

Course overview

This new course is offered for the graduate program in Biological & Biomedical Engineering. Biotherapeutics, including nucleic acids, proteins, antibodies, peptides and cells, are a group of important therapeutical agents and have a wide spectrum of clinical applications. Because of their intrinsic limitations, such as instability and off-target effects, appropriate formulation and delivery strategies are critical. This course is designed to introduce the importance of and technologies for formulation and delivery of biotherapeutics, and covers the fundamental principles of formulation and delivery system development, manufacturing and analytical techniques, and biomedical applications. The course will also discuss translational considerations for formulated biotherapeutic products.

Learning outcomes

This course will provide students with the knowledge and understanding of biotherapeutic formulation and delivery through online lectures, slide presentations, team assignments and discussions, and research proposals on assigned topics.

By the end of this course, students will be expected to:

- Be able to demonstrate an appreciation of the importance of formulation and delivery development for biotherapeutics in bringing biopharmaceutical products to market
- Be able to understand key fundamental principles, current formulation and delivery strategies for various biotherapeutics, and their applications.
- Be able to understand bioprocessing and techniques of biotherapeutic formulation and delivery
- Be able to identify challenges, opportunities, and potential new technologies for engineering future formulations for biomedicines
- Develop skills in literature reading, presentation, and proposal writing

Instructional methods

- Lectures, project proposal, journal presentation, group presentation, and quizzes
- Learning activities and assessments will take place in-person primarily, but could be switched to online (Zoom or MS Teams) if unexpected situation occurs (e.g., pandemic outbreaks).
- Regular attendance and in-class participation are essential to achieving the course objectives. The class contribution grade includes participation in class discussions and your engagement in class. Presence is mandatory and participation is expected. The student should notify the lecturer beforehand if they need to miss a class.

Required course materials

Required reading materials (consisting of selected original research papers and review articles), lecture slides and assignments will be posted on myCourses.

Content

Week 1 (30-Aug & 6-Sep): Introduction and the concepts of nanomedicine for biotherapeutics

Week 2 (11-Sep & 13-Sep): Formulation and delivery approaches for nucleic acids

Week 3 (18-Sep & 20-Sep): Formulation and delivery approaches for proteins

Week 4 (25-Sep & 27-Sep): Formulation and delivery approaches for antibodies

Week 5 (2-Oct & 4-Oct): Formulation and delivery approaches for genome editing machinery

Week 6 (16-Oct & 18-Oct): Formulation and delivery approaches for cells or cell-related medicines

Week 7 (23-Oct & 25-Oct): Biotherapeutics: administration approaches, biopharmaceutics and pharmacokinetics

Week 8 (30-Oct & 1-Nov): Literature presentations

Week 9 (6-Nov & 8-Nov): Drug Delivery Devices and Reservoirs

Week 10 (13-Nov & 15-Nov): Stimuli-Responsive Drug Delivery Systems

Week 11 (20-Nov & 22-Nov): Micro/Nano-Robots

Week 12 (27-Nov): Regulatory considerations, clinical trial applications, and translational perspectives of drug delivery systems

Week 13 (29-Nov & 4-Dec): Team project presentation

Evaluation

Class Participation: 5% (attendance rate; participation in discussions)

Quizzes: 20%

- 10 quizzes; 2% per quiz
- Each quiz will be scheduled as shown above
- Each quiz contains 5 choice questions
- Quiz will be given in class (~5-10 min)

Final Project (individual): 40%

- Proposal is due **Week 5, Oct 2** (1-page summary) for feedback and approval to develop full project
- Final project is due **Week 12, Nov 23** (4000-4500 words including figure captions and tables but excluding title page, table of contents, abstract and references)
- Topic should be the design of new delivery approaches or formulation strategies for any type(s) of biotherapeutics covered in this course.

Literature review presentation (10-15 min; individual): 20%

- Presentation: 15%
- Questions & Answers: 5%

Team Project Presentation (20-25 min; group): 15%

- Presentation: 10%
- Questions & Answers: 5%