

PURDUE UNIVERSITY
REQUEST FOR ADDITION, EXPIRATION,
OR REVISION OF A GRADUATE COURSE
(50000-60000 LEVEL)

CHE 55100

201620 EFD 38-12

DEPARTMENT School of Chemical Engineering EFFECTIVE SESSION Spring 2013

INSTRUCTIONS: Please check the items below which describe the purpose of this request.

<input checked="" type="checkbox"/> 1. New course with supporting documents (complete proposal form)	<input type="checkbox"/> 7. Change in course attributes
<input type="checkbox"/> 2. Add existing course offered at another campus	<input type="checkbox"/> 8. Change in instructional hours
<input type="checkbox"/> 3. Expiration of a course	<input type="checkbox"/> 9. Change in course description
<input type="checkbox"/> 4. Change in course number	<input type="checkbox"/> 10. Change in course requisites/restrictions
<input type="checkbox"/> 5. Change in course title	<input type="checkbox"/> 11. Change in semesters offered
<input type="checkbox"/> 6. Change in course credit/type	<input type="checkbox"/> 12. Transfer from one department to another

<p>PROPOSED:</p> <p>Subject Abbreviation <u>CHE</u></p> <p>Course Number <u>55100</u></p> <p>Long Title <u>Principles of Pharmaceutical Engineering</u></p> <p>Short Title <u>Principles of Pharmaceutical Engr</u></p> <p><small>Abbreviated titles will be entered by the Office of the Registrar if omitted. (30 CHARACTERS ONLY)</small></p>	<p>EXISTING:</p> <p>Subject Abbreviation _____</p> <p>Course Number _____</p>	<p>TERMS OFFERED</p> <p>Check All That Apply:</p> <p><input checked="" type="checkbox"/> Fall <input type="checkbox"/> Spring <input type="checkbox"/> Summer</p> <p>CAMPUS(ES) INVOLVED</p> <p><input type="checkbox"/> Calumet <input type="checkbox"/> N. Central</p> <p><input type="checkbox"/> Fort Wayne <input type="checkbox"/> Tech. Statewide</p> <p><input type="checkbox"/> Indianapolis <input checked="" type="checkbox"/> W. Lafayette</p>
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<p>CREDIT TYPE</p> <p>1. Fixed Credit: Cr. Hrs. <u>3</u></p> <p>2. Variable Credit Range:</p> <p>Minimum Cr. Hrs. _____</p> <p>(Check One) To <input type="checkbox"/> Or <input type="checkbox"/></p> <p>Maximum Cr. Hrs. _____</p> <p>3. Equivalent Credit: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p> <p>4. Thesis Credit: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p>	<p>COURSE ATTRIBUTES: Check All That Apply</p> <p>1. Pass/Not Pass Only <input type="checkbox"/></p> <p>2. Satisfactory/Unsatisfactory Only <input type="checkbox"/></p> <p>3. Repeatable <input type="checkbox"/></p> <p>Maximum Repeatable Credit: _____</p> <p>4. Credit by Examination <input type="checkbox"/></p> <p>5. Special Fees <input type="checkbox"/></p> <p>6. Registration Approval Type: Department <input type="checkbox"/> Instructor <input type="checkbox"/></p> <p>7. Variable Title <input type="checkbox"/></p> <p>8. Honors <input type="checkbox"/></p> <p>9. Full Time Privilege <input type="checkbox"/></p> <p>10. Off Campus Experience <input type="checkbox"/></p>
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Schedule Type	Minutes Per Mtg	Meetings Per Week	Weeks Offered	% of Credit Allocated
Lecture	50	3	16	100
Recitation				
Presentation				
Laboratory				
Lab Prep				
Studio				
Distance				
Clinic				
Experiential				
Research				
Ind. Study				
Pract/Obsev				

Cross-Listed Courses

RECEIVED

SEP 18 2015

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COURSE DESCRIPTION (INCLUDE REQUISITES/RESTRICTIONS):

Concurrent Prerequisites: BIOL 23000

Pre-requisites: CHM 26100 and CHM 26300

This course is designed to provide engineering, science and pharmacy students with an understanding of the structure, economic and regulatory context, product discovery and development pipeline dynamics, intellectual property considerations and common manufacturing technology of the global pharmaceutical industry. Professor Reklaitis.

Calumet Department Head _____ Date _____	Calumet School Dean _____ Date _____	Calumet Undergrad Curriculum Committee _____ Date _____
Fort Wayne Department Head _____ Date _____	Fort Wayne School Dean _____ Date _____	Fort Wayne Chancellor _____ Date _____
Indianapolis Department Head _____ Date _____	Indianapolis School Dean _____ Date _____	Undergrad Curriculum Committee _____ Date _____
North Central Department Head _____ Date _____	North Central School Dean _____ Date _____	APPROVED 9/17/15
West Lafayette Department Head <u>A. Varma</u> 7/11/2012	West Lafayette College/School Dean <u>Michael Brown</u> 10/2/13	Graduate Council Secretary <u>Jane L. Saura</u> 9/18/15
Graduate Area Committee Convener _____ Date _____	Graduate Dean _____ Date _____	West Lafayette Registrar _____ 10/11/15

OFFICE OF THE REGISTRAR

(Grad Form 40G [Excel format] - Does not include the Graduate Council's required supporting document. See pdf version of Form 40G)

Ujs 9/30/15 38-12

To: Faculty of the College of Engineering

From: Faculty of the School of Chemical Engineering

RE: New Graduate Course, CHE 55100, Principles of Pharmaceutical Engineering

The faculty of the School of Chemical Engineering has approved the following new course. This action is now submitted to the Engineering Faculty with a recommendation for approval.

CHE 55100: Principles of Pharmaceutical Engineering

Sem 1, cr. 3, LEC 3

Concurrent Prerequisites: BIOL 23000

Pre-requisites: CHM 26100 and CHM 26300

Description: This course is designed to provide engineering, science and pharmacy students with an understanding of the structure, economic and regulatory context, product discovery and development pipeline dynamics, intellectual property considerations and common manufacturing technology of the global pharmaceutical industry.

Reason: The course has been taught as follows:

Semester Offered	Course Number	Title	# of Students Enrolled
Spring 2005	CHE 597E	Design and Analysis of ChE Experiments	18
Spring 2006	CHE 597E	Design and Analysis of ChE Experiments	14
Spring 2007	CHE 597E	Design and Analysis of ChE Experiments	20
Fall 2007	CHE 597E	Principles of Pharmaceutical Engineering	31
Fall 2008	CHE 59700	Principles of Pharmaceutical Engineering	23
Fall 2009	CHE 59700	Principles of Pharmaceutical Engineering	35
Fall 2010	CHE 59700	Principles of Pharmaceutical Engineering	32
Fall 2011	CHE 59700	Principles of Pharmaceutical Engineering	36

APPROVED FOR THE FACULTY
OF THE SCHOOLS OF ENGINEERING
BY THE ENGINEERING
CURRICULUM COMMITTEE

ECC Minutes 9-20-13

Date _____

Chairman ECC 



A. Varma, Head
School of Chemical Engineering

Date: 7/1/12

Supporting Documentation - ChE 55100 Principles of Pharmaceutical Engineering

Level: dual level

Course Instructor: G.V. Reklaitis

Textbook: Notes, papers and documents from variety of sources posted on Blackboard

Course Operation: The course involves lectures, discussions and readings on a range of pharmaceutical industry topics, including the design and manufacture of active pharmaceutical ingredients and drug products, the intellectual property and global economic considerations as well as the regulations, policies and procedures under which the life cycle of a pharmaceutical product must be managed. Some of the lectures are given by experts in patent law, regulatory affairs as well as selected manufacturing technologies, such as sterile operations. Students work in two member teams to develop reports on specific topics such as (1) profiles of different categories of companies, innovators, generics, biotechs and contract manufacturers and the status of their product pipelines, (2) interpretation of the patents, associated with selected products, to develop feasible processes for the actives and product, (3) analysis of batch process parameters under different demand and cost conditions. Each team is assigned five such projects during the course of the semester, each project requiring a written report as well as preparation and delivery of an in-class presentation. The course grade is also based in part on a written mid-term and a final exam examination.

Topics covered in previous semesters include:

- Overview of Pharmaceutical Industry: companies, basic economics, market trends
- Product families & characteristics
- Product discovery & development pipeline: costs & risks
- FDA organization & functions
- FDA actions & consequences
- Drug approval process: innovators & generics
- Intellectual property & strategy
- Basic Biopharmaceutics
- Pharmaceutical dosage forms
- Drug process development
- Batch processing fundamentals
- Drug Manufacturing
- Current Good Manufacturing Practice (cGMP)
- Validation: process, equipment, methods
- Solids processing
- API Processing
- Parenterals/sterile processing

- Biological products
- Process analytical technology
- On-line sensing & unit level control
- Integrated Process Operations
- Quality by Design and design space concepts

Course Objectives

To help the student to develop an understanding of the structure, economic & regulatory context, product pipeline dynamics & manufacturing technology of the Pharmaceutical Industry. Future trends and needs for pharmaceutical products worldwide and impact on overall healthcare costs.

Course Outcomes

Students will develop

- A Big picture” view of the Pharmaceutical Industry
 - Its structure & key players
 - Economic & Regulatory context
 - International trends and markets
 - Product pipeline dynamics
 - Current manufacturing technology, strengths and limitations
- A working vocabulary of domain concepts
- Appreciation of technical challenges & opportunities over the life cycle of a pharmaceutical product.
- Appreciation of the important role of intellectual property law and the strategies used in maintaining and challenging product patents

Students will enhance their skills in critical review of topics involving the interplay of technology and economics and in succinctly reporting the most important conclusions in written and oral form.

Students will have acquired the technical and economic context for more detailed follow-up courses in ChE, ME and IPPH.

Assessment Methods

Course outcomes are assessed through written project reports, oral presentation of project key findings, degree of engagement in class discussions, as well as written mid term and final examination