors and containers, software defined networking, software defined storage, the three main service layers (IAAS, PAAS and SAAS), and all the protocols that tie all this together. we will also discuss how to quantify the benefits, build cost models, create comprehensive transition plans, and deal with the related challenges you might run into. Part II will cover developing for the cloud, continuous integration/continuous delivery and the devops movement. We will also discuss the strengths and weaknesses of different cloud providers and their administrative considerations, approaches to security, backups, and disaster recovery planning.

MOVING FROM BIG DATA TO KNOWLEDGE
Ted Laderas, PhD, Knight Cancer Institute
Date: *June 5 (11:00 a.m.-12:00 p.m.)*

IT'S IN THE CLOUD – STEPS YOU CAN TAKE TO PROTECT YOUR DATA ASSETS
Chris Apgar, CISSP, CEO and President, Apgar & Associates, LLC
Date: *June 5 (12:30 p.m.-4:30 p.m.)*
Overview: There are a number of myths around cloud computing and information security. One camp believes that cloud computing is the answer to all of the ills facing the HIT industry. The other camp believes cloud computing is far from secure and not worth the risk. The truth is somewhere in the middle. This course will assist HIT and bioscience professionals understand the structure of cloud computing as it relates to information security. This includes a review of tools that can assist in assessing risk and evaluating vendor offerings. Also, the course will address what needs to be "baked in" or included as part of the cloud development process as it relates to information security controls.

TOOLS FOR DATA ANALYSIS
James Foster, Director of Operations, GemTalk Systems, LLC
Date: *June 8 (8:00 a.m.-5:00 p.m.)*
Overview: From laboratory instruments to population studies, bioscience workers generate an enormous amount of complex data. In this class we will look at how that data is produced and how information technology professionals can assist in turning that data into useful information used to treat individual patients, understand biological processes, and improve the lives of people around the world. We will look at both general-purpose tools, such as programming languages and databases, and tools that are designed specifically for scientific and statistical analysis. Finally, we will identify local resources available for further learning in this area.

OPEN STACK ESSENTIALS
Christopher Aedo, Product Architect
Date: *June 9 (8:00 a.m.-12:00 p.m.)*
Overview: OpenStack Essentials provides participants with an introduction to the OpenStack project, the services that make up an OpenStack cloud, and an overview of the steps necessary to operate an OpenStack environment. Students will also gain exposure to configurations, architecture, best practices, and component interactions.

AWS FUNDAMENTALS: REACH FOR THE CLOUD!
Jeffrey Schnick, Database Automation Engineer
Date: *June 9 (1:00 p.m.-5:00 p.m.)*
Overview: Dive into Amazon Web Services basics and gain the skills you need to immediately and effectively participate in big data and other analytics projects. This course will provide an introduction to AWS products, services, terminology and concepts. We will also tackle different types of AWS security aspects such as Security Groups, key pairs and IAM roles. You will get introduced to the fundamental tools for working with AWS, learn how to scale a service in AWS and how to manage disaster recovery. During this class, you will be provided with the tools necessary to put you on your way to become the next expert in AWS and be part of the Big Data and Cloud Computing revolution in Healthcare and biomedicine.

Behind BioCatalyst Cloud Computing

OBA STAFF:

Dennis McNannay, *Executive Director*
Julie Black, *Director of Member Service and Business Development*
Cindy Lum, *Administrative Assistant*
Mark Saltveit, *Manager of Biocatalyst Training Program*

BIOCATALYST CLOUD COMPUTING ORGANIZING COMMITTEE:

Lisa Lukaesko, *Project Manager*
James Beedy
Yoanne Clovis
Andy Doty
Mahmoud Elzein
Uchenna Emechebe
Khoa Tran

COURSE DESCRIPTIONS

OVERVIEW OF FDA REQUIREMENTS FOR REGULATED INDUSTRIES

Date: *June 10 (8:00 a.m.-12:00 p.m.)*
Overview: The FDA affects the job of every person in a medical device or drug company. This course provides participants insights into what 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.

PREPARING FOR REGULATORY INSPECTIONS

Date: *June 10 (1:00 p.m.-5:00 p.m.)*
Overview: 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, for example, using internal auditing as a tool, developing an inspection procedure, educating employees, and conducting mock inspections. Participants will role-play being auditors or industry employees being subjected to an audit.

IMPROMPTU PRESENTING

Date: *June 11 (8:00 a.m.-12:00 p.m.)*
Overview: 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. Topics covered include: your presentation goal, how you decide what information to present and its prioritization, profiling your audience, preparing for Q&A and deciding what visuals are needed, if any.

MICROSOFT WEARABLES AND AZURE IN HEALTHCARE

Chad Layman, CEO and President, Marquam Group and Bob Hestand, Senior Director, Marquam Group
Date: *June 11 (1:00 p.m.-5:00 p.m.)*
Overview: Imagine living in a society where most people carry a device on them that constantly tracks biometric and health data: how would you use this technology, and what IT infrastructure is necessary to support it? Microsoft has positioned itself for this reality by investing in wearable devices such as the Microsoft Band, creating HealthVault to store this sensitive information on the Cloud, and making Azure as the platform able to process this Big Data into meaningful information. In this half-day presentation Marquam Group will discuss the technical capabilities and software development considerations of these technologies and focus on how wearables combined with Azure facilitate this vision. Attendees will understand the spectrum of Azure's offerings and Microsoft's impact on the healthcare industry.

MINI SYMPOSIUM- BIG DATA IN BIOMEDICINE: TOOLS, TECHNIQUES AND TRENDS

Date: Two half-days
Overview: The advance of transformative technologies in biomedical research and healthcare has led to the generation of big data that will help revolutionize these sectors. However, the enormity and complexity of big data presents great challenges in analyses and subsequent applications to biomedicine. This 2-day mini-symposium brings together experts who will present state-of-art tools and techniques that are being developed and deployed to deal with challenges in managing and analyzing big data.

CAREER DEVELOPMENT WORKSHOPS

Date: Two days
Overview: Gain the knowledge and tools to be competitive in today's job market. Our experienced professional partners will walk you through the process of creating a personal brand that gets you noticed. You will get tips on creating a personalized cover letter, a resume that gets read, tips of making a lasting first impression, and essential interview skills to help you land that dream job. Use what you learn at the workshop to "wow" recruiters!