



FACULTY SENATE

November 12, 2014

MEMORANDUM

TO: Dr. Mark A. Hussey, Interim President

FROM: Jim Woodsley, Speaker

SUBJECT: Graduate Council (FS.32.60)

The Faculty Senate submits for your approval the item from the Graduate Council at its regular meeting on November 10, 2014. Attached is a copy of the material sent to our Senators.

Curriculum Change Request

Certificate in Engineering Therapeutics Manufacturing
Certificate in Quality Engineering for Regulated Medical Technologies

cc: Karan Watson
Christine Stanley
Michael Benedik
Sandra Williams
M. Katherine Banks

FACULTY SENATE AGENDA ITEM REVIEW

This item has been reviewed by the Office of the Provost (OP). Below are recommended action(s): RE: FS.32.60

<i>Presidential Action:</i> <input checked="" type="checkbox"/> Recommend Approval <input type="checkbox"/> Review Only	<i>OP Recommended Action</i> <input type="checkbox"/> Hold for Further Review <input type="checkbox"/> Hold Released <input type="checkbox"/> System Review/Submission <input type="checkbox"/> BOR Approval <input type="checkbox"/> THECB Approval/Notification <input type="checkbox"/> SACSCOC Approval/Notification
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Approved: _____ Reviewed: _____

Mark A. Hussey
 Mark A. Hussey
 Date: 12/18/14

Curriculum Changes

Texas A&M University
Request for a Change in Curriculum
Undergraduate ♦ Graduate ♦ Professional

RECEIVED

AUG 28 2014

ESSAP

1. Program request type: Undergraduate Graduate First Professional (ex. DVM, JD, MD, etc.)
2. Request change for: Degree Program Minor Certificate
3. Request submitted by (Department or Program Name): Biomedical Engineering
4. Program Designation and Name (e.g., B.A. in History, Minor in History, Certificate in European Union): Certificate in Engineering Therapeutics Manufacturing
5. Brief description of change: Make adjustments and additions to the courses that can satisfy this requirement.

RECEIVED

SEP 12 2014

GRADUATE STUDIES

6. Rationale for change: There are additional courses that have content relevant to this certificate. In addition, we have added several graduate level courses that will allow masters and doctoral students to pursue this certificate as well.

Use the checkboxes below to make sure that all information is included.

7. a. Proposed curriculum attached. Yes No
- b. Current catalog curriculum with handwritten edits attached. Yes No
- c. Current Howdy degree evaluation with handwritten edits attached. Yes No
- Please make sure the attached proposed curriculum, catalog and Howdy degree evaluation match.*
8. a. Will degree program hours change (increase/decrease) due to the proposed curriculum changes? Yes No
- b. If yes, degree program hours will change from: _____ to: _____
- c. If yes, is the Texas Higher Education Coordinating Board form attached? Yes No
- <http://www.theceb.state.tx.us/index.cfm?objectid=A0F9F7FA-9A92-4F11-2756AD3BBFF01D60>
9. If proposed changes affect other unit(s), are letters of support attached? Yes No

IMPORTANT NOTE: Curriculum changes submitted through the approval process and fully approved by February (December-UCC/GC, January-Faculty Senate, February-President) will be effective in the next academic year. Changes requiring approval beyond the University should complete the internal approval process early in the fall semester whenever possible in order to ensure timely implementation.

Approval recommended by:

<p>Gerard L. Cote <u><i>Gerard L. Cote</i></u> <u>8/28/14</u> Department Head or Program Chair (Type Name & Sign) Date</p> <p><u><i>[Signature]</i></u> <u>9/12/14</u> Chair, College Review Committee Date</p>	<p><u><i>[Signature]</i></u> <u>9/12/14</u> Dean of College Date</p> <p><u><i>[Signature]</i></u> <u>10/20/14</u> Chair, GC or UCC Date</p>
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New Program Request Form for Certificate Programs, Bachelor's and Master's Degrees

Directions: An institution shall use this form to propose a new bachelor's or master's degree program. In completing the form, the institution should refer to the document *Standards for Bachelor's and Master's Programs*, which prescribes specific requirements for new degree programs. **Note:** This form requires signatures of (1) the Chief Executive Officer, certifying adequacy of funding for the new program; (2) a member of the Board of Regents (or designee), certifying Board approval, and (3) if applicable, a member of the Board of Regents or (designee), certifying that criteria have been met for staff-level approval. **NOTE:** Preliminary authority is required for all engineering programs. An institution that does not have preliminary authority for a proposed engineering program shall submit a separate request for preliminary authority prior to submitting the degree program request form. That request shall address criteria set in Coordinating Board rules Section 5.24 (a).

Administrative Information

1. Institution: Texas A&M University

2. Program Name – Show how the program would appear on the Coordinating Board's program inventory (e.g., *Bachelor of Business Administration degree with a major in Accounting*):

Engineering Therapeutics Manufacturing Certificate

3. Proposed CIP Code: 14.0101.0006

4. Brief Program Description – Describe the program and the educational objectives:

Engineering Therapeutics Manufacturing Certificate is intended to meet the requirements of industry by educating engineering BS graduates how to economically, ecologically, and safely design and operate equipment used for the production and separation of biological materials. By the end of the certificate program, students will be able to: (1) Understand the processing of biological materials; (2) Analyze functions and properties of biological materials; (3) Understand the impact of the use/misuse of biological materials; (4) Understand the life cycle and evolution of biological materials; and (5) Design, operate and optimize biological process units.

Number of Semester Credit Hours Required **12 hours**

5. Administrative Unit – Identify where the program would fit within the organizational structure of the university (e.g., *The Department of Electrical Engineering within the College of Engineering*):

College of Engineering, NCTM

6. Proposed Implementation Date – Report the first semester and year that students would enter the program:

Fall semester of Academic Year 2013

7. Contact Person – Provide contact information for the person who can answer specific questions about the program:

Name: Larissa Pchenitchnaia

Title: Senior Project Specialist

E-mail: larissap@tamu.edu

Phone: 979 8455855

~~MAITTA~~ Michael V. Pishko
Professor
bmen@tamu.edu
979-845-2312

Program Information

I. Need

Note: Complete I.A and I.B only if preliminary authority for the program was granted more than four years ago. This includes programs for which the institution was granted broad preliminary authority for the discipline.

A. Job Market Need – Provide short- and long-term evidence of the need for graduates in the job market.

Because of its favorable business and regulatory environments, world-class biomedical R&D, presence of premier universities, access to input materials and availability of industrial processes, Texas is poised to experience extensive growth in biotechnology jobs. The Texas Workforce Commission's Labor Market & Career Information Department reports that, of all Texas manufacturing industries, pharmaceutical and medicine manufacturing is expected to undergo the greatest increase in growth – 23 percent – during this decade. In order to meet the needs of this potential growth, Texas must respond to industry demands for a workforce that is able to keep pace with emerging technologies. Nationally, Texas ranks 3rd in bioscience R&D expenditures, which have increased by 23 percent since 2004, to \$2.45 billion in 2008. Yet Texas only employs 3.5 percent of the nation's therapeutics manufacturing workforce, proof of a significant gap in our commercialization efforts. Because early research is not transitioned into development, production and commercialization, Texas is missing an opportunity to build a large commercial therapeutics manufacturing base and suffering the economic consequences thereof.

In Texas, there is a gap in workforce development in the scientific and regulatory knowledge and advanced technologies manufacturing expertise that is required to make a science lab discovery into a commercialized drug or device. Because Texas has not enriched its talent pool with these skilled workers, all too often the initial discoveries of Texas researchers are either licensed to companies out-of-state, or the Texas firm relocates altogether. To address this critical gap in our state's workforce, this proposal for Engineering Therapeutics Manufacturing Certificate is being submitted.

B. Student Demand – Provide short- and long-term evidence of demand for the program.

Industry and government agencies will benefit from the proposed Engineering Therapeutics Manufacturing Certificate by being able to hire graduating engineers who can fit more easily and readily into biotech and pharmaceutical companies in Texas and the U.S. and who have the knowledge and skills to enable pharmaceutical and biotechnology firms that are commercializing new products and services in Texas and the U.S. to be competitive. These graduates will be more valuable to employers; therefore, the proposed certificate program will add value to industry.

Engineering graduates will benefit from the proposed Engineering Therapeutics Manufacturing Certificate by being able to work more effectively in biotech and pharmaceutical companies immediately after graduation. This program will increase employment prospects for engineering students.

- C. Enrollment Projections – Use this table to show the estimated cumulative headcount and full-time student equivalent (FTSE) enrollment for the first five years of the program. *(Include majors only and consider attrition and graduation.)*

YEAR	1	2	3	4	5
Headcount	20	25	30	35	40
FTSE					

II. Quality

- A. Certificate and Degree Requirements – Use this table to show the certificate and degree requirements of the program. *(Modify the table as needed; if necessary, replicate the table for more than one option.)*

Category	Semester Credit Hours
General Education Core Curriculum <i>(bachelor's degree only)</i>	
Required Courses	63
Prescribed Electives	69
Free Electives	0
Other <i>(Specify, e.g., internships, clinical work)</i>	(if not included above)
TOTAL	12

Corrected
Version



Engineering Therapeutics Manufacturing Worksheet

Student Name: _____ Date: _____ UIN: _____

Required Courses: (Choose One)

X	Course Number	Course Name	Semester Taken	Grade Received
	BAEN 302	Biological and Ag Engineering Fundamental II (OR equivalent)		
	BAEN 601	Advanced Agriculture Systems Analysis		
	CHEN 382	Bioprocess Engineering		
	CHEN 651	Biochemical Engineering		
	ISEN 360	Lean Thinking and Lean Engineering in Process Industries		
	ISEN 645	Lean Thinking and Lean Manufacturing		
	VTPP 435	Physiology for Biomedical Engineers II		

Prescribed Elective Courses: (Choose Three)

X	Course Number	Course Name	Semester Taken	Grade Received
	BAEN 471	Bioreactor Engineering		
	BAEN 479	Biological and Agricultural Engineering Design I		
	BAEN 489	Introduction to Separations		
	BAEN 631	Bioprocesses and Separations in Biotechnology		
	BAEN 653	Bioreactor Design		
	BMEN 430	Medical Device Regulation		
	BMEN 440	Design of Medical Devices		
	BMEN 486	Biomedical Nanotechnology		
	BMEN 487	Drug Delivery		
	BMEN 630	Medical Device Regulation		
	BMEN 640	Design of Medical Devices		
	BMEN 686	Biomedical Nanotechnology		
	BMEN 687	Drug Delivery		
	CHEN 440	Introduction to Transport Phenomena		
	CHEN 463	Systems Biology		
	CHEN 471	Introduction to Biochemical Engineering		
	CHEN 489	Bioprocess Control		
	CHEN 489	Bioreactor Design		
	CHEN 489	Introduction to Bioseparation		
	CHEN 489	Safety in Pharmaceutical and Biotechnology Industries		
	CHEN 489	Designing for Flexibility		
	CHEN 614	Advanced Transport Phenomena I		
	CHEN 624	Chemical Engineering Kinetics and Reactor Design		
	CHEN 629	Transport Phenomena		
	CHEN 631	Process Dynamics and Advanced Process Control		
	CHEN 651	Biochemical Engineering		
	CHEN 655	Process Safety Engineering		
	CHEN 663	Systems Biology		
	ISEN 303	Engineering Economic Analysis		
	ISEN 613	Engineering Data Analysis		

Mark-up

(change approved 7/18/13)

Engineering Therapeutics Manufacturing Certificate Worksheet

(Please type all information. Handwritten worksheets may not be accepted.)

Student Name: _____ Date: _____ UIN: _____
Email: _____

To earn the Therapeutics Manufacturing Certificate, a student must complete a minimum of 12 semester credit hours selected from the list below:

Required Courses (2)* 1 Semester Taken Grade Received

ISEN 360* - Lean Thinking and Lean Engineering in Process Industries _____

Choose One of the Following:

ISEN 645 - Lean Thinking & Lean Manufacturing

BAEN 302 Biological and Ag Engineering Fundamentals II _____

BAEN 601 - Adv. Ag. Systems Analysis _____

CHEN 382 Bioprocess Engineering _____

CHEN 651 - Biochemical ENGR _____

BMEN 282 - Engineering Biology VTPP 435 - Physiology for BMEN _____

Prescribed Elective Approved Additional Courses (Choose 2): 3

BMEN 430: Medical Device Regulation ? BMEN 630 _____

BMEN 440: Design of Medical Devices ? BMEN 640 _____

BMEN 486: Biomedical Nanotechnology ? BMEN 686 _____

BMEN 489: Drug Delivery ? BMEN 687 _____

CHEN 463: Systems Biology ? CHEN 663 _____

CHEN 471/BAEN 471: Introduction to Biochemical Engineering _____

CHEN 489: Safety in Pharmaceutical and Biotechnology Industries _____

ISEN 303: Engineering Economic Analysis _____

CHEN 489/BAEN 489: Introduction to Bioseparations _____

CHEN 489/BAEN 489: Bioreactor Design ? BAEN 653 _____

CHEN 489: Bioprocess Control _____

CHEN 489: Designing for Flexibility _____

BAEN 471 - Bioreactor ENGR

*Note: CHEM 222 Organic and Biological Chemistry/or CHEM 227 is a prerequisite for BAEN 302, CHEN 382 and BMEN 282.

Notes: This form will be verified and approval given upon verification of requirements by the Program Coordinator.

For Engineering Therapeutics Manufacturing Administrators: Verified by:

*New Courses

CHEN 440 - Intro to Transport Phenomena
BAEN 479 - BAEN Design I
BAEN 489 - Intro to Separations
BAEN 631 - Bioprocesses & Separations
CHEN 489 - Safety in Pharm. & Biotech.

CHEN 614 - Advanced Transport Phenomena
CHEN 624 - CHEN Kinetics & Reactor Design
CHEN 629 - Transport Phenomena
CHEN 631 - Process Dynamics & Control

CHEN 651 - Biochem. ENGR
ISEN 613 - ENGR Data Analysis
CHEN 663 - Systems Biol

(original proposal (FYI only))

- B. **Curriculum** – Use these tables to identify the required courses and prescribed electives of the program, and curriculum as it will appear in the undergraduate and graduate catalog. Note with an asterisk (*) courses that would be added if the program is approved. (Add and delete rows as needed. If applicable, replicate the tables for different tracks/options as shown in the undergraduate catalog.)

Prefix and Number	Required Courses	SCH
BAEN 302	Biological and Ag Engineering Fundamentals II	3
	OR	
CHEN 382	Bioprocess Engineering	3
	OR	
BMEN 282	Engineering Biology	3
ISEN 360	Lean Thinking and Lean Engineering in Process Industries	3

Prefix and Number	Prescribed Elective Courses. Choose 2 courses	SCH
CHEN 440	Introduction to Transport Phenomena	3
CHEN 463	Systems Biology	3
CHEN 471/BAEN 471	Introduction to Biochemical Engineering	3
CHEN 489	Safety in Pharmaceutical and Biotechnology Industries	3
ISEN 303	Engineering Economic Analysis	3
CHEN 489/BAEN 489	Introduction to Bioseparations	3
CHEN 489/BAEN 489	Bioreactor Design	3
CHEN 489	Bioprocess Control	3
CHEN 489	Designing for Flexibility	3

	TOTAL SCH	12
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C. **Faculty** – Use these tables to provide information about **Core** and **Support** faculty. Add an asterisk (*) before the name of the individual who will have direct administrative responsibilities for the program. (*Add and delete rows as needed.*)

Name of Core Faculty and Faculty Rank	Highest Degree and Awarding Institution	Courses Assigned in Program	% Time Assigned To Program
*Pishko, M., Professor	PhD in Chemical Engineering from University of Texas - Austin	CHEN 489/BAEN 489 BMEN 487/687	15%
Nikolov, Z., Professor	PhD in Chemical Engineering from Iowa State University	CHEN 489/BAEN 489	15%

Name of Support Faculty and Faculty Rank	Highest Degree and Awarding Institution	Courses Assigned in Program	% Time Assigned To Program
El-Halwagi, M., Professor	PhD in Chemical Engineering from University of California – Los Angeles	CHEN 489	15%
Mannan, S., Professor	PhD in Chemical Engineering from University of Oklahoma	CHEN 489	15%
Jayaraman, A., Associate Professor	PhD in Biochemical Engineering from University of California – Irvine	CHEN 489/BAEN 489	15%
Marty Wortman, Professor	PhD in Industrial Engineering from Virginia Polytechnic Institute and State University	ISEN 360	15%
Karthikeyan, R., Professor	PhD in Biological and Agricultural Engineering from Kansas State University	CHEN 489/BAEN 489	15%

- D. **Students** – Describe general recruitment efforts and admission requirements. In accordance with the institution's Uniform Recruitment and Retention Strategy, describe plans to recruit, retain, and graduate students from underrepresented groups for the program.

This program is open to science and engineering undergraduate students enrolled at TAMU. Interested students should consult with their academic advisors. One section of each course (30 students) will be offered at the beginning of the program. These sections will be assessed, and the number of sections available will then be increased. National Center for Therapeutics Manufacturing will administer the program and manage records for those participating in the certificate program. NCTM faculty and program coordinator will serve as advisors to students and will approve all co-curricular activities. A program coordinator will be responsible for communicating with the registrar's office when a student has successfully completed the certificate requirements.

- E. **Library** – Provide the library director's assessment of library resources necessary for the program. Describe plans to build the library holdings to support the program.

Current library holdings are sufficient.

- F. **Facilities and Equipment** – Describe the availability and adequacy of facilities and equipment to support the program. Describe plans for facility and equipment improvements/additions.

No new facilities or equipment are required.

- G. **Accreditation** – If the discipline has a national accrediting body, describe plans to obtain accreditation or provide a rationale for not pursuing accreditation.

Dwight Look College of Engineering courses are accredited by ABET., Inc. Engineering Therapeutics Manufacturing Certificate will be fully compatible with engineering program accreditations.

- H. **Evaluation** – Describe the evaluation process that will be used to assess the quality and effectiveness of the new degree program.

Learning outcomes based assessment is required for accreditation of engineering courses and programs. The program will address this requirement through the use of direct measures (course exams) and indirect measures (exit student surveys and intern surveys). Assessment results will be reviewed every semester by our Certificate Program Committee.

III. Costs and Funding

Five-Year Costs and Funding Sources - Use this table to show five-year costs and sources of funding for the program.

Five-Year Costs		Five-Year Funding	
Personnel ¹	\$0	Reallocated Funds	\$0
Facilities and Equipment	\$0	Anticipated New Formula Funding ³	\$0
Library, Supplies, and Materials	\$0	Special Item Funding	\$0
Other ²	\$0	Other ⁴	\$0
Total Costs	\$0	Total Funding	\$0

1. Report costs for new faculty hires, graduate assistants, and technical support personnel. For new faculty, prorate individual salaries as a percentage of the time assigned to the program. If existing faculty will contribute to program, include costs necessary to maintain existing programs (e.g., cost of adjunct to cover courses previously taught by faculty who would teach in new program).
2. Specify other costs here (e.g., administrative costs, travel).
3. Indicate formula funding for students new to the institution because of the program; formula funding should be included only for years three through five of the program and should reflect enrollment projections for years three through five.
4. Report other sources of funding here. In-hand grants, "likely" future grants, and designated tuition and fees can be included.

Signature Page

1. Adequacy of Funding – The chief executive officer shall sign the following statement:

I certify that the institution has adequate funds to cover the costs of the new program. Furthermore, the new program will not reduce the effectiveness or quality of existing programs at the institution.

Chief Executive Officer

Date

2. Board of Regents or Designee Approval – A member of the Board of Regents or designee shall sign the following statement:

On behalf of the Board of Regents, I approve the program.

Board of Regents (Designee)

Date of Approval

3. Board of Regents Certification of Criteria for Commissioner of Assistant Commissioner
Approval – For a program to be approved by the Commissioner or
the Assistant Commissioner for Academic Affairs and Research, the Board of
Regents or designee must certify that the new program meets the eight criteria under
TAC Section 5.50 (b): The criteria stipulate that the program shall:

- (1) be within the institution's current Table of Programs;
- (2) have a curriculum, faculty, resources, support services, and other components of a degree program that are comparable to those of high quality programs in the same or similar disciplines at other institutions;
- (3) have sufficient clinical or in-service sites, if applicable, to support the program;
- (4) be consistent with the standards of the Commission of Colleges of the Southern Association of Colleges and Schools and, if applicable, with the standards or discipline-specific accrediting agencies and licensing agencies;
- (5) attract students on a long-term basis and produce graduates who would have opportunities for employment; or the program is appropriate for the development of a well-rounded array of basic baccalaureate degree programs at the institution;
- (6) not unnecessarily duplicate existing programs at other institutions;
- (7) not be dependent on future Special Item funding
- (8) have new five-year costs that would not exceed \$2 million.

On behalf of the Board of Regents, I certify that the new program meets the criteria specified under TAC Section 5.50 (b).

Board of Regents (Designee)

Date