Framingham State University

Program Assessment Plan for (Professional Science Master's) (2017-2022)

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1) PROGRAM MISSION STATEMENT

The mission of the Professional Science Master's (PSM) program in Biotechnology with a concentration in Quality Assurance is to improve biotechnology focused regulatory, scientific and management knowledge by providing an instructional and interactive learning environment to life science professionals. The training will position students for future success in managerial or supervisory roles as they advance in their careers, supporting the university's academic mission and encourage individual responsibility within the community setting. This biotechnology program is flexible and adaptable to the diverse needs of the students and industry requirement, including the option for students to earn a Certificate in Quality Assurance in Biotechnology.

2) PROGRAM LEARNING OBJECTIVES (PLO)

1. *Knowledge Enhancement:* Students will be able to integrate scientific, regulatory and managerial principles behind the development of biotech products by the life science industries.

2. *Regulatory Concepts:* Students will be able to assemble regulatory concepts and documentation used in the global production and management of biotech products.

3. *Ethics & Decision Making:* Students will adapt and apply good ethical and critical thinking to achieve personal, corporate and community goals.

4. *Communication & Team Work:* Students will adapt and apply good presentation and communication skills in an industry team environment.

5. *Career Building:* Students will create and gain a network of industry contacts for the advancement of career.

3) LEARNING OPPORTUNITIES

Curriculum Map:

Course Titles:	**Demonstrate Understanding of Science principles *(PLO, 1)***	**Apply lab techniques to QA/ project management *(PLO, 1)***	**Evaluate and coordinate Quality *(PLO, 2)***	**Evaluate and coordinate reg. compliance *(PLO, 2)***	**Apply knowledge in new circumstances ethically *(PLO, 3)***	**Adapt and innovate to solve problems ethically *(PLO, 3)***	**Integrate, synthesize, relay information *(PLO, 3)***	**Communicate effectively *(PLO, 4)***	**Work in teams *(PLO, 4)***	**Lead groups *(PLO, 4)***	**Deploy skills professionally *(PLO, 5)***
Molecular biotechnology	X				X	X	X	X			X
Data Analyses & Statistics			X	X		X	X	X			
GLP Biotechnology Lab	X	X	X	X	X	X		X			
Drug Development	X		X	X	X	X		X			X
Scientific and Technical Communication							X	X	X	X	X
Bioethics					X	X	X	X			X
Business Operations Mgmt					X	X	X		X	X	
Quality Assurance and Quality Control for Biotech		X	X	X	X	X	X	X	X	X	X
Management and Leadership for Biotech				X	X	X	X	X	X	X	X
Project Management		X			X	X	X	X	X	X	X
Internship / Thesis					X	X	X	X	X		X
Topics in Biochemistry	X					X		X			X
Bioinformatics and Large-scale data analysis	X					X		X			X
Topics in Genetics and Epigenetics	X					X		X			X
Drug Discovery	X		X	X	X	X		X			X

Cells and Systems	X					X		X			X
Applied Immunology	X					X		X			X
Intellectual Properties				X	X	X	X	X	X	X	X

COURSE DESCRIPTIONS

BIOT 903 Drug Development: Process and Regulations
Designed to provide students with an overview of drug development, for both small molecules and biotherapeutics. The course emphasizes the diverse set of activities in pharmaceutical development; discusses key stages and decisions points in the process; and details the importance of quality control and meeting regulatory requirements. Case studies are presented by guest lecturers from the pharmaceutical and biotechnology industry to illustrate the complexities of drug development.
Prerequisite: Acceptance into the P.S.M. program in Biotechnology.

BIOT 908 Quality Assurance and Quality Control for Biotechnology and Biopharmaceuticals
An examination of the application of quality practices in the development, manufacturing, control and assessment of products in the biotechnology and biopharmaceutical industries. Students learn the principles of QSR (Quality Systems Requirements) as they apply to the procurement of materials and the manufacture, validation and release of products. Through the use of case studies, the course presents the commonalities of QSR and the application of GMP (Good Manufacturing Practices) for all product types, as well as the specific requirements and differences among biologics, small molecules and devices.
Prerequisite: Acceptance into the P.S.M. program in Biotechnology.

BIOT 930 Good Laboratory Practices (GLP) in Biotechnology Laboratory Techniques
An exposure to techniques commonly used in the biotechnology industry. It focuses on the use of cell culture in the production of biologically active products. The course emphasizes sterility, purification, assay of a final product, and documentation. Discussion of Good Laboratory Practices and designing lab techniques to meet regulations are included. The course requires written analysis of data. Laboratory (4 hours).
Prerequisite: Acceptance into the P.S.M. program in Biotechnology.

BIOT 941 Molecular Biotechnology
A seminar course which focuses on literature review and analysis. Topics discussed cover several areas in biotechnology, including bioprocessing, biomedical, and agricultural applications. Students are required to write a review-style paper on a topic of their choice and present their paper to their classmates in an oral presentation.
Prerequisite: Acceptance into the P.S.M. program in Biotechnology.

BIOT 952 Scientific and Technical Communication in Biotechnology
A focus on oral and written communication for both scientific and nonscientific audiences for a variety of sources in biotechnology, including journals, investor relations, and regulatory documentation.

Prerequisite: Acceptance into the P.S.M. program in Biotechnology.

BIOT 966 Ethical Implications of Biotechnology
A seminar course that examines the ethical implications of decisions made in biotechnology as well as the responsibilities of life scientists in their communities. Course discussions include stewardship and environmental impacts of biomanufacturing as well as ethical use of laboratory animals.
Prerequisite: Acceptance into the P.S.M. program in Biotechnology.

BIOT 970 Current Topics in Genetics, Epigenetics, and Genomics
An advanced genetics course that examines the relationship between genes and environment, with emphasis on molecular genetics and epigenetics. The course discusses genomics of humans and model organisms, explores common experimental approaches in molecular genetics, and includes a discussion of personalized medicine.
Prerequisite: Acceptance into the P.S.M. program in Biotechnology.

BIOT 972 Cells and Systems
A study of biological systems at the cell, tissue, and organismal levels, including a discussion of proteomics, genomics, regulatory pathways, stochasticity, and the transcriptome. Students focus on techniques that allow the study of groups of functionally interacting structures as a whole.
Prerequisite: Acceptance into the P.S.M. program in Biotechnology.

BIOT 974 Applied Immunology
An advanced study of the principles of immunology and its application to diseases and health. Emphasis is on applications of immunological principles as they pertain to medical diagnostics and biotechnology. The course examines the molecular and cellular components of the immune system relevant to the diagnosis of infectious diseases, genetic- and infection-associated immunodeficiency, cancer, hypersensitivity, autoimmunity, and transplantation.
Prerequisite: Acceptance into the P.S.M. program in Biotechnology and previous completion of an undergraduate microbiology course (or equivalent).

BIOT 978 Drug Discovery
Designed to provide the student with an overview of drug discovery for both small molecules and biotherapeutics. The course emphasizes the interdisciplinary nature of pharmaceutical research and discuss key stages and decisions points in the process. Case studies are used by guest lecturers from the pharmaceutical and biotech industry to illustrate the challenges of identifying human drug targets and delivering drug candidates.
Prerequisite: Acceptance into the P.S.M. program in Biotechnology.

BIOT 995 Biotechnology Internship
An internship which involves an employer-driven project that can be completed in one semester. Individuals currently employed may complete their internship with their current employer but must complete a project distinct from their normal role at the company. At the end of the internship, the student prepares a written summary and analysis of the project

with the guidance of the internship mentor and approval of the industry supervisor. A minimum of 400 hours is required.
Prerequisite: Acceptance into the P.S.M. program in Biotechnology and completion of 10 courses within the program.

BIOT 980 Biotechnology Patent Law
An overview of biotech patent law for life science managers, scientists, researchers, business development managers, and investors. This course provides a fundamental understanding of creating and protecting value in a biotechnology company through established mechanisms grounded in patent and licensing law. Students learn the basics of patent filing, patent strategy, product protection in the United States and other countries, licensing (and other conveyances) for value, as a function of business value creation and business development.
Prerequisites: Acceptance into the P.S.M. program in Biotechnology.

BUIS 956 Project Management for Biotechnology
Designed for life science professionals. This course utilizes the project management model developed by the Project Management Institute to introduce students to a common methodology for project planning and control. Specific emphasis is placed on project management in biotechnology and the life sciences.
Prerequisite: Acceptance into the P.S.M. program in Biotechnology.

CHEM 936 Current Topics in Biochemistry
An advanced biochemistry course designed to enhance the understanding of protein structure, function and biosynthesis; enzyme structure, function and regulation; and carbohydrate metabolism and energetics. This course draws upon the fields of organic chemistry, biochemistry and cell biology for understanding the rationale for the development of new therapeutic agents used in the pharmaceutical industry.
Prerequisite: Acceptance into the P.S.M. program in Biotechnology and previous completion of an undergraduate biochemistry course (or equivalent).

MATH 924 Data Analyses and Statistical Concepts in Biotechnology
Designed for data interpretation, analysis and statistical application in the biotechnology industry. Students perform analysis of quality and assess risk in making business decisions. It includes discussion of appropriate experimental methods. Students apply statistical analysis software commonly used in biotechnology and professional science industries.
Prerequisite: Acceptance into the P.S.M. program in Biotechnology.

MGMT 921 Business Operations Management for Biotechnology
Designed for science professionals to develop and apply skills and knowledge for managing business operations. Topics include concepts and techniques for planning, designing, controlling and improving business operations. Real-world business cases are used to develop students' management capacity and capability. Areas of focus include the process view of organizations, performance measures, products and product attributes, production processes, process competencies, procurement and supply chain management and regulatory requirements.

Prerequisite: Acceptance into the P.S.M. program in Biotechnology.

MGMT 945 Management and Leadership for Biotechnology
Designed for life science professionals. The course addresses managerial and leadership styles and the dynamics of organizational behavior. Topics include managerial effectiveness strategies, leadership styles, organizational structuring issues, interpersonal relationships, and the building and managing of teams. This course includes case studies from the biotechnology industry.
Prerequisite: Acceptance into the P.S.M. program in Biotechnology.

4) ASSESSMENT METHODS AND TIMELINE

Indicate when and how program learning objectives will be assessed. Refer to the curriculum map to draft a student learning objective assessment timeline. It is recommended that you outline a 5-year plan for assessment in which you will assess all of your PLOs.

Academic Years	Objectives(s)	Course(s)	Assessment Evidence (direct/indirect)	Assessment Method	Responsibility
WHEN	WHICH Objectives(s) will you examine in each period (Use number)?	WHERE will you look for evidence of student learning (i.e., list course(s) that will generate evidence for each objective.	WHAT student work or other evidence will you examine in order to assess each objective?	HOW will you look at the evidence; what means will you use to analyze the evidence collected for each objective	WHO will oversee collecting, analyzing, reporting, results? List names or titles.
Year 1 (2017-2018) Report 1/19	Knowledge enhancement	Courses in (1) Molecular biotech, (2) Elective course & (3) Elective course	Research papers, class presentations, problem sets, case studies, class participation	Rubrics (AACU), surveys, interviews of students & faculty members, group discussions	Sunny Tam
Year 2 (2018-2019) Report 1/20	Regulatory concepts	Courses in (1) QA, (2) GLP lab, (3) GCP Statistics, & (4) Drug Development	Research papers, class presentations, problem sets, case studies, class participation & regulatory documentation	Rubrics (AACU), surveys, interviews of students & faculty members, group discussions	Sunny Tam
Year 3 (2019-2020) Report 1/21	Ethics & decision making	Courses in (1) Bioethics & (2) Leadership	Research papers, class presentations, problem sets, case studies, class participation	Rubrics (AACU), surveys, interviews of students & faculty members, group discussions	Sunny Tam
Year 4 (2020-2021) Report 1/22	Communication & team work	Courses in (1) Project management, (2) Operational management & (3) Technical writing	Research papers, class presentations, problem sets, case studies, class participation	Rubrics (AACU), surveys, interviews of students & faculty members, group discussions	Sunny Tam

Year 5 (2021-2022) Report 1/23	Career building	Capstone Internship/Thesis & National certifications	Resume writing, class discussion, & professional societies participations	Rubrics (AACU), Data analysis, writing & publishing	Sunny Tam

Program Size and Sampling Technique

a. State the number of students in the program or the number who graduate each year.
The program currently has 30 students enrolled.

b. Describe the sampling technique to be used
The complete population of the students will be sampled every year.

5) PLAN FOR ANALYZING RESULTS

- List who is responsible for distributing results and who will receive results?
All the adjunct faculty members along with the Graduate Studies Dean will receive results from the Assessment Coordinator.

- State how and at which forums discussion of results will take place.
Please see below.

6) DISTRIBUTION. The program will distribute or publish these items in the following ways:

ITEM	***Distribution Method***					
	FSU Catalog (provide section title)	**Website** (provide URL)	**Annual Reports**	**Brochures**	**Course Syllabi**	**Other** (please describe, e.g. department meeting, advising session)
Program Mission	Yes	Yes	Yes	Yes	No	Dept. Meeting
Program Learning Objectives	Yes	Yes	Yes	Yes	No	Dept. Meeting
Learning Opportunities (Curriculum Map)	Yes	Yes	Yes	No	No	Dept. Meeting
Assessment Plan	Yes	Yes	Yes	No	No	Dept. Meeting

Website URL: www.framingham.edu/biotech

Attach any rubrics or instrumentation that you plan to use for assessment of Program Learning Objectives

The following VALUE Rubrics by the Association of American Colleges & Universities (refer to https://www.aacu.org/value-rubrics) will be used for assessment of some Program Learning Objectives:

1) Teamwork
2) Inquiry and analysis
3) Critical thinking
4) Creative thinking
5) Written communication
6) Oral communication
7) Problem solving
8) Ethical reasoning

[1] If you have questions or need assistance, please contact Dr. Mark Nicholas, Director of Assessment at mnicholas1@framingham.edu or 508-626-4670

2 Accredited programs can provide supplemental documents that indicate the answers to these questions as long as specific page references are provided in each cell of the tables in this form. When the answers are not accessible in that way, please cut and paste into your assessment plan.

Credits: This Template was developed using ideas from templates developed at University of Rhode Island and University of Hawaii in Manoa.