Hands-On cGMP Biomanufacturing Operations

Course fee: $3,200
For course dates, visit go.ncsu.edu/btec_short_courses

In this very popular four-day course, you will obtain a basic knowledge of biomanufacturing operations and how cGMP requirements are implemented at commercial scale. You’ll engage in pilot-scale laboratory experiences that examine process utilities, media and solution preparation, bioreactor operation, centrifugation, chromatography, and tangential flow filtration in a simulated commercial cGMP (current Good Manufacturing Practice) facility. Broadly applicable to anyone interested in learning about large-scale biomanufacturing operations and gaining hands-on experience in a simulated cGMP environment, this course is perfect for new employees, support personnel from Quality Control and Quality Assurance, and vendors and suppliers providing equipment and services to the industry.

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

Course schedule

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lecture: Overview of</td>
<td>Lecture: CIP (Clean in Place) and</td>
<td>Workshop: Process evaluation</td>
<td>Lab: Ion exchange chromatography for product</td>
</tr>
<tr>
<td>biomanufacturing processes</td>
<td>SIP (Steam in Place)</td>
<td>and capability (failure investigation)</td>
<td>capture</td>
</tr>
<tr>
<td>and products</td>
<td>Lab: CIP</td>
<td>Lecture: Centrifugation principles and</td>
<td>Lecture: Ultrafiltration</td>
</tr>
<tr>
<td>Lecture: Introduction to</td>
<td>Lab: Pressure hold and SIP</td>
<td>equipment</td>
<td>principles, equipment, and operation</td>
</tr>
<tr>
<td>cGMP and biosafety</td>
<td>Lab: Media filtration and testing</td>
<td>Lab: Recovery of <em>E. coli</em> by disc-stack</td>
<td>Lab: Concentration of product</td>
</tr>
<tr>
<td>Lecture: cGMP bioreactor</td>
<td>Lecture: Cell growth and critical</td>
<td>centrifugation</td>
<td>by ultrafiltration</td>
</tr>
<tr>
<td>design</td>
<td>process parameters (contamination ID)</td>
<td></td>
<td>Lab: Fill of bulk drug</td>
</tr>
<tr>
<td>Lab: Bioreactor orientation</td>
<td>Lab: Monitoring 300 L fermentation and</td>
<td></td>
<td>substance (bulk fill)</td>
</tr>
<tr>
<td></td>
<td>cascade control of DO (dissolved oxygen)</td>
<td></td>
<td>Workshop: Step yield calculations</td>
</tr>
<tr>
<td>Lab: HPW and clean steam</td>
<td>Lab: Autoclave prep and loading</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab: Safety and cleanroom</td>
<td>Lab: Shake flask inoculation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>procedures</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

“As a professional from the world of semiconductors, I had very little understanding of biotech at the time of enrollment despite having visited numerous customer sites. After taking this short course I feel like an expert — really left with a solid understanding on bio-tech tools and processes.”

“… I found BTEC’s Biomanufacturing Operations course to be a tremendous program, packed with well-organized, well-taught information. … I can’t say enough good things about this course, only that I should have taken it five years ago when I began work in this industry!”

“The lecture vs hands on time was [a] perfect balance. The information never became stale or stagnant.”

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

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.

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. Charles Rutter, a senior scientist at BTEC, has expertise in fermentation processes using bacteria, yeast, and algae. In addition, he has experience with bioreactor process development for non-model organisms and with molecular and synthetic biology for development of novel microbial strains. Dr. Rutter earned his doctorate in chemical and biomolecular engineering from Georgia Institute of Technology.

Dr. Kriststina 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.