

TO: The Engineering Faculty

FROM: The Office of Professional Practice and the William D. Young Institute for Advanced Manufacturing of Pharmaceuticals

RE: New Engineering Certificate

The Office of Professional Practice and the William D. Young Institute for Advanced Manufacturing of Pharmaceuticals have approved the following new Certificate from the College of Engineering. This action is now submitted to the Engineering Faculty with a recommendation for approval.

TITLE:

Undergraduate Certificate in Pharmaceutical Manufacturing

DESCRIPTION:

The Certificate in Pharmaceutical Manufacturing (16 credits) is open to undergraduate students interested in careers in the pharmaceutical industry, especially within the manufacturing and supply chain sectors. The certificate is designed to supplement the baccalaureate plans of studies in different majors, including (but not limited to) engineering, computer science, chemistry, biology, pharmaceutical sciences, health sciences, technology, and business, chemistry, biology, pharmaceutical sciences, and health sciences. The undergraduate certificate provides broad technical exposure to these topics through relevant courses and experiential learning opportunities. Combined with their Purdue major plans of study, students who attain this certificate will be well positioned to advance into successful careers working in the global pharmaceutical industry.

RATIONALE:

The pharmaceutical and life sciences industry talent needs are shifting driven by the new therapeutic product modalities (e.g., cell and gene therapies), digitization, and advanced data analytics. The technological disruptors are creating a skill mismatch between the traditional degrees associated with the pharmaceutical sector and future demands. By 2030 a projected 90,000 current jobs in the pharma industry will disappear due to automation while up to 120,000 of different jobs in high-skilled occupations will be created. Purdue University has gained an understanding of the industry's needs through collaboration with Work Force of the Future initiative, sponsored by the ISPE Global Pharmaceutical Manufacturing Leadership Forum, and partnerships with major regional life sciences industry employers such as Eli Lilly. While the degrees most associated with this sector (chemistry, chemical engineering, and pharmaceutical sciences) will continue to be valuable, the disciplines of data science, artificial intelligence, mechanical engineering, biomedical engineering, industrial engineering, as well as robotics and automation technologies will play significant roles within these organizations. Graduates of such

programs currently have limited exposure to drug development and regulatory process required to ensure public safety.



Director,
Office of Professional Practice



Co-Director,
William D. Young Institute for Advanced
Manufacturing of Pharmaceuticals

Co-Director,
William D. Young Institute for Advanced
Manufacturing of Pharmaceuticals

Co-Director,
William D. Young Institute for Advanced
Manufacturing of Pharmaceuticals

Link to Curriculog entry:

<https://purdue.curriculog.com/proposal:23145/form>

Undergraduate Certificate in Pharmaceutical Manufacturing

Originating/Sponsoring Units: Office of Professional Practice and William D. Young Institute
for Advanced Manufacturing of Pharmaceuticals

The Certificate in Pharmaceutical Manufacturing (16 credits) is open to undergraduate students interested in careers in the pharmaceutical industry, especially within the manufacturing and supply chain sectors. The certificate is designed to supplement the baccalaureate plans of studies in different majors, including (but not limited to) engineering, computer science, chemistry, biology, pharmaceutical sciences, health sciences, technology, and business, chemistry, biology, pharmaceutical sciences, and health sciences. The pharmaceutical and life sciences industry talent needs are shifting driven by the new therapeutic product modalities (e.g., cell and gene therapies), digitization, and advanced data analytics. The technological disruptors are creating a skill mismatch between the traditional degrees associated with the pharmaceutical sector and future demands. By 2030 a [projected](#) 90,000 current jobs in the pharma industry will disappear due to automation while up to 120,000 of different jobs in high-skilled occupations will be created. Purdue University has gained an understanding of the industry's needs through collaboration with Work Force of the Future initiative, sponsored by the ISPE Global Pharmaceutical Manufacturing Leadership Forum, and partnerships with major regional life sciences industry employers such as Eli Lilly. While the degrees most associated with this sector (chemistry, chemical engineering, and pharmaceutical sciences) will continue to be valuable, the disciplines of data science, artificial intelligence, mechanical engineering, biomedical engineering, industrial engineering, as well as robotics and automation technologies will play significant roles within these organizations. Graduates of such programs currently have limited exposure to drug development and regulatory process required to ensure public safety. The undergraduate certificate provides broad technical exposure to these topics through relevant courses and experiential learning opportunities. Combined with their Purdue major plans of study, students who attain this certificate will be well positioned to advance into successful careers working in the global pharmaceutical industry.

Requirements for the Certificate

I. At least 1 credit hour of orientation seminar from the course list below:

- ENGR 10301 Pharmaceutical Careers and Drug Development
- IPPH 10000 Pharmaceutical Sciences Orientation

II. Experiential Learning in Pharmaceutical Manufacturing: at least 6 credit hours or equivalent of

- Full-time internship or co-op in areas relevant to pharmaceutical manufacturing.
 - A 10-week or more of full-time internship/co-op is equivalent to 4 credit hours.
 - Summer Undergraduate Research Fellowship or similar full-time undergraduate research internship is considered equivalent to 2 credit hours.
 - Relevant Study Abroad courses.

III. At least 9 credit hours of courses in at least two out of four technical areas below (with at least 6 credit hours should be at 400-level or above):

- Pharmaceutical Product Development and Regulatory Affairs

- Pharmaceutical Manufacturing Science and Technology (Materials, Measurement and Manufacturing)
- Data Analytics and Computing
- Supply Chain and Business Operations

The table below shows courses that have been identified as meeting the objectives of this program in the four technical areas.

Pharmaceutical Product Development and Regulatory Affairs
ABE 51100 Drug Development
ABE 51200 Good Regulatory Practices
ABE 51300 Quality Management Audits and Inspections
BIOL 39500 Macromolecules
BIOL 41500 Intro. to Molecular Biology
BIOL 41600 Viruses and Viral Diseases
BIOL 51600 Molecular Biology of Cancer
BIOL 53601 Biological and Structural Aspects of Drug Design and Action
BIOL 53700 Immunology
BIOL 59500 Immunology, Cancer and Infectious Disease
BIOL 59500 Neural Mechanisms Health Disease
BIOL 59500 Pathways in Human Health and Disease
BIOT 102 Survey of Good Manufacturing Practices (Ivy Tech)
BIOT 103 Safety and Regulatory Compliance for Biotechnology (Ivy Tech)
BIOT 104 Quality Practices (Ivy Tech)
BIOT 105 Survey of Regulatory Affairs (Ivy Tech)
BME 55600 Introduction to Clinical Medicine for Engineering Solutions
BME 56100 Preclinical and Clinical Study Design
BME 56200 Regulatory Issues Surrounding Approvals of Biomedical Devices
BME 56300 Quality Systems for Regulatory Compliance
BME 56400 Ethical Engineering of Medical Technologies
BME 57100 Drug Delivery (IUPUI)
CHE 59700 Analytical Approach to Healthcare Delivery
IE 53000/STAT 51300 Quality Control
IE 55800 Safety Engineering
IE 59000 Human Factors and Medical Devices
IPPH 58300 Advanced Biopharmaceutics
MCMP 42200 Immunology
MCMP 54400 Drug Classes and Mechanisms
PHAD 50100 Food and Drug Law Administration
PHRM 46000 Drug Discovery and Development I

PHRM 46100 Drug Discovery and Development II
PHRM 48500 Intercultural and Global Health Issues
PHRM 82400 Principles of Pathophysiology and Drug Action
PHRM 82800 Dosage Forms I
PHRM 82900 Dosage Forms II

Pharmaceutical Manufacturing Science and Technology
ABE 30300 Applications of Physical Chemistry to Biological Processes
ABE 30400 Bioprocess Engineering Laboratory
ABE 30700 Momentum Transfer in Food and Biological Systems
ABE 30800 Heat and Mass Transfer in Food and Biological Systems
ABE 37000 Biological/Microbial Kinetics and Reaction Engineering
ABE 45700 Transport Operations in Food and Biological Engineering I
ABE 46000 Sensors and Process Control
ABE 55700 Transport Operations in Food and Biological Systems II
ABE 55800 Process Design for Food and Biological Systems
BIOL 59500 Methods and Measurements in Physical Biochem
BIOT 110 Pharmaceutical Product Manufacturing (Ivy Tech)
BME 30400 Biotransport Fundamentals
BME 38100 Implantable Materials and Biological Response (IUPUI)
BME 38800 Applied Biomaterials (IUPUI)
BME 46100 Transport Processes in Biomedical Engineering (IUPUI)
BME 47000 Biomolecular Engineering
BME 58200 Advanced Biomedical Polymers (<i>IUPUI</i>)
CHE 53600 Particulate Systems
CHE 55100 Principles of Pharmaceutical Engineering
CHE 55300 Pharmaceutical Process Development and Design
CHE 55400 Smart Manufacturing in the Process Industries
CHE 55500 Computer Integrated Process Operations
CHE 59700 Industrial Chemical Technology
CHE 59700 Process Safety
CHM 32100 Analytical
CHM 42400 Instrumental
CHM 33900 Biochemistry
CHM 43300 Biochemistry
CHM 43800 Biotechnology
IE 37000 Manufacturing Processes I
IE 57400 Industrial Robotics and Flexible Assembly
IE 59000 Nanomanufacturing

IPPH 56200 Introduction to Pharmaceutical Manufacturing Processes
IPPH 58000 Physical Chemical Principles
IPPH 58000 Physical Chemical Principles
IPPH 58700 Pharmaceutical Solids
ME 53101 (ABE 50501) Particle, Powder, and Compact Characterization
ME 53102 (ABE 50502) Particle, Powder, and Compact Characterization Laboratory
ME 59500C Powder Storage and Flow
MGMT 45200 Manufacturing Strategy and Process Innovation
MSE 51200 Powder Processing
MSE 53500 Lean Manufacturing
PHRM 83600 Biochemistry for Pharmaceutical Sciences II

Data Analytics and Computing
ABE 30100 Numerical and Computational Modeling in Biological Engineering
BME 36600 Foundations of Biomedical Data Science
BME 40100 Mathematical and Computational Analysis of Complex System Dynamics in Biology, Medicine, and Healthcare
BME 50100 Multivariate Analyses in Biostatistics
CHE 32000 Statistical Modeling and Quality Enhancement
CNIT 48800 Data Warehousing
CNIT 57000 IT Data Analytics
CS 24200 Introduction to Data Science
ECE 20875 Python for Data Science
ECE 47300 Introduction to Artificial Intelligence
HORT 53000 Introduction to Computing for Biologists
IE 33200 Computing in Industrial Engineering
IE 33500 Operations Research Optimization
IE 33600 Operations Research Stochastic Models
IE 48100 Intro to System Simulation
IE 49000 Machine Learning and its Applications
IE 53300 Industrial Applications of Statistics
IE 53500 Linear Programming
IE 53600 Stochastic Models in Operations Research I
IE 58000 System Simulation
IE 59000 Predictive Modeling
ILS 10300 Introduction to Data Lifecycle Management
ILS 23000 Data Science and Society: Ethical Legal Social Issues
ILS 29500 Special Topics in Information and Data Science
MGMT 47500 Machine Learning for Business

MGMT 47900 Data Visualization
MGMT 48800 Data-Driven Decisions in Digital Markets
MGMT 54400 Database Management Systems
PHIL 20800 Ethics of Data Science
POL 22800 Data Science and Public Policy
STAT 35500 Statistics for Data Science

Supply Chain and Project Management
IE 49000 Supply Chain Engineering
IE 56600 Production Management Control
IE 57900 Design and Control of Production and Manufacturing Systems
IE 58200 Advanced Facilities Design
MGMT 46300 Supply Chain Analytics
MGMT 46400 Logistics: Concepts and Models
MGMT 46501 Strategic Sourcing and Procurement
MGMT 26100 Introduction to Supply Chain Management
MGMT 40500 Six Sigma and Quality Analytics
MGMT 46200 Advanced Manufacturing Planning and Control Systems
MGMT 46600 Project Management

CATALOG INFORMATION

Proposed CIP Code: 51.2010

Rationale for Proposed CIP Code: Fits the description of 51.2010 Pharmaceutical Sciences: A program that focuses on the basic sciences that underlie drugs and drug therapy and that prepares individuals for further study and/or careers in pharmaceutical science and research, pharmaceutical administration and sales, biotechnology, drug manufacturing, regulatory affairs, and related fields. Includes instruction in mathematics, biology, chemistry, physics, statistics, pharmaceuticals, pharmacology and toxicology, dosage formulation, manufacturing, quality assurance, and regulations.

Proposed Program Code: PHMF-CERT

Proposed Certificate Code: PHMF

Proposed Credits: 16

Projected Headcount: 100

Length of Certificate: Award of at least 1 but less than 2 academic years

Characteristics: Undergraduate certificate open to various majors at Purdue, includes a required experiential learning component.

Assessment of Need: Please see rationale. Assessment of need conducted by ISPE Workforce of the Future and other industry partners

Cost and Support: The program is closely aligned with the Lilly Scholars program and will be coordinated by staff in Office of Professional Practice

Similar and Related Programs: There is no directly similar program at the undergraduate level. At the graduate level there is a graduate certificate in Biotechnology Quality & Regulatory Compliance College of Agriculture.

Quality and Other Aspects: The program will be coordinated by faculty across multiple colleges through William D. Young Institute for Advanced Manufacturing of Pharmaceuticals.