NC STATE UNIVERSITY

2015

PROFESSIONAL DEVELOPMENT
SHORT COURSES

For biomanufacturing and bioprocessing professionals

BUILD YOUR EXPERTISE WITH BTEC TRAINING

www.btec.ncsu.edu
BTEC PROFESSIONAL DEVELOPMENT
SHORT COURSES

In an industry that’s always evolving, keeping up to date is a real challenge. This year, gain the knowledge and build the skills needed to take your career to the next level with a BTEC course! If you attend a course at North Carolina State University’s Biomanufacturing Training and Education Center in Raleigh, you can...

Learn how to apply current best practices
Our faculty and staff understand the needs of industry and how biomanufacturing firms operate. Instructors with industry expertise design BTEC courses to meet the requirements of bioprocessing and biomanufacturing scientists, engineers and other professionals.

Get job-focused, hands-on training with the latest technology
Courses at BTEC involve doing, not just sitting and listening. And that doing happens in the nation’s largest and most comprehensive biomanufacturing training facility. BTEC’s bench- and pilot-scale teaching laboratories are furnished with approximately $15 million of the latest industry-standard equipment. Fixed and single-use, upstream, downstream, process utilities, and analytical equipment—our labs have it all.

Or learn online at your convenience
In partnership with the American Institute of Chemical Engineers (AIChE), BTEC now offers two online courses for chemical engineers interested in learning about biotechnology and biomanufacturing. See page 17 for details.

Check the schedule on the next page and join us for a unique learning experience! See the back cover for registration information.
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COURSE TRACKS

Refer to the following tracks to determine which courses will be most useful to you.

**ANALYTICAL TECHNOLOGIES**

Focusing on analytical methods used in biomanufacturing, this track offers courses ranging from hands-on training in common analytical techniques—including HPLC, gel/capillary electrophoresis, mass spectrometry, and ELISA—to assay development and validation.

**BIOMANUFACTURING**

These courses provide hands-on experience with the facilities, utilities, unit operations, and equipment involved in manufacturing biomolecules in accordance with current Good Manufacturing Practice (cGMP) regulations.

**BIOPROCESS DEVELOPMENT**

Courses in this track deal with the implementation of new technologies or the development of processes for commercial production of therapeutic proteins.

**BIOPROCESS ENGINEERING**

These courses focus on the engineering fundamentals of bioreactor technology, critical process parameters, and computer control schemes for the production of high-value biomolecules using microbial or animal cells.

**SPECIAL OFFERINGS**

This track offers a variety of courses on selected topics, which may vary from year to year.

Our instructors

BTEC’s professional short course instructors have extensive experience in the biomanufacturing and pharmaceutical industries. Passionate about training, our instructors draw on their practical experience and use a combination of lecture, hands-on labs, and case studies to ensure that participant needs are met. To learn more about individual instructors, please see the BTEC directory at go.ncsu.edu/btec-directory.

Customized training solutions

If the timing of our scheduled courses is challenging or your organization has a specialized training need, talk to us about creating a course for your employees! Advantages include:

- Tailored content – Topics of particular interest to the organization can be addressed;
- Confidentiality – Organization-specific challenges and issues can be discussed in a confidential manner;
- Cost savings – Customized training can be more cost-effective than sending groups to an open-enrollment course.

To discuss customized training for your organization, please contact John Balchunas, BTEC’s Assistant Director of Professional Development Programs, at john_balchunas@ncsu.edu.
Assay Development and Validation for Biomolecules

July 14–15, 2015
Fee: $1,360
14 hours of instruction (1.4 Continuing Education Units)

In this course, you will gain a fundamental understanding of successful bioanalytical assay development and validation and the complexities involved in biopharmaceutical analysis. You will get hands-on experience with designing and developing an ELISA. After assay optimization, the ELISA will be validated by considering ICH guideline Q2(R1) and FDA Guidance: Bioanalytical Method Validation. You will also learn about troubleshooting, data analysis, and experimental design. This course is appropriate for professionals new to the biopharmaceutical industry or entering new work assignments encompassing analytical or QC environments. Professionals with previous QC/Analytical experience who want to learn new techniques and expand their knowledge will also find this course beneficial.

Instructor: Nathaniel Hentz, Ph.D.
Assistant Director, Analytical Lab, BTEC

Biopharmaceutical Analysis

July 28–30, 2015
Fee: $1,900
21 hours of instruction (2.1 Continuing Education Units)

This course provides an overview of the analytical technologies used in biomanufacturing QC/analytical laboratories. You will get hands-on experience with HPLC, MALDI-TOF mass spectrometry, spectroscopy, gel electrophoresis, and ELISA. You will also learn about troubleshooting, data analysis, and experimental design. This course is appropriate for professionals new to the biopharmaceutical industry or entering new work assignments encompassing analytical or QC environments. Professionals with previous QC/Analytical experience who want to learn new techniques and expand their knowledge will also find this course to be of value.

Instructor: Nathaniel Hentz, Ph.D.
Assistant Director, Analytical Lab, BTEC
Hands-on Viral Vaccine Manufacture

May 18–22, 2015
Fee: $2,850
37.5 instructional hours (3.7 Continuing Education Units)

This five-day course provides participants with a broad understanding of viral vaccine production. After first learning about vaccine fundamentals, including vaccine types, virus types and structure, and basic vaccine immunology, participants will focus on the steps necessary to produce, recover, and purify virus, using influenza A as a model. Through a combination of lecture and hands-on laboratory activities, participants learn the fundamentals of egg-based and cell-based virus production, and virus recovery and purification methods including ultracentrifugation, chromatography, and ultrafiltration. Basic analytical techniques for quantifying and characterizing virus are also examined. At the end of the course, attendees will have a thorough understanding of the “how and why” behind vaccine manufacture and consequently be better equipped to manufacture viral vaccines and troubleshoot vaccine processes. This course is appropriate for biomanufacturing professionals, including staff in quality assurance, quality control, validation, or manufacturing management roles.

Instructors: This course is facilitated by a team of BTEC and NC State faculty, including Driss Elhanafi, Ph.D., Gary Gilleskie, Ph.D., Nathaniel Hentz, Ph.D., Sarwat Khattak, Ph.D., Matt Koci, Ph.D., Baley Reeves, Ph.D., Jennifer Ruiz, Ph.D., and Lucas Vann, M.S.
cGMP Biomanufacturing Operations
July 7–10, 2015
Fee: $2,320
30 hours of instruction (3.0 Continuing Education Units)

Obtain a basic knowledge of biomanufacturing operations and how cGMP requirements are implemented at commercial scale. 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-cGMP commercial facility. This course will benefit scientists and engineers who are new to the biomanufacturing industry, biomanufacturing support personnel who may not be directly involved with execution of the processes they support, and vendors supplying the biomanufacturing industry, among others.

Instructors: Gary Gilleskie, Ph.D., Director, Operations, and Teaching Associate Professor, BTEC
Baley Reeves, Ph.D., Sr. Bioprocessing Scientist, BTEC
Lucas Vann, M.S., Sr. Bioprocessing Scientist, BTEC

GE Chromatography Column Packing
July 14–16, 2015
Fee: $3,150
18.5 hours of instruction (1.8 Continuing Education Units)

A well-packed chromatography column is critical to achieving the required purity for a biopharmaceutical product. Taught by experts from GE Healthcare, one of the world’s leading providers of chromatography supplies and equipment for the biopharmaceutical industry, this course provides participants with the hands-on packing experience and the information needed to design procedures that ensure packing is done right the first time. Topics include different packing techniques suitable for production-scale columns, appropriate cleaning and sanitization techniques for resin and chromatography equipment, tests used to evaluate column-packing quality, and techniques for resolving packing issues. This course is appropriate for production and manufacturing science/technical services personnel working with column packing; process development scientists and engineers and systems engineers will also find the course useful.

Instructors: Jennifer Cheung, M.Eng., Ziawei Fung, M.S., Francis Nguyen, B.S.
GE Healthcare Life Sciences
Microbial Contamination Control in Bioprocessing Operations

December 8–10, 2015
Fee: $1,630
21 hours of instruction (2.1 Continuing Education Units)

Gain a fundamental understanding of sources of microbial contamination in biopharmaceutical manufacturing. Learn how to evaluate contamination risks and implement corrective and preventative measures to ensure a state of microbiological control in facilities and processes. Learn about recent regulatory expectations for control of contamination. Professionals who would benefit from this course include those responsible for any aspect of microbial control in quality assurance, quality control, regulatory assurance, process and cleaning validation, equipment qualification and maintenance, facility and systems design, or manufacturing.

Instructor: Lucia Clontz, D.H.Sc., M.S.
Senior Manager, QA Compliance Fresenius Kabi USA – Raleigh and BTEC Teaching Fellow

DELIVERY METHODS

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COURSE CONTENT

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Stem cells—including induced pluripotent stem cells (iPSC), mesenchymal stem cells (MSC) and embryonic stem cells (ESC)—have promising applications in regenerative medicine, drug screening, and disease modeling. Stem cells also show promise for non-therapeutic applications such as cell-based sensors for chemical/biological threat monitoring, manufactured ‘meat’ for food consumption, and engineered leather for industrial/consumer goods. To realize this promise, stem-cell-based products must be manufactured consistently, must be cost-effective, and must adhere to strict cGMP standards, beginning from the raw material stage to the final end product.

This course provides training in stem cell manufacturing pertaining to the expansion of stem cell types to pilot-level quantities. The first part of the course will cover fundamental concepts of stem cell biology, sources of stem cells, and their use in therapeutic and non-therapeutic applications. The second part of the course will cover current bioreactor technologies utilized in the expansion of stem cells, their design principles, and key features of each technology.

This course is sponsored by RoosterBio, a company passionate about stem cell technology. RoosterBio is accelerating the clinical translation of mesenchymal stem cells (MSC) technology by offering cells in open source formats that enable technology and product development. More information about RoosterBio can be found online at www.roosterbio.com.

Instructors: Binil Starly, Ph.D.
Associate Professor, Engineered Tissue Systems Manufacturing Laboratory
Edward P. Fitts Department of Industrial and Systems Engineering
NC State University

Ke Chang, Ph.D.
Associate Professor of Regenerative Medicine
Department of Molecular Biomedical Sciences
NC State University College of Veterinary Medicine
Joint Department of Biomedical Engineering, UNC/NC State
Applied Principles and Techniques of Depth Flow Filtration (DFF) and Tangential Flow Filtration (TFF) for BioPharm Downstream Purification

April 14–17, 2015
October 13–16, 2015

Fee: One-day lecture only: $695; Three-day lab only: $1995 (One-day lecture is a prerequisite); Full four-day workshop: $2420

Hours of instruction: One-day lecture – 7.25 hours (0.7 CEUs); Three-day lab – 22.5 hours (2.2 CEUs); Four-day workshop – 29.75 hours (2.9 CEUs)

This course focuses on the fundamental principles and optimum applied techniques for depth flow filtration (DFF) and tangential flow filtration (TFF) used in biopharmaceutical downstream processes. Choose the course format that’s most useful for you—one day, three days, or a full four days.

The one-day lecture is designed to help individuals gain a solid understanding of the parameters and factors that affect DFF and TFF membrane performance and product recovery for both cell clarification and UF/DF biopharmaceutical applications. During the three-day hands-on laboratory workshop, DFF and TFF application trials are performed using state-of-the-art benchtop systems. Data developed during these trials is applied to a real scale-up system problem and SOP. The principles and techniques presented in the prerequisite lecture course are applied in this workshop, which is limited to 12 participants.

This course is designed for engineers, scientists, managers, technical personnel, and researchers who require an in-depth review of filtration principles and their application to processes in the areas of process development, manufacturing, and quality assurance/validation.

Instructor: John Rozembersky, M.S.
President, Rozembersky Group, Inc.

Register online now at go.ncsu.edu/btec_short_courses
Molecular Perspectives in Downstream Processing and Biopharmaceutical Formulation

June 16–18, 2015
Fee: $1,725
21 instructional hours (2.1 CEUs)

In this three-day lecture/lab course, participants learn the colloidal and macromolecular molecular-level physical science concepts that underlie biologic downstream processing and biopharmaceutical formulation science. Topics include:

- The identification of biomacromolecule physical properties exploited in downstream processing and how to experimentally characterize them;
- Factors that affect biomacromolecule conformational stability and how to quantify them;
- Experimental methods for assessing protein colloidal stability and the extent of aggregation; and
- The molecular-level phenomena impacting filtration operations as well as chromatography retention mechanisms and processing parameters.

This course will benefit biomanufacturing, process development and biopharmaceutical formulation personnel and others interested in the molecular-level physical science underlying downstream processing and formulation.

Instructor: John van Zanten, Ph.D.
Teaching Assistant Professor, BTEC

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Fundamentals of Mammalian Cell Line Development

July 28–30, 2015
Fee: $1,845
22.5 instructional hours (2.2 Continuing Education Units)

Individuals attending this course gain a fundamental knowledge of the latest, most advanced cloning strategies vital to mammalian cell line development for protein production. Emphasis is on the choice of the expression vector, the host cell genetics and physiology, and screening strategies to assure the highest production yields using Chinese hamster ovary (CHO) cells as the expression model. Practical hands-on laboratory sessions include DNA cloning, cell transfection, selection/screening for best producer, and the expression/analysis of the protein of interest. This course is useful to professionals with new assignments that include mammalian cell line development and to scientists and engineers with experience in other aspects of molecular biology planning or with limited experience in molecular biology/genetic expression.

Instructor: Driss Elhanafi, Ph.D.
Sr. Bioprocessing Scientist, BTEC
Downstream Biopharmaceutical Processes: Fundamentals and Design

July 21-23, 2015
August 4-6, 2015
Fee: $1,950
22.25 hours of instruction (2.2 Continuing Education Units)

Gain a deeper understanding of the fundamental principles underlying recovery/purification operations for biopharmaceutical production—including centrifugation, homogenization, chromatography, and ultrafiltration—and how these operations are developed and scaled for use in production. Lectures provide theoretical insight into downstream operations and regulatory expectations for process development. Hands-on lab activities provide experience in experimental methods for determining process parameter ranges and material attributes (if applicable) for the different operations. The course covers material that is especially relevant to scientists and engineers working in downstream biopharmaceutical process development, particularly those new to the field. Its overview of fundamental principles and development methodologies for operations associated with downstream processing also makes the course worthwhile for downstream manufacturing management, process validation staff, and quality assurance professionals.

Instructors: Gary Gilleskie, Ph.D.
Director, Operations, and Teaching Associate Professor, BTEC

Baley Reeves, Ph.D.
Sr. Bioprocessing Scientist, BTEC
Introduction to Design of Experiments (DoE) for Bioprocess Analysis and Optimization

February 10–12, 2015
October 7–9, 2015
Fee: $1,650
21.5 hours of instruction (2.1 Continuing Education Units)

Learn how to apply the fundamental principles of Design of Experiments (DoE) methods to the analysis and optimization of bioprocesses. DoE is critical to defining the design space for a process, which is central to the quality-by-design concepts presented in the ICH Guideline for Development and Manufacture of Drug Substances Q11. This course focuses on the application of DoE methods through the use of JMP statistical software, bioprocess case studies and hands-on laboratory activities. The case studies focus on microbial fermentation, chromatography and pharmaceutical product/process development and provide real data. This course is suitable for bioprocess development scientists and engineers; process validation staff interested in defining operating ranges and attribute specifications; and other professionals with previous hands-on bioprocess experience who want to learn about DoE.

Instructor: Marcello Fidaleo, Ph.D.
Assistant Professor, University of Tuscia, Viterbo, Italy
and BTEC Teaching Fellow
Cell Culture Engineering

June 9–11, 2015
Fee: $2,100
22.5 hours of instruction

This course will primarily provide hands-on experience with the growth and production of CHO cells in a bench-scale stirred tank bioreactor, a rocker bag bioreactor and a 50-L single use bioreactor. Course topics will include cell culture media, inoculum, cell banking, GMP requirements for upstream mammalian cell culture, scale up, single use bioreactor versus stainless steel bioreactor design and the use of DOE and data analysis in cell culture development. This course is appropriate for professionals with some biopharmaceutical experience, those within the biotech industry who want to gain an understanding of upstream processing, and those involved in bioreactor equipment design and biopharmaceutical facilities design.

Instructor: Sarwat Khattak, Ph.D.
Sr. Bioprocessing Scientist, BTEC

Fermentation Engineering

July 14–16, 2015
August 11–13, 2015
Fee: $1,900
21 hours of instruction (2.1 Continuing Education Units)

Learn fermentation principles and engineering fundamentals of growing recombinant microorganisms in a bioreactor to express therapeutic proteins. Gain a fundamental understanding of the relationship between process design and product quality. Engage in hands-on pilot-scale laboratory experiences that define and explore the critical control parameters required to achieve a robust fermentation process. This course is of benefit to experienced fermentation supervisors and/or managers; scientists with experience in validation, quality assurance, or research and development; and those who hold an engineering degree, have limited biotechnology or fermentation experience, and are seeking an advanced hands-on course on the engineering aspects of fermentation.

Instructor: Lucas Vann, M.S.
Sr. Bioprocessing Scientist, BTEC
Commercialization of New Biological Drugs

June 23, 2015
July 21, 2015
Fee: $500
7.5 instructional hours (.7 Continuing Education Units)

Many professionals in the biotechnology/pharmaceutical and allied industries focus on just one or two aspects of the development and manufacture of biological products used to treat or prevent human disease. This course familiarizes participants with the entire 12- to 15-year life cycle of a new biological product as it progresses from the laboratory to the commercial market. In addition to participating in other classroom activities, attendees will use a computer game to apply new learning. Designed for those interested in gaining a better understanding of the life cycle of new biological products, research/development scientists; manufacturing professionals; engineering, quality and administrative personnel; contractors; and managers of emerging companies will benefit from this course.

Instructor: Rick Lawless, MBA, CPIP
Associate Director, Strategic Programs, BTEC

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BTEC has partnered with the Society for Biological Engineering (SBE), a technical community of the American Institute of Chemical Engineers (AIChE), to offer two eLearning courses. Each seven-hour course is available on demand.

**Biotechnology for Chemical Engineers**

Available on demand  
Fee: $795 for AIChE/SBE members  
Continuing Education Units: .7

Learn the fundamentals of biotechnology with this course designed for chemical engineers working in design, operations, or other support functions. The course focuses on the methods used to develop cell lines to produce a variety of biological drug products. It begins by presenting an overview of microorganisms, other cells, and identification techniques commonly used. These concepts are then used to introduce the methods used for cell line development, metabolic engineering, and several “omics” tools. The final sessions focus on expression and purification of biological drug products; monitoring cell growth and product expression; and fermentation/cell culture.

**Biomanufacturing for Chemical Engineers**

Available on demand  
Fee: $795 for AIChE/SBE members  
Continuing Education Units: .7

Chemical engineers or other technical professionals with no biological experience learn the fundamentals of biomanufacturing in this course, which focuses on the unit operations utilized to manufacture biological drug products. After an overview of product types, processes, and current Good Manufacturing Practice, participants learn about the maintenance of cell lines and growth of cells in a bioreactor. Topics such as mass transfer, process control, and product expression are emphasized. In the second half of the course, lectures focus on downstream unit operations that harvest cells, remove byproducts or contaminants, and fill the final bulk product.
COMMENTS BY COURSE PARTICIPANTS

Participants’ reactions to BTEC’s short courses are typically very positive. Here’s a sampling from the past year.

Applied Principles and Techniques of Depth Flow Filtration (DFF) and Tangential Flow Filtration (TFF) for BioPharm Downstream Purification

“John is a great instructor. He takes this class to a different higher level and makes it fun and easy!”

Biopharmaceutical Analysis

“The instructors are excellent—knowledgeable, well prepared, patient!”

cGMP Biomanufacturing Operations

“… 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!”

“Terrific class. I plan on sending my team to attend.”

“Very well organized and logical—perfect technical level for myself. Excellent instructors. Great labs. Well run!”

Downstream Biopharmaceutical Processes: Fundamentals and Design

“This is a fantastic facility and I’ll definitely be back!”

Fermentation Engineering

“The mix of hands-on equipment experience and theoretical background is exactly what I needed.”

“I am recommending the course to my fellow co-worker and others I know in the industry! I have 34 years in industry and still learned a number of new ideas.”

Hands-on Viral Vaccine Manufacture

“Very good mixture of lectures and hands-on lab exercises.”

Molecular Perspectives in Downstream Processing and Biopharmaceutical Formulation

“It was a great first experience. Will surely be back for more courses at BTEC.”
ABOUT BTEC

BTEC is...

- A unique multi-disciplinary center providing hands-on education and training by instructors with industry expertise. Our mission is to develop skilled professionals for the biomanufacturing industry.

- 82,500 gross square feet of state-of-the-art training facilities, the largest and most comprehensive such establishment in the nation. In addition to bench- and intermediate-scale labs, BTEC features a simulated-cGMP production environment and the latest equipment, matching that in use at the industry’s leading firms.

- A part of the NC State University College of Engineering. BTEC is located on the university’s Centennial Campus in Raleigh and is convenient to the renowned Research Triangle Park (RTP).

- A partner in NCBioImpact, the state’s largest training consortium, which works to fuel the growth of the emerging biomanufacturing industry. Other members are the North Carolina Biotechnology Center, the North Carolina Biosciences Organization, the North Carolina Community College System’s BioNetwork, and BRITE, the Biomanufacturing Research Institute and Technology Enterprise, located at North Carolina Central University.
MORE INFORMATION AND REGISTRATION

For detailed course descriptions, instructor profiles, and registration information, visit go.ncsu.edu/btec_short_courses.

Discounts available

- Learn more, save more! Register for more than one course, and each course after the first is discounted 20%.
- Attend as a group and save! If 5 or more employees from any single company register for the same course, each gets a 20% discount.
- Other discounts are available to the following: members of the Society for Industrial Microbiology and Biotechnology; employees of companies that participate in the Biotech Manufacturers Forum; and faculty and staff working in academic institutions.

For details, see go.ncsu.edu/btec_short_courses.

NC State University
Biomanufacturing Training and Education Center (BTEC)
850 Oval Drive
Suite 195
Raleigh, NC 27606
(919) 513-2000
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