ENGINEERING (ENGR)

ENGR 500: Intro to Polymer Material Sci
This course will explore fundamental process-structure-property-performance relationships in polymers and their hybrids. Topics include mechanical properties, manufacturing processes, chain structure, polymer synthesis, molecular weight, crystallinity, rubber elasticity, viscoelasticity, and cross-linking. Laboratory demonstrations will reinforce basic lecture concepts. Finally, students will use Ansys Granta Edupack software in projects to make polymer selections for specific applications and perform "eco-audits" to explore life cycle impacts. Biodegradation and compostability will also be discussed in the context of natural and sustainable biopolymers.
Credits: 3
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 600: Bioanalytical Reg/Qual Princip
This master level course will introduce the students to the concepts and requirements for global pharmaceutical quality and regulatory compliance associated with approval of a new biologic and biosimilar. The FDA'a concepts of Quality by Design (QBD), Process Analytical Technology (PAT) and Critical Quality Attributes (CQAs) (product and process) will be through case studies and examples to provide the foundation for ensuring that product quality, safety and efficacy are built into process during design and not introduced as an afterthought. This introductory course provides the basic principles of QBD, PAT and CQAs using case studies and definition and terms relevant to understanding how a modern biopharmaceutical products are developed and marketed in a highly regulated environment.
Credits: 3
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 601: Intro Upstream Unit Operations
This advanced level course is focused on the application of principles of cell culture operations in fed-batch and perfusion bioreactors from bench scale to production scale. Students will be introduced to design, scale up and scale down approaches through case studies, hands-on laboratory studies, seminars, individual and group projects and formal class lectures. Examples will include cell culture operations used to produce biopharmaceutical medicine including peptides, proteins and monoclonal antibodies for variety of diseases including cancers, diabetes, rheumatoid arthrosis, scoliosis, to name but a few. Prerequisites: (Course XXX-XX for science track and Course XXX-XX for engineering track students)
Credits: 3
College: School of Design & Engineering
Schedule Type: Lecture/Lab

ENGR 602: Intro Downstream Unit Ops
This master level course introduces students to the first principles and application of preparative chromatography for downstream purification as well as other key unit operations including tangential flow filtration (TFF) for product formulation and concentration. Students will be introduced to design, scale up and scale down approaches through case studies, hands-on laboratory studies, seminars, individual and group projects and formal class lectures. Examples will include industrial operations used to produce biopharmaceutical medicine including peptides, proteins and monoclonal antibodies for variety of diseases including cancers, diabetes, rheumatoid arthrosis, scoliosis, to name but a few.
Credits: 3
College: School of Design & Engineering
Schedule Type: Lecture/Lab

ENGR 603: Appl Math & Stat Mtds in Bio
This master level course is designed to give participants the basic knowledge and confidence in the practical design and realistic analysis of data within the contexts of bioprocess research and development and Biomanufacturing. Students will gain basic experience in displaying, summarizing, analyzing and interpreting bioprocessing data using standard mathematical and statistical methods. At the end of this course students will understand the statistical concepts of bias, variability, and sampling distributions, be able to select the appropriate statistical method for a given data set, evaluate the quality of data collected from observational and experimental studies, design simple studies, use statistical computer software to explore and analyze data, understand statistical language as used in bioprocess development and biomanufacturing, and lastly, interpret statistical results and communicate them to other scientists and engineers.
Credits: 1.5
College: School of Design & Engineering
Schedule Type: Lecture, On-Line

ENGR 604: Biopharm Process Ops
This masters level hands-on course provides practical firsthand experience with many of the techniques and principles taught in the complimentary lecture courses in upstream and downstream operations. The experiments are designed to teach students a broad understanding of key unit operations and the challenges of working in a Good Manufacturing Practice-like (GMP-like) environment. The focus of the course will include technical aspects, documentation, batch record keeping and reporting of data. Major operations will include downstream bio-separation techniques, including chromatography, tangential flow and depth filtration, as well as upstream operations including seeding and bioreactor utilization. As a result, students will gain a thorough understanding of unit operations performed in a GMP setting.
Credits: 3
College: School of Design & Engineering
Schedule Type: Lecture/Lab

ENGR 605: QbD, Proc Sel & Optimization
This master level course introduces students to the concepts of quality-by-design (QbD) and its application specifically to biopharma and biomanufacturing through contextual examples, case studies, seminars, lecture and team work projects. As the attributes of biopharmaceutical and biologic products are poorly understood early in process design and development, often times these products are defined by their manufacturing processes which are often not fully characterized in first generation manufacturing. QbD is a systematic scientific, risk-based, holistic and proactive approach to biopharmaceutical development. This approach to biopharmaceutical development adopts a deliberate design effort from product conception through commercialization with a full understanding of how product critical quality attributes (CQAs) and process parameters impact safety, efficacy, and performance.
Credits: 1.5
College: School of Design & Engineering
Schedule Type: Lecture/Lab, On-Line

ENGR 606: Proc Charac & Validation
This master level course introduces students to the concepts of tech transfer, process characterization and risk-based validation specifically in the contexts of manufacturing of biopharmaceuticals and biologics. The course will be delivered through examples, case studies seminars and class lectures and team work projects. Process Characterization and process validation are major components within FDA's regulatory expectation for product approval. This course is intended to introduce the students to regulatory guidelines, recommended techniques and expectations through good practice and well established tools developed over the past two decades by regulatory and bio manufacturers.
Credits: 1.5
College: School of Design & Engineering
Schedule Type: Lecture, On-Line

ENGR 607: Bus & Entr in Life Sciences
This master level course is designed to train students in entrepreneurial leadership in biopharmaceutical– based industries. The course consists of two elements. The first element focuses on the practical application of preparing a business plan for new ventures. This component centers on bioprocessing of new products and their potential translation into real-world outcomes through a viable business. The second element is designed to introduce the students to the key aspects of implementing the objectives of a business plan once appropriate funding has been obtained. Legacy and next generation biologics including stem cells, gene therapy, tissue engineering and regenerative medicine are proving exceptionally efficacious. As a result, the market is growing and new companies are being created at incredibly fast rates. In this course, students will be given basic understanding of the challenges and opportunities in developing a new company for the creation of biopharmaceutical grade products based on these emerging discoveries.
Credits: 1.5
College: School of Design & Engineering
Schedule Type: Lecture, On-Line

ENGR 608: Capstone Design Project
The Capstone course may be taken as a team design project or alternatively, and where appropriate as an independent bioprocess research and development (BR&D) project. In both cases the course is thesis-based and the focus will be projects in biopharmaceutical processing and Biomanufacturing operations. Students taking the design project will work under supervision in small teams to design, for example, a complete biomanufacturing plant capable of producing commercial quantities of an API or DP. Each team will work on a separate and specific project leading to a process design. Typical examples include manufacturing of insulin, human growth hormone, tissue plasminogen activator, monoclonal antibodies for caners, and autoimmune diseases. Students will evaluate potential commercial opportunities and manufacturing options, selecting the expression system, designing the upstream operations, from vial to production bioreactor, harvesting and downstream purification sequence of operations. A detailed literature survey will be included to understand the best industry practices. Team discussion and consultation with subject matter experts within JIB and with external companies will then be followed leading to specification of the purity profile for the product. This is then followed by preparation of detailed engineering flow sheet that includes each unit operation. Selection and sizing of each equipment for each unit operation will then be carried to meet a specified annual demand for the product. Finally an economic evaluation of the process will be carried out to evaluate the cost of good and potential pricing of the product. The final design will be evaluated and interpreted using available simulation and modelling techniques. A group report and individual report will be presented by each student in the team. A student or small group of students taking the BR&D option will work with one or more faculty members on a project which may include a specific unit operation or an integration of operations. Typical projects include, but are not limited to, continuous bioprocessing, cell line development and optimization, media optimization, scale-down model development, CFD modeling of bioprocess operations. Where possible and to add value, preference will be given to projects are industry sponsored. Students are required to report their results regularly (weekly or biweekly) to their supervisors. Students on both tracks (Design and BR&D) are required to submit and defend their final report, create and present a poster based on the results of their work and give a public (open) power-point presentation. If and when required, for example in the case of an industry sponsored projects, students will be required to obtain the necessary approval form their sponsoring companies for open presentations.
Credits: 6
College: School of Design & Engineering
Schedule Type: Lecture/Lab

ENGR 609: Bioprocess Engineering for Sci
This master level course introduces students to the basic underlying transport processes of momentum, mass and heat transfer pertinent to biopharmaceutical process development. The course will demonstrate the power of mathematical techniques, modeling and statistical methods to resolve practical issues in a biomanufacturing setting. The course is experiential and includes project work, seminars, workshops and formal class room presentations and discussions to illustrate concepts.
Credits: 3
College: School of Design & Engineering
Schedule Type: Lecture, On-Line

ENGR 610: Basic Life Sci for Engineers
This master level course introduces students with first degrees in engineering and related disciplines to underlying principles and applications of key concepts in microbiology, biochemistry, and biology to highlight the importance of cells, genes and proteins as the basis of disease and as therapeutics. The course will cover basic recombinant DNA technology as used in the production of therapeutic proteins and monoclonal antibodies. The course will cover basic properties of amino acids, peptides, proteins and monoclonal antibodies, structure-function of proteins and DNA, and cellular reactions involved in cell growth and metabolism, translation, transcription, and replication. Topics will cover different expression systems, basic design of vectors, cell transfection and protein expression and associated analytical methods and techniques. The course is experiential and includes project work, seminars, workshops and formal class room presentations and discussions and group work to illustrate concepts.
Credits: 3
College: School of Design & Engineering
Schedule Type: Lecture, On-Line

ENGR 611: Princ BioPharm Proc Engineerin
This master level course introduces students to the basic methods and techniques used in industry for the manufacture of biopharmaceuticals and biologics. The intent is to introduce the students to the challenges as well as opportunities in bioprocess development of a new biologic with the focus specifically in this course on developing a process flow diagram for a molecule in early phase development and using quality-by-design and risk-based management to optimize it for late phase clinical and launch. Students will work in small groups under JIB faculty/staff supervision to define, a process and create flow diagram and plan a series of studies for execution, report and present their plan in written and oral (presentational) format. By delivering the course outcomes, students will learn how bioprocess development of biologics fits into biomanufacturing and the challenges of taking discoveries from research to market. Specific examples including peptides, proteins and monoclonal antibodies for diseases including cancers, diabetes, rheumatoid arthrosis's, Alzheimer's', heart-related diseases and many more. Students will be introduced to real world examples using process history and development of commercial biologics to provide the basis for a "phase appropriate" approach to process development in biomanufacturing and why in the case of biologics, the process is the product.
Credits: 3
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 612: Emerging Therapeutics
This course focuses on the on-going development and history of advanced bio-therapeutics ranging from recombinant antigen-based vaccines to genetic-based vaccines, and from protein replacement biotherapeutics to next generation immuno-therapeutics based on cell and gene therapy. Through specific examples, and case studies this course follows recent and on-going product and process developments in emerging therapeutics to help understand technical and economic challenges associated with the launch of new products. The course will also consider new collaborative opportunities to mitigate these challenges, while increasing the chances of success, including new partnerships (academic-industry-government agencies) aimed at spreading cost, reducing risk, and increasing efficiency.
Credits: 1.5
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 613: Vector & Cell Line Design
This course focuses on providing the foundational education for students who wish to focus their careers in cell line engineering and development, cloning operations, and construct / vector design. Individuals attending this course gain fundamental knowledge of the latest, most advanced cloning strategies vital to cell line development for protein and vaccine production, including verification and sequence analysis of the gene and protein of interest, codon optimization, vector construction, and clone / host cell selection and engineering.
Credits: 3
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 614: Vaccine Formulation
Several vaccine formulation technologies are available, including liquid, lyophilized, oil-in-water emulsion, water-in-oil emulsion, liposomal and nanoparticle, all of which may include adjuvants. If selected and formulated correctly adjuvants can dramatically enhance the effectiveness of the active pharmaceutical ingredient (API), causing a reduction in dose required to elicit an immune response. Adjuvants are often used for their dose-sparring potential, but the development of adjuvants and their use in vaccine formulation remains more of an art than a science. This course focuses on the development of formulation strategies for therapeutic and preventive vaccines and is crucial to the understanding of advanced vaccine manufacturing and development.
Credits: 1.5
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 615: Biologics & Biosimilars
In order to design and produce biologics and biosimilars, in-depth knowledge of the regulatory requirements and underlying biological principles related to molecule identity and production are required. This course addresses these issues through an exploration of key concepts in microbiology, biochemistry and biology, with an emphasis on their importance to the verification of the identity of a therapeutic molecule and the various regulations required to do so. To highlight the importance of the production process, recombinant DNA technology with an emphasis on the basic design of vectors, cell transfection, protein expression and associated analytical methods and techniques will also be addressed. The course is experiential and includes project work, hands-on activities, formal class room presentations and group work to illustrate concepts.
Credits: 1.5
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 616: CMC & Pharm Good ManuPractices
The underlying principles and application of Chemistry, Manufacturing, Control (CMC) and Pharmaceutical Good Manufacturing Practices (GMP) are key aspects in the production of biologics and biosimilars. Their utilization enables the identification of key molecule-based issues early in the development process and provides sufficient information to assure the identity, quality, purity, strength, and stability of the drug product to meet regulatory requirements and specifications. This course provides participants with the knowledge and expertise required to utilize CMC and GMP to design GMP analytical packages to demonstrate a consistent and reliable manufacturing process. These concepts will also be applied to formulation development followed by clinical trial supply manufacturing that is both fully GMP compliant and monitors all areas of risk to ensure product quality.
Credits: 1.5
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 617: Quality Systems for Reg Compl
A comprehensive understanding of the underlying principles and applications of key concepts in pharmaceutical quality systems is paramount to the production of safe and efficacious therapeutics. This course is designed to train students on the utilization of Quality Management System (QMS) in a GMP environment and the maintenance of pharmaceutical quality. The course will focus on the internationally harmonized guidance ICH Q 10, with an emphasis on quality tools and techniques used in a GMP pharmaceutical environment to ensure the quality of the pharmaceutical product with a focus on patient safety.
Credits: 1.5
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 618: Tech & Regulatory Aspects
A fundamental biopharmaceutical QC requirement for both GMP inspection of laboratories and product registration, is the analytical test method validation. This course is designed to provide students with an indepth understanding of the technical and regulatory aspects of the analytical methods utilized to characterize drug-related samples to ensure that the results are trustworthy, as the analytical methods may be utilized as the basis for decisions related to patient safety.
Credits: 1.5
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 619: Biopharm & Biologics
This course is part of the Innovation MBA (iMBA) concentration in Biopharmaceutical Commercialization and is intended for students that are new to the biopharmaceutical and biologics industries. Through a series of case studies and reallife experiences, the course introduces the various regulatory guidelines (FDA and EMA) which are followed by the pharmaceutical industry for the approval of biopharmaceuticals and biosimilars. The course also highlights the important regulatory and draft FDA guidelines for next generation therapeutic modalities, such as CAR-T cell, gene therapy and novel vaccines. The regulatory guidelines for implementing QbD in biopharmaceutical processes will be introduced.
Credits: 3
College: School of Design & Engineering
Schedule Type: Lecture, On-Line

ENGR 620: Biopharm Commercialization
Commercialization represents the biopharma function that is most visibly tied to overall company health. This function is responsible for bringing drugs to market and overseeing their financial performance. They must work closely with development teams to manage portfolio and pipeline, while also translating successful clinical trials into viable products that are embraced by prescribers and consumers. Interaction with manufacturing is critical as well, as supply chain and demand must be aligned across these functions. Ultimately, if commercialization teams are high-functioning, this translates into strong company performance and investor confidence.
Credits: 3
College: School of Design & Engineering
Schedule Type: Lecture, On-Line

ENGR 621: Intro Biopharm &Biologics Prod
This master level course is part of the Innovation MBA (iMBA) concentration in Biopharmaceutical Commercialization. It is intended for non-scientists and those who are new to the biopharmaceutical and biologics industries. Through a series of case studies and real-life experiences, the course introduces the history of biopharmaceutical development; beginning with first generation treatments, including insulin, human growth hormones and tissue plasminogen activator, to next generation therapeutic modalities, such as CAR-T cell, gene therapy and novel vaccines. Upon completion of this course, participants will be prepared to engage in high level discussions and decisions across all major functional areas related to the commercialization of products in the biopharmaceutical industry. This course will provide participants with a basic scientific background and the ability to participate and contribute to business-related operations that are critical to expanding areas within biopharma, including proteins and monoclonal antibodies, modern vaccines and cell/gene therapies.
Credits: 3
College: School of Design & Engineering
Schedule Type: Lecture, On-Line

ENGR 622: Bio-Therapeutic Formulation
The formulation of therapeutics is an integral step in the manufacturing process which ensures the stability and safe delivery of the drug product. Participants in this course will be introduced to the challenges and opportunities in formulation practice with a focus on the development of liquid formulation for proteins and monoclonal antibodies for subcutaneous and intravenous delivery. The course also includes an in-depth exploration of industry standard best practices using quality-by-design and risk-based management approaches to identify and optimize liquid formulations for early to late-phase clinical studies and product launch.
Credits: 1.5
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 623: Intro to Life Cycle Analysis
The goal of this course is to bring perspective to the practical application of life cycle assessment (LCA) to products, processes, and business activities. The course will address how industry and government are applying LCA and assess its potential as it evolves both as an environmental tool and as an ethic, much as pollution prevention has. Case studies will be offered as examples of how the use of LCA can lead to beneficial results. The course will cover all facets of LCA to help the student thoroughly understand the subject. Discussion will range from the full, robust LCA model (inventory, impact assessment, and improvement analysis) to issues surrounding the development of a streamlined approach. Applications in life-cycle design and ecolabeling will be presented, as well as initial attempts to include life cycle thinking in the development of public policy in the United States and abroad. Of course, no discussion of industrial applications would be complete without consideration of life cycle costing and its importance as a factor in corporate decision making.
Credits: 3
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 624: Lean Manufacturing
This course is designed to give students an overview of a "Lean Enterprise Systems" as an approach companies use to achieve world-class performance and customer satisfaction. This course will show how Continuous Improvement principles improve an organization's ability to provide added customer value to products and services. The focus of the course will be on introducing these key concepts, methods, and tools by demonstrating how they are applied in decision-making situations.
Credits: 3
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 800: Doctoral Research I
This doctoral level course is the first in a series of three courses which provide students the forum to survey the landscape of their dissertation topic with an emphasis on a deep understanding of fundamental principles and latest research in the field. Students will use this foundation to develop an experimental plan with their committee and complete an in-depth literature review for their dissertation. By the completion of this initial Doctoral Research Course / Semester, candidates will present an in-depth background overview of their research topic in oral and written form. The presentation and report should address the history / background of the topic, as well as comprehensive analysis of the literature relevant to the dissertation topic.
Credits: 6
College: School of Design & Engineering
Schedule Type: Hybrid, Lecture

ENGR 801: Doctoral Research II
This doctoral level course is the second in a series of three courses which provide students the forum to survey the landscape of their dissertation topic with an emphasis on a deep understanding of fundamental principles and latest research in the field. Students will use this foundation to develop an experimental plan with their committee and complete an in-depth literature review for their dissertation. By the completion of this second Doctoral Research Course / Semester, candidates will outline the objectives of their research and develop a detailed project proposal and present it to their research committee for review and approval. The proposal should clearly relate to the objectives and include a tentative experimental plan, timeline and needs analysis.
Credits: 6
College: School of Design & Engineering
Schedule Type: Hybrid

ENGR 802: Doctoral Research III
This doctoral level course is the third in a series of three courses which provide students the forum to survey the landscape of their dissertation topic with an emphasis on a deep understanding of fundamental principles and latest research in the field. Students will use this foundation to develop an experimental plan with their committee and complete an in-depth literature review for their dissertation. By the completion of this third Doctoral Research Course / Semester, candidates will finalize their experimental plan /project proposal incorporating the feedback and analysis provided by their research committee. If time allows and the proposal is fully approved; the candidate will be eligible to begin experimentation. The course will also afford the candidate the opportunity to prepare a publishable manuscript for the dissemination of the results of their literature review, as well as opportunities to identify appropriate venues for the presentation of the research. The course will culminate with the first-year candidacy exam.
Credits: 6
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 803: Doctoral Research IV
This doctoral level course is the first in a series of three which provide students the forum to begin their hands-on experimentation as related to their dissertation topic. As by this point, all students have developed a deep understanding of fundamental principles / latest research within their area of interest, and have gained approval for their experimental plan, it is paramount to the success of the candidate that they be provided a forum to earn credit for their work while also tracking progress and milestones.
Credits: 6
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 804: Doctoral Research V
This doctoral level course is the second in a series of three and provides students the forum to continue their hands-on experimentation as related to their dissertation topic. As by this point, all students have developed a deep understanding of fundamental principles / latest research within their area of interest, it is fundamental to the students' success that they be provided a forum to earn credit for their work while also tracking progress and milestones throughout their second year of study.
Credits: 6
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 805: Doctoral Research VI
This doctoral level course is the third in a series of three which provide students the forum to continue / complete their hands-on experimentation as related to their dissertation topic. As by this point, all students have developed a deep understanding of fundamental principles / latest research within their area of interest, it is fundamental to the students' success that they be provided a forum to earn credit for their work while also tracking progress and milestones throughout their second year of study.
Credits: 6
College: School of Design & Engineering
Schedule Type: Lecture

ENGR 806: Doctoral Research VII
This doctoral level course is the first in a series of three and provides students a forum to complete their hands-on experimentation as related to their dissertation topic and or start to craft this critical document for dissemination. As by this point, all students should be at or near completion of the hands-on portion of their programmatic journey, it is paramount to the success of the candidate that they be provided a forum to earn credit for their work while also tracking progress towards the completion of the dissertation and oral defense.
Credits: 6
College: School of Design & Engineering
Schedule Type: Independent Study, Lecture