

Certificate in

Pharmaceutical Engineering

PROFESSIONAL DEVELOPMENT

ENTIRE CERTIFICATE ONLINE!

Our successful Certificate in Pharmaceutical Engineering is available through convenient online classes. The five required courses in this program are designed to promote the development of pharmaceutical engineers who can streamline and optimize drug development and delivery.

Explosive advances in science and technology have revolutionized the research and discovery of new, life saving drugs. These advances have also radically changed pharmaceutical manufacturing and delivery systems, increasing the challenge of designing optimal manufacturing processes for the efficient, safe production of pharmaceutical products.

To successfully meet this challenge, you need to be fluent in the language of basic chemical process engineering principles, and knowledgeable in the engineering science and unit operation of pharmaceutical manufacturing.



WHO SHOULD ATTEND?

- Chemical, electrical, mechanical, and process engineers
- Project, industrial and computer software engineers
- Regulatory/validation and quality control/assurance personnel
- Facility managers
- Architects and construction field personnel
- Managers working in the pharmaceutical industry
- Recent engineering and chemistry graduates

LEARN WHAT YOU NEED TO KNOW ABOUT:

- FDA regulations and the drug approval process
- Quality control and assurance issues related to manufacturing drugs for mass production
- Manufacturing and commercially distributing safe and effective drug products
- Integrated design elements and practices required for the delivery of GMP compliant facilities
- How to interact with regulatory agents and communicate information about validation programs

Register today at www.csufextension.org or 657.278.2611

For more information, contact Veronica Martinez: 657.278.3123, vmartinez@fullerton.edu

Cal State Fullerton
university extended education
www.csufextension.org

THE CLASSES

Online classes at Cal State Fullerton are delivered through Blackboard, a Web-based course management system.

To learn more about how this works, please visit <http://distance-ed.fullerton.edu/> and view the FAQs, which include a tutorial in Blackboard classes.

BIOTECHNOLOGY AND BIO-PROCESSES

(2 CEUs/20 hours)

Prerequisite: none. Drug discovery research has shifted away from a chemistry-based product development cycle to a more biology-based approach. In the drug development process, it is crucial that pharmaceutical engineers are aware of and adhere to basic principles contained in biological processes. Learn to understand the behavior of individual molecules in disease-causing organisms, how the body reacts to certain drugs, and how long a drug must remain in the body to be effective. You will analyze the development of new and cost effective vaccines and receive an introduction to the biological processes specific to this development, including cell biology and the principles of contamination, sterilization and fermentation.

PROCESS ENGINEERING IN THE PHARMACEUTICAL INDUSTRY

(2 CEUs/20 hours)

Prerequisite: none. Process engineering is the technology used to refine materials through different manufacturing processes in order to convert them into products with desired specific attributes. Process engineering is needed to develop the engineering science and skills to maintain and improve the efficiency, safety, cleanliness, and economy of the processes that are undertaken in the pharmaceutical industry. Topics include manufacturing operations and plant processes, process control, instrumentation issues and materials engineering.

FACILITIES DESIGN AND MAINTENANCE

(2 CEUs/20 hours)

Prerequisite: none. Learn about the design, construction and management of pharmaceutical and biotech facilities. Examine the requirements for design and construction of the complete adaptable manufacturing facility. Develop requirements and gather data for a small-scale pharmaceutical manufacturing facility to illustrate how such facilities can be designed and maintained. Topics include water systems, critical utilities, “cleanrooms” and process equipment design.

VALIDATION AND VERIFICATION

(2 CEUs/20 hours)

Prerequisite: none. Process validation has been a legal requirement in the pharmaceutical industry for over two decades. You will gain theoretical and practical information pertaining to validation of processes involved in the manufacturing of pharmaceutical products with focus on sterile manufacturing processes. The class objective is to present information conducive to a better understanding of this demanding process. You will be better prepared to establish process equipment evaluation and validation programs on a sound basis.

REGULATORY AFFAIRS AND QUALITY ASSURANCE IN THE PHARMACEUTICAL INDUSTRY

(2 CEUs/20 hours)

Prerequisite: none. In this class, you will learn how to meet the challenge of maintaining compliance with Federal regulations and the FDA's expectations. You will be introduced to Federal Regulation 21CFR211 and the Current Good Manufacturing Practices of Finished Pharmaceuticals with respect to drug manufacturing. Learn about the FDA perspective on regulations and guidance practices as well as current areas targeted by the FDA. Gain practical knowledge of GMP applications as related to real-world operations and quality issues as well as current FDA requirements.

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