

Northampton Community College (NCC) worked with a dozen regional biotechnology industry partners to develop programs and facilities to meet an industry-identified need for training of entry-level production workers.

With funding from a United States Department of Labor grant, NCC and its partners built a state-of-the-art aseptic processing training area. This lab provides a certified but non-regulated training area for simulations without the need to worry about product exposure or process deviations or excursions.

For more information, please contact CBI at 610-332-8668 or cbi@northampton.edu.



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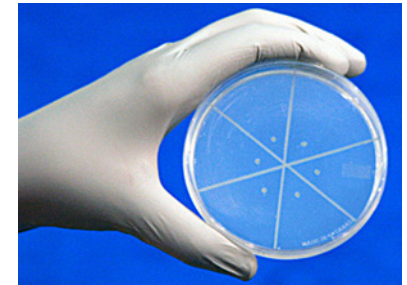
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Northampton Community College

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Bio manufacturing & Cleanroom Training Programs



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Facility

Constructed in 2008 with the help of an expert in designing and certifying controlled environments, NCC's Aseptic Processing Training area (cleanroom) features:

- 340 square foot ISO Class 7 Cleanroom (formerly Class 10,000) with ISO Class 5 (formerly Class 100) hoods, including VLF, HLF & BSC
- 300 square foot ISO Class 8 (formerly Class 100,000) gowning training and cleanroom cleaning area
- Adjacent SMART technology classroom for full instructional flexibility

This facility is available for customized training and for contracting our open enrollment, one day training courses for your company.

Customized Services

Customized, in-house or on-campus training can be developed by our team to meet the specific needs of your organization. Training can be accomplished without disrupting schedules or compromising ongoing production at your facility. The time and location are all coordinated around your schedules.

Full Day Training Sessions

One day training courses are available on-site or on-campus at our cleanroom. Workshops are six hours in length and can be scheduled at a time that best accommodates your company.

Introduction to Biomanufacturing

Covers the basics of biologics vs. traditional pharmaceuticals, upstream processing, downstream processing and future trends in the field.

Introduction to cGMP

(Current Good Manufacturing Processes)

Brief overview of regulatory aspects with a focus on why they are important. Ends with a hands-on simulation game for reviewing and practicing the use of basic documents (i.e. SOP's, specification sheets and batch records).

Introduction to Aseptic Processing

What is aseptic processing, what is a cleanroom and what types of products need to be processed in a cleanroom? Includes practice simulation of cleanroom processes with optional critique of individual product handling skills.

Overview of Cleanroom Microbiology

Introduction to the microbes commonly involved in cleanroom contaminations. Hands-on activities demonstrate most common modes of cleanroom contamination and reinforce the individual's role in contamination control.

FDA Inspection Preparation

This overview of what to expect when being inspected will include small group evaluation of case studies and trend sheets from actual inspections by the US Food and Drug Association (FDA).

Testimonials

"Sanofi Pasteur has partnered with Northampton Community College (NCC) to utilize their aseptic processing facility to train employees who work in and around the company's Industrial Operations cleanrooms. This NCC facility has provided us with the opportunity to train personnel in the correct use of cleanrooms with a classroom component that looks at cleanroom design, current good manufacturing practices and federal regulations that govern our industry. In summary, the cleanroom facilities at NCC offer a unique, valuable training alternative that we could not duplicate within our own laboratories."

Rick Smith

Vice President, Strategic Programs & Projects
sanofi pasteur, Inc.

"It was very easy working with the NCC staff. The program manager, Cindy Adams, is very professional and responsive and their instructor, David Long, is an excellent presenter and has a wealth of industry experience in cleanroom operations. I would certainly use them again for training our staff."

Hector M. Garcia,
Director, Quality Assurance
Particles Sciences, Inc.