

# Biomanufacturing Training Education Center (BEC)

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## **BEC 220 Introduction to Drug Development and Careers in Biomanufacturing** (1 credit hours)

Introduction to discovery and development of biopharmaceuticals, industrial enzymes, food ingredients and biologics. Discussion of majors that prepare students for positions in the biotechnology industry. Lectures from staff and from professionals in the biotechnology industry focus on drug development, biopharmaceutical process development, design of biomanufacturing facilities, overview of methods used for manufacturing biopharmaceuticals, drug and enzyme purification, formulation, as well as careers in FDA compliance documentation related to manufacturing products using microbial biotechnology.

*Typically offered in Fall and Spring*

## **BEC 330 Principles and Applications of Bioseparations** (2 credit hours)

Objectives, strategies, and approaches for recovery and purification of biomolecules, especially recombinant proteins. Description of common purification equipment, processes and materials used for cell lysis, precipitation, flocculation, membrane filtration, column chromatography, and centrifugation. Laboratories provide students with exposure to various techniques and the parameters that control protein isolation and purification of a recombinant protein. This is a half-semester course. Students who have completed BIT(CHE) 464 may not complete this course for credit.

Prerequisite: CH 223 or CH 227

*Typically offered in Fall and Spring*

## **BEC 363 Foundations of Recombinant Microorganisms for Biomanufacturing** (2 credit hours)

Introduction to basic biomanufacturing techniques with particular focus on the most commonly used recombinant microbes in industry. Includes microbial identification, metabolism, and growth kinetics; recombinant production and analysis of low molecular weight molecules, alcohols, recombinant enzymes and others. The laboratory portion of this half-semester course provides students with practical experience on basic biomanufacturing techniques carried out in small scale

Prerequisite: BIO 183

*Typically offered in Fall, Spring, and Summer*

## **BEC 425/BEC 525 Molecular Biology for Biomanufacturing** (2 credit hours)

This course is an introduction to fundamental molecular biology techniques, applied to generate bacterial cell lines for the production of recombinant proteins. Course material provides a comprehensive description of an expression system, with emphasis on the central dogma of molecular biology, detailed gene structure, vector components and bacterial host cell characteristics. Different genetic, physiologic and growth condition aspects are included to ensure the overproduction of a functional protein of interest. This comprises different molecular approaches for gene cloning, bacterial selection/screening and regulation of genetic expression. The course provides hands-on experience during laboratory sessions, where students isolate a gene of interest, clone the gene into an expression vector, transform bacteria, select for positive clones, grow recombinant cells, and induce the production of the protein of interest. Techniques such as SDS-PAGE, Western blot, and ELISA are used for the detection and quantification of the active recombinant protein.

Prerequisite: BIO 183 or equivalent

*Typically offered in Fall, Spring, and Summer*

## **BEC 426/BBS 526/FS 526/BEC 526/BBS 426/FS 426 Upstream Biomanufacturing Laboratory** (2 credit hours)

This course is an introduction to current food manufacturing practice (CGMP) as applied to the growth of microbial cells in bioreactors. Hands-on experience is obtained in the operation and control of 30 liter bioreactors to study agitation, oxygen transfer, cleaning, sterilization, media preparation and the growth of recombinant E. coli for protein production. Credit will not be awarded in both BBS 426 and BBS/FS 526. This is an eight week course.

Prerequisite: (MB 351 and FS 231) CHE/BEC 463

*Typically offered in Fall and Spring*

## **BEC 436/BEC 536 Introduction to Downstream Process Development** (2 credit hours)

Objectives, strategies, and approaches for recovery and purification of biomolecules, especially recombinant proteins. Laboratories in the intermediate-scale pilot plant provide students with exposure to various unit operations and the parameters that control protein isolation and purification of a recombinant protein produced by an E. coli. This is a half-semester course. Students who have completed BEC 436 may not take BEC 536 for credit.

Prerequisite: BEC 330 or graduate standing

*Typically offered in Fall and Spring*

## **BEC 440/BEC 540 Expression Systems in Biomanufacturing 1** (3 credit hours)

Introduction to bacterial and yeast expression systems, their advantages and disadvantages. Basic techniques in molecular biology, cell transformation and optimization of protein expression. Selection, archiving and characterization of production line. Study of parameters affecting expression and yield. The lab portion of the course provides students with practical experience in DNA and protein expression techniques in bacterial and yeast expression systems. Credit not given for both.

Prerequisite: BEC 363 or (MB 351 and MB 352)

*Typically offered in Fall only*

**BEC 441/BEC 541 Expression Systems in Biomanufacturing II** (3 credit hours)

Introduction to insect and mammalian cell expression systems, their advantages and disadvantages. Advanced techniques in DNA cloning, cell transformation, and optimization of protein expression. Selection, archiving and characterization of production line. The lab portion of the course provides students with practical experience in DNA cloning and protein expression techniques in insect and mammalian cell expression systems. Credit not given for both.

Prerequisite: BEC 440/540 or BIT 410/510

*Typically offered in Spring only*

**BEC 445/BEC 545 Cell Line Development for Biomanufacturing** (2 credit hours)

This course provides the basic and advanced principles of genetic engineering in yeast and mammalian cells for the overproduction of a protein of interest. Students will use classical and novel strategies to establish a stable Chinese hamster ovary (CHO) cell line based on the industrially relevant strain, DG44 (DHFR system). Students will also generate a yeast expression system based on *Pichia pastoris* for the production of the same protein. The generation of two different cell lines for the overproduction of the same protein of interest should provide students with an appreciation of each system in terms of cost, speed, productivity and product quality.

Corequisite: BEC 425/525 or Prerequisite: BIT 410, BEC 440, MB 351, MBA 352/354

*Typically offered in Fall and Spring*

**BEC 448/BEC 548/CHE 548/CHE 448 Bioreactor Design** (2 credit hours)

This course will cover critical aspects of bioreactor design, including design of reactors for enzyme-catalyzed reactions, fermentation of microorganisms, and scale-up considerations for bioreactors. Hands-on experiments involving fermentation of microorganisms and scale-up of bioreactors will be included. Students cannot get credit for both CHE 448 and CHE 548.

Prerequisite CHE 446 or instructor permission; Co-requisite BCH 451 or instructor permission

*Typically offered in Spring only*

**BEC 462/BEC 562/CHE 462/CHE 562 Fundamentals of Bio-Nanotechnology** (3 credit hours)

Concepts of nanotechnology are applied in the synthesis, characterization, recognition and application of biomaterials on the nanoscale. Emphasis will be given to hands-on experience with nanostructured biomaterials; students will also be familiarized with the potential impact of these materials on different aspects of society and potential hazards associated with their preparation and application.

Prerequisite: MA 241 and PY 208 and (CH 223 or CH 227)

*Typically offered in Spring only*

**BEC 463/BIT 563/CHE 563/BEC 563/BIT 463/CHE 463 Fermentation of Recombinant Microorganisms** (2 credit hours)

Introduction to fermentation and protein chemistry. Theory behind laboratory techniques and overview of industrial scale expression systems. Laboratory sessions involve use of microbial expression vectors, fermentation systems, and large-scale purification of recombinant protein. Half semester course, first part.

Prerequisite: CH 223 or CH 227; Corequisite: (BIT 410 or BCH 452 or MB 352 or BEC 363)

*Typically offered in Fall, Spring, and Summer*

**BEC 475/BEC 575 Global Regulatory Affairs for Medical Products** (3 credit hours)

This lecture-based course introduces students to the quality systems used to meet the regulatory requirements for developing, testing, manufacturing, and selling medical products in the global marketplace. It provides a general background for those going into the medical products field, but is especially useful to students preparing for a career in the Regulatory Affairs or Quality Assurance Department within a pharmaceutical, biomanufacturing, or medical device company. BEC 575 students must have graduate standing.

Prerequisite: Senior standing

*Typically offered in Fall and Spring*

**BEC 480/BEC 580 cGMP Fermentation Operations** (2 credit hours)

Application of microbial fermentation techniques at production scale and evaluation of the inherent issues resulting from the integration of microbial fermentation unit operations, scale-up/production, and current Good Manufacturing (cGMP) compliance. Lectures prepare students for pilot-scale laboratory experiences in media preparation, bioreactor operation, process utilities, and manufacturing quality systems that simulate microbial cell growth and product expression in a commercial cGMP facility. This is a half-semester course. Students who have completed BEC 480 may not take BEC 580 for credit.

Corequisite: BBS/BEC/FS 426

*Typically offered in Fall and Spring*

**BEC 483/BME 583/BEC 583/BME 483 Tissue Engineering Technologies** (2 credit hours)

In this half-semester laboratory module, students will gain practical experience with two key elements of tissue engineering: tissue building and angiogenesis. Using advanced culture techniques, students will construct a complex living tissue that closely resembles its natural counterpart, then assess its ability to support ingrowth of capillaries (angiogenesis). The effects of different biomaterials and angiogenic factors will be evaluated. The engineered tissue will be embedded, sectioned and stained for histological analysis.

Prerequisite: BIT 466/566 or permission of instructor

*Typically offered in Fall only*

**BEC 485/BEC 585 cGMP Downstream Operations** (2 credit hours)  
Application of downstream bioprocessing techniques at production scale and evaluation of the inherent issues resulting from the integration of recovery and purification unit operations, scale-up/production issues, and current Good Manufacturing Practice (cGMP) compliance. Lectures prepare students for pilot-scale laboratory experiences in cell removal, cell disruption, purification, and manufacturing quality systems that simulate downstream bioprocessing in a commercial cGMP facility. This is a half-semester course. Students who have completed BEC 485 may not take BEC 585 for credit.

Corequisite: BEC 436/536  
*Typically offered in Fall and Spring*

**BEC 488/CHE 488/BEC 588/CHE 588 Animal Cell Culture Engineering** (2 credit hours)  
Design and operation of animal cell culture bioreactors for therapeutic protein production. Topics include: batch, fed-batch and perfusion bioreactors, agitation and aeration for mixing and oxygen mass transfer, bioreactor monitoring and control, optimizing bioreactor performance, single-use [disposal] bioreactors, and the production of gene therapy vectors. This is a half-semester course. Time outside of the regularly scheduled class time may be required.

Prerequisite: BEC 463 or CHE 563 or BEC 363 or BEC 440/540 or BEC 441/541 or equivalent; or consent of instructor.  
*Typically offered in Spring only*

**BEC 495 Special Topics in Biomufacturing** (1-4 credit hours)  
Offered as needed to present materials not normally available in regular course offerings or for offering of new courses on a trial basis. Departmental approval required.

*Typically offered in Fall, Spring, and Summer*

**BEC 497 Biomufacturing Research Projects** (1-3 credit hours)  
Introduction to biomufacturing research through experimental, theoretical, and literature studies. Oral and written presentation of reports. Departmental approval required. Individualized/Independent Study and Research courses require a Course Agreement for Students Enrolled in Non-Standard Courses be completed by the student and faculty member prior to registration by the department.

*Typically offered in Fall, Spring, and Summer*

**BEC 515 Biopharmaceutical Product Characterization Techniques** (2 credit hours)  
This 8 week graduate course introduces engineering students to bioanalytical testing to processes that produce structurally complex biopharmaceuticals. Students will gain hands-on experience including assay validation, drug/biologic substance characterization (structural and activity) and biopharmaceutical purity. The technologies and related theory will include rapid micro SDS-PAGE, lab-on-a-chip, HPLC, mass spectrometry, UV/Vis absorbance and fluorescence spectroscopy. Students will also learn assay development and validation concepts as per ICH Q2(R1) and other U.S. and international government regulatory guidelines.

Prerequisite: CH 222 or equivalent  
*Typically offered in Fall only*

**BEC 525/BEC 425 Molecular Biology for Biomufacturing** (2 credit hours)

This course is an introduction to fundamental molecular biology techniques, applied to generate bacterial cell lines for the production of recombinant proteins. Course material provides a comprehensive description of an expression system, with emphasis on the central dogma of molecular biology, detailed gene structure, vector components and bacterial host cell characteristics. Different genetic, physiologic and growth condition aspects are included to ensure the overproduction of a functional protein of interest. This comprises different molecular approaches for gene cloning, bacterial selection/screening and regulation of genetic expression. The course provides hands-on experience during laboratory sessions, where students isolate a gene of interest, clone the gene into an expression vector, transform bacteria, select for positive clones, grow recombinant cells, and induce the production of the protein of interest. Techniques such as SDS-PAGE, Western blot, and ELISA are used for the detection and quantification of the active recombinant protein.

Prerequisite: BIO 183 or equivalent  
*Typically offered in Fall, Spring, and Summer*

**BEC 526/BBS 426/FS 426/BEC 426/BBS 526/FS 526 Upstream Biomufacturing Laboratory** (2 credit hours)  
This course is an introduction to current food manufacturing practice (CGMP) as applied to the growth of microbial cells in bioreactors. Hands-on experience is obtained in the operation and control of 30 liter bioreactors to study agitation, oxygen transfer, cleaning, sterilization, media preparation and the growth of recombinant E. coli for protein production. Credit will not be awarded in both BBS 426 and BBS/FS 526. This is an eight week course.

Prerequisite: (MB 351 and FS 231) CHE/BEC 463  
*Typically offered in Fall and Spring*

**BEC 532 Biological Processing Science** (2 credit hours)  
Fundamental scientific principles underlying the recovery, purification and formulation of biologics (biotherapeutics), especially proteins, are examined. Emphasis is placed on delineating the key chemical and physical properties of biomolecules that impact processing and formulation development. Laboratories in the analytical and small-scale purification facility provide students with 'hands-on' exposure to key scientific principles and small scale unit operations. This is a half-semester course.

Prerequisite: BCH 451 or graduate standing  
*Typically offered in Fall and Spring*

**BEC 536/BEC 436 Introduction to Downstream Process Development** (2 credit hours)  
Objectives, strategies, and approaches for recovery and purification of biomolecules, especially recombinant proteins. Laboratories in the intermediate-scale pilot plant provide students with exposure to various unit operations and the parameters that control protein isolation and purification of a recombinant protein produced by an E. coli. This is a half-semester course. Students who have completed BEC 436 may not take BEC 536 for credit.

Prerequisite: BEC 330 or graduate standing  
*Typically offered in Fall and Spring*

**BEC 540/BEC 440 Expression Systems in Biomanufacturing 1** (3 credit hours)

Introduction to bacterial and yeast expression systems, their advantages and disadvantages. Basic techniques in molecular biology, cell transformation and optimization of protein expression. Selection, archiving and characterization of production line. Study of parameters affecting expression and yield. The lab portion of the course provides students with practical experience in DNA and protein expression techniques in bacterial and yeast expression systems. Credit not given for both.

Prerequisite: BEC 363 or (MB 351 and MB 352)

*Typically offered in Fall only*

**BEC 541/BEC 441 Expression Systems in Biomanufacturing II** (3 credit hours)

Introduction to insect and mammalian cell expression systems, their advantages and disadvantages. Advanced techniques in DNA cloning, cell transformation, and optimization of protein expression. Selection, archiving and characterization of production line. The lab portion of the course provides students with practical experience in DNA cloning and protein expression techniques in insect and mammalian cell expression systems. Credit not given for both.

Prerequisite: BEC 440/540 or BIT 410/510

*Typically offered in Spring only*

**BEC 545/BEC 445 Cell Line Development for Biomanufacturing** (2 credit hours)

This course provides the basic and advanced principles of genetic engineering in yeast and mammalian cells for the overproduction of a protein of interest. Students will use classical and novel strategies to establish a stable Chinese hamster ovary (CHO) cell line based on the industrially relevant strain, DG44 (DHFR system). Students will also generate a yeast expression system based on *Pichia pastoris* for the production of the same protein. The generation of two different cell lines for the overproduction of the same protein of interest should provide students with an appreciation of each system in terms of cost, speed, productivity and product quality.

Corequisite: BEC 425/525 or Prerequisite: BIT 410, BEC 440, MB 351, MBA 352/354

*Typically offered in Fall and Spring*

**BEC 548/CHE 548/CHE 448/BEC 448 Bioreactor Design** (2 credit hours)

This course will cover critical aspects of bioreactor design, including design of reactors for enzyme-catalyzed reactions, fermentation of microorganisms, and scale-up considerations for bioreactors. Hands-on experiments involving fermentation of microorganisms and scale-up of bioreactors will be included. Students cannot get credit for both CHE 448 and CHE 548.

Prerequisite CHE 446 or instructor permission; Co-requisite BCH 451 or instructor permission

*Typically offered in Spring only*

**BEC 562/CHE 462/CHE 562/BEC 462 Fundamentals of Bio-Nanotechnology** (3 credit hours)

Concepts of nanotechnology are applied in the synthesis, characterization, recognition and application of biomaterials on the nanoscale. Emphasis will be given to hands-on experience with nanostructured biomaterials; students will also be familiarized with the potential impact of these materials on different aspects of society and potential hazards associated with their preparation and application.

Prerequisite: MA 241 and PY 208 and (CH 223 or CH 227)

*Typically offered in Spring only*

**BEC 563/BIT 463/CHE 463/BEC 463/BIT 563/CHE 563 Fermentation of Recombinant Microorganisms** (2 credit hours)

Introduction to fermentation and protein chemistry. Theory behind laboratory techniques and overview of industrial scale expression systems. Laboratory sessions involve use of microbial expression vectors, fermentation systems, and large-scale purification of recombinant protein. Half semester course, first part.

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*Typically offered in Fall and Spring*

**BEC 575/BEC 475 Global Regulatory Affairs for Medical Products** (3 credit hours)

This lecture-based course introduces students to the quality systems used to meet the regulatory requirements for developing, testing, manufacturing, and selling medical products in the global marketplace. It provides a general background for those going into the medical products field, but is especially useful to students preparing for a career in the Regulatory Affairs or Quality Assurance Department within a pharmaceutical, biomanufacturing, or medical device company. BEC 575 students must have graduate standing.

Prerequisite: Senior standing

*Typically offered in Fall and Spring*

**BEC 577/CHE 577 Advanced Biomanufacturing and Biocatalysis** (3 credit hours)

Overview of biomanufacturing using microorganisms (bacteria, yeast, fungi), eukaryotic cells (hybridomas, insect, plant, CHO) and recombinant enzymes focusing on methods used in industry. Course will emphasize process design for optimization of heterologous protein expression, metabolic/cell line engineering, metabolomics, protein engineering to alter enzymes and antibodies. Pathway engineering strategies include developing microbes to produce new therapeutic compounds or overproduce primary metabolites, antibiotics, biotherapeutics, therapeutic enzymes, diagnostics, recombinant vaccines, and biopharmaceuticals. Utilization of immobilized biocatalysts, and microbial kinetics are covered.

Graduate standing in engineering or life-science graduate program

*Typically offered in Spring only*

**BEC 580/BEC 480 cGMP Fermentation Operations** (2 credit hours)

Application of microbial fermentation techniques at production scale and evaluation of the inherent issues resulting from the integration of microbial fermentation unit operations, scale-up/production, and current Good Manufacturing (cGMP) compliance. Lectures prepare students for pilot-scale laboratory experiences in media preparation, bioreactor operation, process utilities, and manufacturing quality systems that simulate microbial cell growth and product expression in a commercial cGMP facility. This is a half-semester course. Students who have completed BEC 480 may not take BEC 580 for credit.

Corequisite: BBS/BEC/FS 426

*Typically offered in Fall and Spring*

**BEC 583/BME 483/BEC 483/BME 583 Tissue Engineering Technologies** (2 credit hours)

In this half-semester laboratory module, students will gain practical experience with two key elements of tissue engineering: tissue building and angiogenesis. Using advanced culture techniques, students will construct a complex living tissue that closely resembles its natural counterpart, then assess its ability to support ingrowth of capillaries (angiogenesis). The effects of different biomaterials and angiogenic factors will be evaluated. The engineered tissue will be embedded, sectioned and stained for histological analysis.

Prerequisite: BIT 466/566 or permission of instructor

*Typically offered in Fall only*

**BEC 585/BEC 485 cGMP Downstream Operations** (2 credit hours)

Application of downstream bioprocessing techniques at production scale and evaluation of the inherent issues resulting from the integration of recovery and purification unit operations, scale-up/production issues, and current Good Manufacturing Practice (cGMP) compliance. Lectures prepare students for pilot-scale laboratory experiences in cell removal, cell disruption, purification, and manufacturing quality systems that simulate downstream bioprocessing in a commercial cGMP facility. This is a half-semester course. Students who have completed BEC 485 may not take BEC 585 for credit.

Corequisite: BEC 436/536

*Typically offered in Fall and Spring*

**BEC 588/CHE 588/BEC 488/CHE 488 Animal Cell Culture Engineering** (2 credit hours)

Design and operation of animal cell culture bioreactors for therapeutic protein production. Topics include: batch, fed-batch and perfusion bioreactors, agitation and aeration for mixing and oxygen mass transfer, bioreactor monitoring and control, optimizing bioreactor performance, single-use [disposal] bioreactors, and the production of gene therapy vectors. This is a half-semester course. Time outside of the regularly scheduled class time may be required.

Prerequisite: BEC 463 or CHE 563 or BEC 363 or BEC 440/540 or BEC 441/541 or equivalent; or consent of instructor.

*Typically offered in Spring only*

**BEC 590 Industry Practicum in Biomufacturing** (3 credit hours)

This is an industry case study course emphasizing scientific, engineering, analytical, and professional skills related to biomufacturing of human therapeutics; the course will provide students with the opportunity to design a complete cGMP process and facility capable of licensure.

*Typically offered in Fall only*

**BEC 595 Special Topics in Biomufacturing** (1-6 credit hours)

Offered to present graduate course content not available in existing courses or for offering of new graduate courses on a trial basis. Departmental approval required.

**BEC 601 Biomufacturing Seminar** (1 credit hours)

Weekly seminars on topics of current interest in biomufacturing and affiliated subjects. Seminars will be presented by resident faculty members, graduate students and visiting lectures from industry, government regulatory agencies such as the FDA or from academic programs related to biomufacturing.

*Typically offered in Fall and Spring*

**BEC 620 Leadership and Preparation for Industry Internship in Biomufacturing** (2 credit hours)

Advanced communication skills specific to the regulatory requirements of the biomufacturing and biopharmaceutical industries regulated by the U.S. FDA. Instructors teach writing professional and technical resumes, advanced interview skills, team or project leadership, teamwork and communication skills required by industry to prepare and present discipline-specific documents to the FDA. Students learn change management in a biopharmaceutical company and how to develop emotional intelligence. Interviews by industry professionals give each student experience and feedback. Restricted to students with graduate standing.

*Typically offered in Spring only*

**BEC 621 Communicating and Industry Internship in Biomufacturing** (1 credit hours)

Organize information learned in a biomufacturing internship and demonstrate effective oral presentation of proprietary information. Create a professional presentation about their industry internship experience and write a paper describing their experience. Biomufacturing Graduate Faculty evaluates each industry internship experience by student presentation and written paper. An industry internship is required of all Professional Science Masters (PSM) degree programs in the U.S. Restricted to BIOM graduate students and students applying to the BIOM program.

Prerequisite: BEC 620

*Typically offered in Fall only*

**BEC 669 Biomufacturing Research Projects** (1-4 credit hours)

Introduction to biomufacturing research through experimental, theoretical and literature studies under the mentorship of a member of the graduate faculty. Oral and written presentation of reports. Departmental approval required.

Prerequisite: Graduate standing in engineering, biological science or physical science

*Typically offered in Fall, Spring, and Summer*