Microbial Contamination Control in Bioprocessing Operations

Course fee: $2,400
For course dates, visit go.ncsu.edu/btec_short_courses

In this course, you’ll gain a fundamental understanding of the sources of microbial contamination in biopharmaceutical manufacturing. You’ll learn how to evaluate contamination risks and implement corrective and preventative measures to ensure a state of microbiological control in facilities and processes. In addition, you’ll learn about recent regulatory expectations for control of contamination. In attending this course, you will learn about:

- Potential sources of microbial contamination
- Regulatory expectations for a contamination control strategy
- Best practices in management of microbial contamination, to include monitoring programs for detection of bioburden and endotoxin
- Best practices in equipment, process, and facility design
- Risk assessment applied to control of contamination, and
- Best practices in sanitization and disinfection

For additional information, please contact BTEC Professional Development and Marketing Coordinator Erica Vilsaint at embrown4@ncsu.edu.

Course schedule

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<tr>
<th>Day 1</th>
<th>Day 2</th>
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<tr>
<td>Describe quality concepts in control of contamination</td>
<td>Identify potential sources of microbial contamination and design contamination control strategies for materials, facility, clean utilities, equipment, process, and personnel</td>
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<td>Explain the difference between terminal sterilization and aseptic processing</td>
<td>Explain best practices for equipment cleaning and sanitation</td>
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<td>List potential microbial contaminants in bioprocessing</td>
<td>Identify bioprocessing equipment and its critical design features to ensure contamination control</td>
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<td>Describe biofilms and their impact on production</td>
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<td>Describe microbial detection methods and data analysis</td>
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<td>List various types of chemical disinfectants and their applications</td>
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<td>Describe methods for disinfectant qualification</td>
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<td>Explain selected tests for microbial detection and identification</td>
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<td>Describe quality systems for GMP production</td>
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<td>Apply risk management tools to control microbial contamination</td>
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<td>Troubleshoot contamination events</td>
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**DELIVERY METHODS**

- 50% Lecture
- 10% Discussion/group activity
- 40% Hands-on laboratory experience

**COURSE CONTENT**

- 45% Fundamentals and concepts
- 50% Industry applications
- 5% Emerging technologies

**REGISTER NOW:** go.ncsu.edu/btec_short_courses
What short course participants say about this course

“I much enjoyed the course and I would even retake the course again just because of the material presented and the instructor.”

“The course was very informative and it used real life situations that [are] applicable to biomanufacturing.”

“Instructor was very knowledgeable of the subject. Information was not too deep or shallow.”

About the instructor

Lucia Clontz, D. H.Sc., M.S., is the site quality head for Xellia Pharmaceuticals in Raleigh. She has more than 26 years of industry experience in quality, pharmaceutical microbiology, laboratory management, operational excellence initiatives, and training. She is a published author, speaker and workshop leader at both national and international conferences, and in 2004, she received the Parenteral Drug Association’s Distinguished Editor/Author award. She served as a member of the United States Pharmacopeia (USP) Pharmaceutical Waters Expert Panel (2010-2020) and currently holds an appointment as a BTEC Teaching Fellow.

Important information for short course participants

Location

This course is held on site at BTEC. The Golden LEAF BTEC building is located at 850 Oval Drive on NC State University’s Centennial Campus.

Payment

BTEC accepts payment from all major credit cards including American Express, Visa, and MasterCard. If you wish to pay by company check, please email melody_woodyard@ncsu.edu for additional information immediately after registering.

Discounts available

A 20% discount is available to:

• Employees of NC Biotech Manufacturers Forum (BMF) member companies
• Groups of five or more from one company registering for the same offering of this course
• Individuals registering for more than one course at a time
• Faculty/staff working in academic environments

Pre-course communication

Registered course participants will receive an email three weeks before the scheduled course with detailed information regarding travel to BTEC, parking information, and a short pre-course questionnaire.

Cancellation policies

CANCELLATION BY REGISTRANT

To cancel a registration and be eligible for a refund of course fees, you must notify BTEC by email. Fees are refunded according to the following schedule:

• 100% refund – If notification is received at least 15 business days in advance of course start date
• 75% refund – If notification is received 10–14 business days in advance of course start date
• 50% refund – If notification is received 6–9 business days in advance of course start date
• No refund will be issued if notice is received 5 or fewer business days in advance of course start date

Substitutions may be made up to two business days prior to the course start date.

CANCELLATION BY BTEC

BTEC retains the right to cancel a professional development short course no less than 10 business days in advance of the scheduled course start date. Registrants will be notified by BTEC if a course is cancelled and will receive a full refund of registration fees paid. BTEC is not responsible for airfare penalties or other costs incurred due to cancellation.