Office of the Registrar FORM 40G REV, 4/10

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

CHE 55300

DEPARTMENT School of Chemical Engin	pering	EFFECTIVE SESSION.	Spring 2013 20	1620	39-12
STRUCTIONS: Please check the items below wi			Vital Inches		
1. New course with supporting 2. Add existing course offered 3. Expiration of a course 4. Change in course number 5. Change in course title 6. Change in course creditly;	at another campus	posal form)	9. Change in col	tructional hours urse description urse requisites/restrictions	
PROPOSED;	EXISTING:			TERMS OFFERED	
Subject Abbreviation CHE Course Number 55300	Subject Abbreviation Course Number		Fal Co	Check Af That Apply: Spring Summer MPUS(ES) INVOLVED N. Central	
Dong Title Pharmaceutical Process, December 1889 [Pharm Process Develop & De			Cont Ed Ft Wayne Indianapol	The state of the s	
Abbreviated tile will be entered by the Office of		ERS ONLY)			
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tesearch nd. Study Pract/Observ				SEP	1.8 201
Concurrent Prerequisites: CHE 34800 ar Pre-requisites: CHE 30600 and CHE 378 This course introduces the engineering or synthetic organic chemistry methods to a industry will be reviewed, including batch separation systems. Both dedicated and will be covered. Professor Rel	nethodologies involved in n industrial process. The reaction, solid-liquid seg mulit-product production	e basic features of comp peration, crystallization,	mon unit operations underlying, mixing, batch	sed in the phamaceutical distillation and other	nthentic
Calumet Department Head Date	Calumet School Dean	Date	Calumet Undergrad Cu	riculm Committee	Date
Fort Wayne Department Head Date	Fort Wayne School Dean	Date	Fort Wayne Chancellor		Date
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Forth Central Department Head Date	North Central School Dean	Date Date	Date Approved by Grad	Juste Council	
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(Grad Form 40G [Excel format] - Does no	ot include the Graduate	Council's required support	orting document. See	pdf version of Form 40G)

Uje 9/30/15 39-12

To: Faculty of the College of Engineering

From: Faculty of the School of Chemical Engineering

RE: New Graduate Course, CHE 55300, Pharmaceutical Process, Development, and Design

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 55300, Pharmaceutical Process, Development, and Design

Sem 2, cr. 3, LEC 3

Concurrent Prerequisites: CHE 34800 and CHE 45600

Pre-requisites: CHE 30600 and CHE 37800

Description: This course introduces the engineering methodologies involved in translating a laboratory recipe for a drug compound produced via synthetic organic chemistry methods to an industrial process. The basic features of common unit operations used in the pharmaceutical industry will reviewed, including batch reaction, solid-liquid separation, crystallization, drying, mixing, batch distillation and other separation systems. Both dedicated and multi-product production system design and batch and semi-continuous operating modes will be covered.

Reason:

The course has been taught as Pharmaceutical Process, Development, and Design, CHE 597D in the fall 2005 semester with 24 students, the fall 2006 semester with 33 students, and as Pharmaceutical Process, Development, and Design, CHE 59700 in the spring 2008 semester with 4 students, the spring 2009 semester with 15 students, spring 2010 semester with 8 students, the spring 2011 semester with 22 students, and the spring 2012 semester with 9 students.

> AVarmony. A. Varma, Head

School of Chemical Engineering

Date: 7/1/12

Supporting Documentation - ChE 55300, Pharmaceutical Process Development and Design

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 issues related to batch process design and operations. The models and experimental data required to predict, optimize and scale-up the main unit operations are covered. Professional engineering software is used to carry out case studies on specific unit operations as well as to design and schedule integrated process trains. Students work in two member teams to carry out case studies involving modeling and optimization of specific unit operations. Additional case studies involve design and operations of integrated process train. These projects require 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 project report.

Topics covered in previous semesters include:

- Overview of Pharmaceutical Process Development & Design
- Status of relevant engineering software
- Characteristics of Batch operations
- Optimization of Integrated Process Trains
- Batch reactor design & operation
- Reaction calorimetry & safety
- Mixing & scale-up
- Solid-liquid separations
- Crystallization
- Drying
- Batch distillation
- Liquid-liquid separations
- Impact of API on solid dosage form design
- Current Good Manufacturing Practice
- Process analytical technology
- Batch process control
- Production planning & scheduling
- Industrial case studies

Course Objectives

To introduce the student to the engineering decision processes involved in translating a laboratory recipe for a synthetic organic pharmaceutical substance to an integrated batch process

for its manufacture. The basics of the main unit operations are covered, including engineering models for predictive design and strategies for integrated process design, control and operation.

Course Outcomes

Students will develop the following knowledge and skills

- The thermodynamic, reaction and transport phenomena arising in the typical batch unit operations used in the pharma and specialty chemicals industries, including batch reaction, crystallization, solid-liquid separation, mixing, distillation, drying and liquid-liquid extraction.
- The use experimental data and relevant models to design and predict the performance of these units.
- Use of engineering software to conduct studies of these operations and interpret and critically assess the results such software produces.
- Understand different modes of operation for batch processes and their scheduling
- Understand aspects of the design of batch process in which the set of batch operations are integrated
- Use of planning/scheduling software to conduct design and operational studies of integrated process.

Students will enhance their skills in succinctly reporting the most important conclusions of their team projects in written and oral form.

Assessment Methods

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