Downstream Biopharmaceutical Processes: Fundamentals and Design

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

In this three-day course, you will gain a deeper understanding of the fundamentals of recovery/purification operations for biopharmaceutical production and how these operations are developed for use at production scale. This course provides both theoretical and practical insight through lectures and laboratory activities. In attending this course, you will learn:

- Theoretical and operational principles that underlie homogenization, centrifugation, chromatography, and tangential flow filtration—i.e., the downstream unit operations
- Regulatory expectations for design of downstream processing steps
- Experimental methods for determining process parameter ranges and material attributes (if applicable) for each unit operation
- Basic scale-up calculations and considerations for each operation
- How these unit operations come together to form an integrated process train for a variety of production scenarios, including intracellular products from E. coli, extracellular products from CHO, and inclusion body production.

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

Course schedule

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<th>Day 1</th>
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<td>Lecture: Overview of downstream processing and process development methodology</td>
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<td>Lab: Lab tour and safety checklist</td>
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<td>Lecture: Harvest operations principles and equipment</td>
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<td>Lab: Design of a production-scale centrifugation step for recovery of E. coli</td>
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<td>Lab: Operating ranges for the homogenization of GFP cell paste</td>
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<td>Lecture: Protein structure and properties</td>
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<td>Workshop: Design of harvest operations</td>
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<td>Lecture: Chromatography principles and equipment</td>
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<td>Lab: Introduction to the AKTAexplorer System</td>
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<td>Lecture: Chromatography design</td>
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<td>Lab: Design of an anion exchange chromatography for capture of GFP from clarified lysate</td>
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<td>Lecture: Ultrafiltration principles, equipment, and design</td>
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<td>Lab: Operating ranges for formulation of GFP “drug substance” by UFDF</td>
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<td>Workshop: Evaluation of anion exchange chromatography data</td>
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REGISTER NOW: go.ncsu.edu/btec_short_courses
What short course participants say about this course

“Dr. Gilleskie was extremely knowledgeable. He was very approachable and efficient at explaining the topics covered and always answered every question.”

“The course instructors were very engaging, knowledgeable, and taught a course that is very applicable to a development lab setting.”

“This was one of the best training courses I’ve taken! Thank you very much!”

“Great course – one of the best I have attended in almost 12 years!”

About the instructors

**Dr. Gary Gilleskie** is executive director and teaching associate professor with NC State University’s Biomanufacturing Training and Education Center (BTEC). He is responsible for the daily operations of the center, and he also develops and teaches courses focused on the downstream production of biopharmaceuticals for audiences ranging from NC State students to industry professionals to the U.S. Food and Drug Administration. Dr. Gilleskie, who received his doctorate in chemical engineering from the University of Minnesota, has more than 15 years of industrial experience in recovery and purification operations in both the chemical and biopharmaceutical industries.

**Dr. Krisstina Burgess** is currently a senior scientist at BTEC. She is responsible for teaching downstream bioprocessing courses to audiences including NC State students, industry professionals, and the U.S. Food and Drug Administration. She also manages BTEC’s intermediate and large-scale downstream operations facilities. Prior to joining BTEC, Dr. Burgess worked in industry for 14 years, served as an independent consultant to several biopharmaceutical firms, and was a contractor for the North Carolina Community College System’s BioNetwork program. She received her doctorate in chemistry from Emory University.

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.