

# QUALITY ASSURANCE CERTIFICATE PROGRAM



**Bergen Community College has partnered with North Jersey and Metropolitan Divisions American Society for Quality to provide our businesses and business professionals up to date training in quality systems and regulatory issues.**



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# QUALITY ASSURANCE CERTIFICATE PROGRAM

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## Certificate in Pharmaceutical Quality Control Technician

Bergen Community College School of Continuing Education is offering a Certificate in Quality Assurance for the Life Sciences. These 6 courses will prepare you for a job in the more than 2,500 pharmaceutical/biotech manufacturing companies in Northern New Jersey which employ over 40% of Bergen County's workforce. Products manufactured by these companies include foods and beverages, pharmaceuticals, fragrances, cosmetics, medical test materials, medical devices such as pacemakers and implants and all the packaging materials for these products.

### **CD 530 Excel for Quality Control**

13 sessions; \$500

001, Wed.; February 1-May 2, 2012

(no class 3/21)

**Hours:** 6:00-9:30 p.m.

**Location:** TBA

Become proficient in Quality Assurance uses of spreadsheets and learn how to create graphs of numerical data. Topics include: the entering and editing data; sorting data, format and filtering of data; use of formulas; graphing and utilization of the basic statistical Excel functions for evaluations and other. **Prerequisite:** Basic PC skills.

**Instructor:** Susan Smarth

### **CD 529 Quality Improvement Associate Certification – CQIA**

13 sessions; \$500

001, Mon.; February 6-April 30, 2012

**Hours:** 6:00-9:30 p.m.

**Location:** TBA

This course introduces the student to the basics of quality systems and their implementation. It covers the history of Quality Systems & Processes, Statistical Processes used to control Variation, Teams, Roles & Responsibility, Decision Making, Continuous Improvement, Problem Solving, Process Control and Customer-Supplier Relationships. The certified Quality Improvement Associate review centers on the ASQ Body of Knowledge to help prepare the student for the ASQ certification examination.

This preparatory course covers the entire Body of Knowledge to ensure the student is familiar with all required material and is better able to understand how to apply quality standards and technical concepts in support of inspection activities.

**Instructor:** Susan Smarth

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### **CD 016 Formulation of Solutions**

6 sessions; \$650

001, Sat. February 4-March 10, 2012

(no class 3/24, 4/7)

**Hours:** 8:00 a.m.-4:00 p.m. (plus 45-hrs of online study)

**Location:** TBA

This 6-week laboratory based course will prepare

you for entry level work formulating solutions in the biotechnology/pharmaceutical/chemical industries. Laboratory is run like an industrial lab workday. Background material is provided in recorded online lectures and assignments. You will prepare simple solutions and buffers via titration and SOP. You will learn to calculate how to prepare solutions from chemical formulas, how to calculate dilution, proper measuring and weighing techniques and labeling requirements. You will quality control the product by pH and ionic strength and Spectrophotometry. You will prepare an SOP for a buffer, a product specification sheet and an MSDS for your product. All work will be done in accordance with FDA regulations.

**Instructor:** Soledad Focht

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### **CD 017 Protein Purification**

6 sessions; \$650

001, Sat.; March 31-May 5, 2012

**Hours:** 8:00 a.m.-4:00 p.m. (plus 45 hrs. of on-line study)

**Location:** TBA

This 6-week laboratory based course will prepare you for entry level work purifying proteins in the biotechnology/pharmaceutical industries. Laboratory is run like an industrial lab workday. Background material is provided in recorded online lectures and assignments. You will purify antibody from serum of sheep utilizing the techniques of precipitation, dialysis, centrifugation, and affinity chromatography. You will quality control product via, protein assay, immunoassay and electrophoresis. You will prepare the following documents product specification sheet and Material Safety Data Sheet for your product. All work will be done in accordance with FDA regulations. **Required background:** Formulation of Solutions or equivalent experience, working knowledge of simple statistical Excel functions and basic pipetting skills.

**Instructor:** Soledad Focht

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### **CD 018 Quality Control of Product Stability**

11 sessions; \$650

001, Mon/Wed; May 7-June 13, 2012

(no class 5/28)

**Hours:** 6:00-10:00 p.m. (plus 45-hrs of online study)

**Location:** TBA

This 6-week laboratory based course, will teach you how to determine the shelf life of a product and how to determine the efficacy of the microbial inhibitors used to prevent microbial growth. Laboratory is run like an industrial lab workday. Background material is provided in recorded online lectures and assignments. You will prepare a solution used in Elisa Testing and stress it at various temperatures: The solutions will be tested weekly to ascertain functionality and cosmetic appearance. The data collected will be used to predict shelf life and determine storage conditions. These same test solutions will be inoculated with common bacteria and tested as above to ascertain the samples resilience to contamination. All work will be done in accordance with FDA regulations. **Required background:** Formulation of Solutions or equivalent experience, working knowledge of simple statistical Excel functions and basic pip petting skills.

**Instructor:** Judith Fitzpatrick, PhD

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### **CD 019 Procedure Validation**

11 sessions; \$650

001, Mon/Wed.; June 18-July 25, 2012

(no class 7/4)

**Hours:** 6:00-10:00 p.m.

**Location:** TBA

This 6-week laboratory based course will teach you to how to validate a process and produce a validation pack: The process you will validate is an Elisa Kit. Laboratory will be run like an industrial lab workday. Background material is provided in recorded online lectures and assignments. Validation involves determining the limits of detection, interfering substances, repeatability, precision and accuracy. All work will be done in accordance with FDA regulations. **Required background:** Formulation of Solutions or equivalent experience, working knowledge of simple statistical Excel functions and basic pip petting skills.

**Instructor:** Judith Fitzpatrick, PhD.

**For more information on  
Quality Assurance programs, go to  
[www.bergen.edu/qa](http://www.bergen.edu/qa)**

### **CD 525 Certified Six Sigma Green Belt (CSSGB)**

22 sessions; \$550

001, Tue./Fri.; February 21-June 8, 2012

(no class 4/6, 5/16,5/18)

**Hours:** 6:00-8:30 p.m.

002, Mon./Th.; April 16 -July 9, 2012

**Hours:** 6:00-8:30 p.m.

**Location:** TBA

Six Sigma Quality is the key to success in today's competitive world. Six Sigma Green Belts are employees who spend some of their time on process improvement teams. The Six Sigma Green Belt analyzes and solves quality problems, and is involved in six sigma, lean, and other quality improvement projects. Cross functional Six Sigma teams use the DMAIC approach: DEFINE, MEASURE, ANALYZE, IMPROVE, CONTROL. Six Sigma Green Belts are in increasing demand, and often go on to become Six Sigma Black Belts. This ASQ course gives you the knowledge needed to serve as a Green Belt on a Process Improvement Team. This ASQ course references the American Society for Quality Six Sigma Green Belt Body of Knowledge, uses Green Belt materials from the Quality Council of Indiana, and is taught by an ASQ Certified Six Sigma Black Belt. This course prepares you for taking the American Society for Quality (ASQ) Six Sigma Green Belt Quality Certification Exam in December.

**Instructor:** Carl Perini

### **CD 575 Application of High Performance Liquid Chromatography in Chemical/ Pharmaceutical Analysis**

10 sessions; \$2,000

001, Wed.; February 8-May 23, 2012

(no class 3/24, 4/7)

**Hours:** 6:00-10:00 p.m.

**Location:** TBA

This 70-hour course provides to students a solid training on both basic theory and hands-on practice in utilizing High Performance Liquid Chromatography (HPLC) for the separation of multiple organic compounds in a complex chemical system. Applying the analytical technique to the qualitative and quantitative analyses of the active ingredients in pharmaceutical and food products will be demonstrated and exercised. The measurement of key chromatographic parameters for assessing chromatographic quality (i.e., %RSD, theoretical plate counts, resolution, tailing factor, etc.) will also be taught and practiced. Both the software and hardware aspects of the modern analytical technology will be covered in the teaching. By the end of the course, students will be coached to complete the validation of two HPLC test methods designed for analyzing the content of Caffeine and Acetaminophen in beverages and cold tablets, respectively.

**Instructor:** Ara Kahyaogiu

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