

COURSE SYLLABUS-Fall 2020

CHE494 BIOPHARMACEUTICAL PROCESS DEVELOPMENT AND MANUFACTURING

1. Course Title

Prefix: CHE 494, Number: xx and Title: Biopharmaceutical Process Development and Manufacturing

2. Course Credit

3 Credit Hours

3. Placement in Curriculum

Elective course in chemical engineering.

4. Prerequisites

None

5. Course Professor and Teaching Assistant

Lead Professors

Name: Nandkishor K. Nere

Title: Adjunct Professor

Phone:

Email: nnere2@illinois.edu

Name: Meenesh R. Singh

Title: Assistant Professor

Phone: 312-413-7673

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Teaching Assistant

Name: TBD

Title:

Phone:

Email:

6. Lecture and Office Hours

Lecture Hours

Time- Tuesdays, 5:00 pm to 8:00 pm, with 30 mins break.

Lecture Type-Online Synchronous

Platform- Blackboard Collaborate Ultra or Zoom

Office Hours

Time- As per request

Meeting Type- Online Meetings

Platform: WebEx, Link: <https://uichicago.webex.com/meet/mrsingh>

7. Course Description

(From the course catalog)

8. Course Rationale

Biopharmaceutical process development and manufacturing (BPDM) is central and unique to the chemical engineering discipline. The core elements of BPDM are – 1) drug substance (active pharmaceutical ingredient) polymorph screening, process development and scale up and 2) drug product process development and scale up, with underlying safety and cleaning considerations in biopharmaceutical manufacturing. Some of the techniques covered in these elements of BPDM are also used in other process chemical and allied industries, namely, agrochemicals, polymers, fragrances, flavors, food additives, dyes and chemicals, ceramics, explosives and many more. The goal of chemical engineers in BPDM is to consistently achieve the desired quality with maximum yield of the final product in the most safe and efficient manner by developing robust drug substance and drug product processes. This course will teach fundamental concepts in BPDM, provide practical advice on the process development, optimization and scale-up using pertinent enabling tools and technologies.

9. Course Learning Objectives

Module-1: Introduction to Biopharmaceuticals Process Development and Manufacturing (2 lectures)

- Drug discovery-development-manufacturing cycle
- Dosage forms
- Introduction to combination products
- Role of chemical engineers and pharmaceutical scientists
- Analytical chemistry tools and technologies
 - Chemical and physical stability
 - Drug dissolution
- cGMP Considerations: SOPs, Documentation, Regulatory Filing
- Engineering challenges and opportunities

Module-2: Drug Substance (Active Pharmaceutical Ingredients)s Development (4 lectures)

- API-solid form screening and selection
- Essentials of small molecule API process development
 - Reaction engineering
 - Separations
 - Extraction
 - Distillation
 - Crystallization
 - Filtration, washing and drying
- Essentials of biologics process development
 - Bioreactor processing
 - Purifications
 - TFF
 - Chromatography
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- API Process Scale-up (Nandkishor Nere)

Module-3: Drug Product Development (4 lectures)

- Formulation screening and selection
- Essentials of small molecule drug product development
 - Blending
 - Direct compression
 - Roller compaction
 - Wet granulation
 - Hot melt extrusion
 - Milling
 - Tableting
 - Coating
- Essentials of biologics drug product development
 - Solutions-mixing, shear
 - Lyophilization
 - Freezing and thawing
 - Filling
- Drug Product Process Scale-up

Module-4: Enabling Technologies in Biopharmaceutical Industry (3 lectures)

- Continuous processing
- Applications of Predictive Modeling
 - Molecular modeling
 - Computational fluid dynamics
 - Discrete element methods
 - Fluid-structure interaction modeling

- Emerging technologies
 - Electrochemistry
 - Photo-chemistry
 - Biocatalysis
 - Mechanochemistry

Module-5: Biopharmaceutical Manufacturing (2 Lectures)

- Safety
- Cleaning
- Key considerations in the manufacturing of small molecules
- Key considerations in the manufacturing of biologics molecules
- Closing Summary

10. Materials

Required Text

There are no required text for this course

Recommended (Optional) Text

James D. Litster and Bryan Ennis. *The Science and Engineering of Granulation Processes*. Kluwer Press, 2004.

Doraiswami Ramkrishna. *Population Balances: Theory and Applications to Particulate Systems in Engineering*. Academic Press, 2000.

T. Allen. *Powder Sampling and Particle Size Measurement*. Elsevier, 2003

M.J. Rhodes. *Introduction to Particle Technology*. Wiley Publication, 2008

Allan S. Myerson. *Handbook of Industrial Crystallization*. Butterworth-Heinemann, 2011

D. J. am Ende and M. T. am Ende (Eds.), *Chemical Engineering in the Pharmaceutical Industry: Active Pharmaceutical Ingredients*, 2nd Edition, 2019, Hoboken, NJ, Wiley.

D. J. am Ende and M. T. am Ende (Eds.), *Chemical Engineering in the Pharmaceutical Industry: Drug Product Design, Development, and Modeling*, 2nd Editorial April 2019 (ISBN: 978-1-119-28550-2)

AAPS Advances in the Pharmaceutical Sciences Series: Development of Biopharmaceutical Drug-Device Products, Jameel, F., Skoug, J. Nesbitt, R. (Eds.) 2020), Springer Nature Switzerland AG

Other Resources

11. Course Outline

Weekly schedule of topics to be covered in lectures with tentative speakers are listed below

Week	Module	Topics to be covered	Textbook Chapters
Week 1	Module 1	Introduction to BPDM (NK Nere and Meenesh) -Discovery, Process, Drug delivery	D. J. am Ende and M. T. am Ende (Eds.), Chemical Engineering in the Pharmaceutical Industry: Active Pharmaceutical Ingredients, 2nd Edition, (pp. 847-860), Hoboken, NJ, Wiley.
Week 2	Module 1	Analytical Chemistry Tools and Technology (Steven Doherty)	References from Steve?
Week 3	Module 2	API-Solid Form Screening and Selection (Shuang)	Pertinent Publications (max 2-3)
Week 4	Module 2	Essentials of API Process Development (Nandkishor Nere, Meenesh Singh, Eric Sacia)-Overall process flow intro, Reactions and Extraction along with Scale-up	Pertinent Publications (max 2-3)
Week 5	Module 2	Distillation (30 min), Crystallization (90 min), Filtration, Washing and Drying (Jim Marek, Meenesh/Nandkishor/Manish/Moussa/Dan)	Pertinent Publications (max 2-3)
Week 6	Module 2	Essentials of Biologics Process Development (Ying Wang/Lei Cao)	Pertinent Publications (max 2-3)
Week 7	Module 3	Formulation Screening and Selection (Yi Shi/Jeff Zhang/)	Pertinent Publications (max 2-3)
Week 8	Module 3	Essentials of Drug Product Development (Blending, roller compaction, tabletting, coating, Bill Ketterhagen, Leo, Brendon, Dan Pohlman (Wet granulation, hot melt extrusion, Rachel Evans))	Pertinent Publications (max 2-3)
Week 9	Module 3	Essentials of Biologics Drug Product Development (Feroz Jameel-Formulation, Overall process, lyophilization)	AAPS Advances in the Pharmaceutical Sciences Series: Development of Biopharmaceutical Drug-Device Products, Jameel, F., Skoug, J. Nesbitt, R. (Eds.) 2020), Springer Nature Switzerland AG.
Week 10	Module 3		

		Freeze-Thawing, Pooling, and reconstitution Filling (Marina and Basma)	
Week 11	Module 4	Continuous Processing (Eric Moschetta, Moiz Diwan)	Pertinent Publications (max 2-3)
Week 12	Module 4	Applications of Predictive Modeling (Kushal Sinha and Bill Ketterhagen., Eric Murphy, Gaythri)	Pertinent Publications (max 2-3)
Week 13	Module 5	Emerging Technologies (Eric Moschetta, Kaid Harper, Manish)-Electrochemistry, Photochemistry, Biocatalysis, Allied separations, Green chemistry	Pertinent Publications (max 2-3)
Week 14	Module 5	Safety and Cleaning in Biopharmaceutical Manufacturing (Steve Richter, Jie Chen, Darren Coetze, Sligo)	Pertinent Publications (max 2-3)
Week 15	Module 5	Chemistry Manufacturing and Control (CMC) Regulatory filing and key Considerations in Manufacturing (Manish, Sherwin, Wenbin)	

Student assessment through two mini projects with lecture specific milestones:

Define and declare well in advance (Not later than 3rd week 10th week of the course

Give heads-up in the first lecture itself

Participation/Attendance

Active participation in lectures is recommended. Class participation has 10% weightage to overall grade evaluation.

Academic Honesty

Students in CHE 494 are continuing on a program of study to become chemical engineers. Engineers are expected to uphold a strict code of ethics in which they: (1) build their professional reputations on the merits of their services and (2) act in such a manner as to uphold and enhance the honor, integrity, and dignity of the engineering profession. In addition to these broad ethical guidelines, students in CHE 494 will be expected to be honest and refrain from cheating on exams, and homework assignments (you should not turn in a homework that you did not work yourself).

Students caught cheating will be prosecuted to the maximum extent possible under UIC guidelines. Personally, I take all accusations of academic dishonesty very seriously, and I am asking each you to report any incidents or suspected incidents of cheating to me directly. I will keep your identity confidential.

Accommodations

The University of Illinois at Chicago is committed to maintaining a barrier-free environment so that students with disabilities can fully access programs, courses, services, and activities at UIC. Students with disabilities who require accommodations for access to and/or participation in this course are welcome, but must be registered with the Disability Resource Center (DRC). You may contact DRC at 312-413-2183 (v) or 773-649-4535 (VP/Relay) and consult the following:

<http://drc.uic.edu/guide-to-accommodations>.

Course Communication Policy

Send email correspondence with subject “[CHE 494]”

Course Communication Guidelines (Netiquette)

Netiquette is a set of rules for behaving properly online. Much of our communication in this course will take place in the forums and through email. Here are some guidelines for online communication in this course:

- Be sensitive to different cultural and linguistic backgrounds, as well as different political and religious beliefs.
- Use good taste when composing your responses. Swearing and profanity should be avoided. Also consider that slang terms can be misunderstood or misinterpreted.
- Don't use all capital letters when composing your responses. This can be considered

“shouting” on the Internet and is regarded as impolite or aggressive. It can also be stressful on the eye when trying to read your message.

- Be respectful of others’ views and opinions. Avoid “flaming” (publicly attacking or insulting) others.
- Be careful when using acronyms. If you use an acronym it is best to spell out its meaning first, then put the acronym in parentheses afterward, for example: Frequently Asked Questions (FAQs). After that you can use the acronym freely throughout your message.
- Use good grammar and spelling, and avoid using text messaging shortcuts.
- In emails, always identify yourself and what class and section you are in. It is a good practice to put your course and section in the subject line. This helps your instructor identify course related emails.

12. Technology Requirements

Computer/Technology Requirements

Online students will need regular access to a personal computer that runs on a broadband Internet connection.

Blackboard Learning Management System

For all technical questions about Blackboard, email ACCC-Learning Technology Solutions at LTS@uic.edu

Web Conferences/Synchronous sessions

All lectures will be delivered synchronously and recorded for review. We will use Blackboard Collaborate Ultra for lecture- https://uic.blackboard.com/webapps/collab-ultra/tool/collabultra?course_id= 169486 1

13. Grading and Evaluation

Final Grade Calculation

Assessments	Date	Percentages
Module Assignments	Monthly	20%

Class Participation	Weekly	10%
Final Course Project	TBD	70%
Total Percentage For Course		100%

Assignments: Any assignment you turn in is to be a product of your own efforts and your own understanding. If you do not understand what you are writing – DON'T WRITE IT. Anyone who copies the solution from another student or a solution manual is guilty of academic dishonesty. Anyone suspected of copying may be given an announced quiz to determine if their work was their own. Even if you "worked with someone", you must do it yourself.

Grading

In determining the final course grade, the following scale is used:

>85% = A

75% - 85% = B

60% - 75% = C

< 60% = F

Late Work Policy

The only late work that will be considered are those instances where the student has communicated with their instructor regarding unavoidable circumstances, such as reporting an illness and submitting a doctor's note to their instructor. All other late work submission will not be graded.

Final Exams

Although the demands of some disciplines may require specific scheduling of end of term projects or final exams, in general, final examinations, if they are to be given, should only be administered during the sixteenth week of the semester (eighth week of the summer term). They may not be given earlier. The dates and times of the exams are scheduled by the Office of Classroom Scheduling and are arranged so that a student, ideally, will have no more than two exams in a day. Any student having more than two final examinations scheduled in one day is entitled to rescheduling. No formal instruction of any kind may be given during the final examination period. Faculty are expected to teach through the last week of the semester and should not administer major exams during the last two weeks of the term. Variance from these guidelines must meet approval from the unit /department head. For a schedule of exams and exam policies see:

http://www.uic.edu/depts/oar/current_students/calendars/final_exam_schedule.html

GRIEVANCE PROCEDURES

UIC is committed to the most fundamental principles of academic freedom, equality of opportunity, and human dignity involving students and employees. Freedom from discrimination is a foundation for all decision making at UIC. Students are encouraged to study the University's "[Nondiscrimination Statement](#)". Students are also urged to read the document "[Public Formal Grievance Procedures](#)". Information on these policies and procedures is available on the University web pages of the Office of Access and Equity: <http://oae.uic.edu/>.

14. Course Evaluation

Student evaluations of teaching play a fundamental role in improving course content, format, and delivery (teaching) at UIC. The Office for Faculty Affairs offers all Colleges and Departments the opportunity to participate in an online course evaluation system.

Students receive an email invitation in their 'uic.edu' inbox with the following title in the subject line: "UIC Student Evaluation of Teaching [Course Name] [Instructor Name] [Semester, Year]." The body of the email will reiterate the course name, instructor name, and semester. It will contain a link and a unique student password for the online evaluation for that course. Students will need an electronic device with Internet access to complete the evaluation online. **Submitted course evaluations cannot be removed from the system** so it is vital that students pay attention to the *instructor name* and *course name* when completing their evaluations. **Students must complete the online evaluations before 12 am on the first day of finals.** No exceptions are made if the evaluation is not submitted before 12 am on the first day of finals.

For more information about the program and timelines for when the system is open to students to complete the evaluations, please visit:

<https://faculty.uic.edu/development/teachingandlearning/evaluations/>

15. Course Topics

Modules	Title
Module 1	API Process Development and Scaleup
Module 2	Drug Product Development and Scaleup
Module 3	Enabling Technologies

16. UIC Resources

If you find yourself having difficulty with the course material or any other difficulties in your student life, don't hesitate to ask for help! Come to me, or if it is about an issue beyond this class, please contact your college advisors, or get help from any number of other support services on campus. You can get a referral to the right place, or help on the spot, from a concerned advisor in the Undergraduate Success Center (USC) at usc@uic.edu.

See also:

The Writing Center offers friendly and supportive tutors who can help you with reading and writing in any of your courses, not just English. Tutors are ready to help other writing as well, such as job applications, personal statements, and resumes. The tutor and you will work together to decide how to improve your writing. If you have not started your assignment, that is OK. A tutor can help you brainstorm or make an outline. Tutors understand that you might be using the Writing Center for the first time. They are ready to guide you through your first session. You can choose to work with a tutor in real time using chat and a white board, or submit up to 5 pages of text and receive written feedback within 48 hours. To schedule an appointment, visit <https://uic.mywconline.com/>. For more information, visit the Writing Center website at <https://writingcenter.uic.edu/>.

The Math and Science Learning Center, located in the Science and Engineering South Building (SES) at 845 W. Taylor St. 3rd Floor, Room 247, is a meeting place for students in Math, Biological Sciences, Chemistry, Earth and Environmental Sciences, and Physics. At the MSLC, students can meet with graduate teaching assistants for tutoring in 100-level courses, arrange informal group study sessions with other students, or meet up with friends to attend one of the workshops, seminars, or other activities sponsored by the SLC during the semester. Visit the website at <https://mslc.uic.edu/>, call 312-355-4900 or email at mslc@uic.edu.

The UIC Library

The library is located both on east and west campus, provides access to resources, study rooms, and research support both online via chat and in person. At Daley Library on the east side of campus, stop by the reference desk in the IDEA Commons, or make an appointment for research help on either side of campus. Learn more about library policies at <http://library.uic.edu/>. To find research materials in specific subject areas view the Research Guides at <http://researchguides.uic.edu/>.

The Academic Center for Excellence can help if you feel you need more individualized instruction in reading and/or writing, study skills, time management, etc. Phone: (312) 413-0031.

Counseling Services are available for all UIC students. You may seek free and confidential services from the Counseling Center www.counseling.uic.edu. The Counseling Center is located in the Student Services Building; you may contact them at (312) 996-3490. In addition to offering counseling services, the Counseling Center also operates the InTouch Crisis Hotline from 6:00 p.m.-10:30 p.m. They offer support and referrals to callers, as well as telephone crisis interventions; please call (312) 996-5535.

Campus Advocacy Network

Under the Title IX law you have the right to an education that is free from any form of gender-based violence and discrimination. Crimes of sexual assault, domestic violence, sexual harassment, and stalking are against the law and can be prevented. For more information or for confidential victim-services and advocacy contact UIC's Campus Advocacy Network at 312-413-1025 or visit <http://can.uic.edu/>. To make a report to UIC's Title IX office, email TitleIX@uic.edu or (312) 996-5657.

CAMPUS SECURITY

As a UIC student, you've chosen to live in one of the nation's largest cities. But, as at any university, crime is a reality. At UIC, we are strongly committed to our public safety programs, and we encourage students to be proactive in learning what programs and services are available in case of an emergency. You are DISCOURAGED from staying in university buildings alone, including lab rooms, after hours and are ENCOURAGED to use the POLICE/STUDENT patrol escort if you are uncomfortable traveling anywhere on campus. You may request an escort to accompany you to your campus destination on foot by calling 312-996-2830, and between 11:00 pm and 7:00 am you can dial the Red Car service (312-996-6800) if you are alone and need to leave the building. Through Red Car, the university has established a safe evening transportation service for university employees, students, visitors, and other authorized individuals. The car travels between university facilities within the following general boundaries: Clinton Street on the east; Western Avenue on the west; Jackson Boulevard on the north; and, 16th on the south. This service is available only to individuals possessing a valid UIC i-card. The i-card is required to ensure the safety of the driver and other passengers. Consult the following for more information: <http://www.uic.edu/uic/studentlife/campus/safety.shtml>

Also you can subscribe your cell phone to receive text message alerts. An immediate SMS text alert will be sent in case of a serious crime in progress, a weather emergency, or other urgent situation. (https://accountportal.uic.edu/auth/manage?dispatch=set_sms_panel). Finally, by dialing 5-5555 from a campus phone, you can summon Police or Fire for any on-campus emergency. You may also set up the complete number, 1-312-355-5555, on speed-dial on your cell phone. For more information contact:

<http://www.uic.edu/uic/studentlife/campus/emergency-information.shtml>

Emergency Response Recommendations

You may wish to include the following section on emergency response systems at UIC:

The emergency response guide can be found at the following website: <https://ready.uic.edu/>. Please review and acquaint yourself with the guide and recommendations for various emergency situations.