

BOARD OF HIGHER EDUCATION

REQUEST FOR COMMITTEE AND BOARD ACTION

COMMITTEE: Assessment and Accountability

NO.: AAC 07-03

COMMITTEE DATE: October 11, 2006

BOARD DATE: October 19, 2006

MOVED:

The Board of Higher Education hereby approves the request of **Mount Wachusett Community College** to award the **Associate in Science in Biotechnology/Biomanufacturing and Certificate in Biotechnology/Biomanufacturing**.

One year after graduating the program's first class, the College shall submit to the Board a status report addressing its success in reaching program goals as stated in the application and in the areas of enrollment, curriculum, faculty, resources, and program effectiveness.

Authority: Massachusetts General Laws Chapter 15A, Section 9(b)

Contact: Aundrea Kelley, Associate Vice Chancellor for Academic Policy

BOARD OF HIGHER EDUCATION

October 2006

Mount Wachusett Community College

Associate in Science in Biotechnology/Biomanufacturing
Certificate in Biotechnology/Biomanufacturing

INTENT, MISSION AND NEED

Mount Wachusett Community College (MWCC) has submitted an expedited proposal to offer an Associate in Science in Biotechnology/Biomanufacturing and a Certificate in Biotechnology/Biomanufacturing. The College Board of Trustees approved the proposed program on April 13, 2006. No comments were offered in response to the July 17, 2006, circulation of the Letter of Intent.

The proposed program is consistent with the College's mission to assist in the economic development of North Central Massachusetts through the promotion of a skilled workforce for high-demand industries that continue to grow or are new to the communities served by the College's four campuses (Gardner, Orange, Leominster, and Devens).

The overall purpose of the proposed degree and certificate program is to graduate students who possess the requisite skills for entry-level positions in biotechnology, specifically biomanufacturing. The actual manufacturing of biotechnology products involves three main areas: 1) culturing cells that produce the product (upstream manufacturing), 2) purification of the product from the cell culture (downstream manufacturing), and 3) the quality control of the product during manufacture. The proposed program will focus on training workers in the three main areas of manufacturing and in the processes required by technicians in Quality Control and Quality Assurance.

With the recent announcement of Bristol Myers Squibb's (BMS) plan for a \$1.1 billion manufacturing facility sited within a few minutes of the College's Devens campus, MWCC will be positioned to offer the location, facilities, faculty and education for citizens seeking initial careers or those looking at retooling for the future. A primary objective of the proposed program is to supply a steady stream of competent biomanufacturing technicians to the new Bristol Myers Squibb Devens facility. With full plant production scheduled to occur in 2009-10, the launch of the proposed MWCC program in 2007 is intended to allow the formation of strong connections to Bristol Meyers Squibb and other regional biotechnology/biomanufacturing facilities.

Need and Demand

In general, trained technicians hold about 40 percent of all jobs in advanced industries, such as biotechnology. Approximately 400 of the 600 employees at Devens will be defined as technicians (*Worcester Telegram*, June 2, 2006) and may earn up to \$60,000 per year. Separate from the new BMS facility, the Massachusetts Biotechnology Council (MBC), in a report titled *MassBiotech 2010*, predicts a total growth in the Commonwealth of more than 100,000 biotechnology jobs by the end of the decade.

In addition to filling biotechnology manufacturing positions, technicians can be involved in research efforts and in process development efforts. Descriptions of ten key position types, expected to be in demand by BMS and other regional biotech companies, is contained in Attachment A.

Five Massachusetts community colleges currently offer biotechnology programs: Middlesex, Massachusetts Bay, Quinsigamond, North Shore and Springfield Technical Community Colleges. Since current degree/certificate programs cannot meet increasing demands of the industry or even that of the new BMS Devens plant, MWCC believes that this proposed program is critical to addressing future needs.

CURRICULUM (Attachment B)

The curriculum was developed through the Biology Department of the Division of Science, Technology, and Mathematics during the fall and spring semesters of the 2005-2006 academic year. The proposed program will become an integral part of the Natural Sciences (Biology) Department, which currently employs seven biology-chemistry-physics instructors. The Clinical Laboratory Science program recently approved by the Board of Higher Education will also complement the biotech/biomanufacturing curriculum.

The 28-credit certificate program comprises seven courses, including one in biochemistry, one in mathematics and five in biotechnology. The 64-credit associate degree program comprises nine general education courses and an in-depth study of biotechnology/biomanufacturing through five biotech specific courses and four associated biology and chemistry courses. All the biotech courses are lab-based and intended to simulate a typical laboratory experience in preparation for entry-level employment. Degree or certificate students about to enter the workforce will be required to complete a substantial internship and capstone seminar. The College intends that the curriculum will evolve as the BMS plant is constructed and matures and as contacts are developed through the formation and participation of a local advisory board containing biomanufacturing specialists from BMS and other regional industries.

ADMISSION AND ENROLLMENT

MWCC intends to initially enroll 20 students, perhaps more, depending upon prior coursework completed, as early as fall 2007. Applicants must possess a high school diploma or GED.

Program Enrollment Projection – Certificate and Degree Program

	# of Students Year 1 9/1/2007	# of Students Year 2 9/1/2008	# of Students Year 3 9/1/2009	# of Students Year 4 9/1/2010
New Full Time	20	20	25	28
Continuing Full Time	–	14	18	19
New Part Time	–	8	12	12
Continuing Part Time	–	–	8	10
Totals	20	42	63	69

The Certificate program will be most appropriate for students with strong backgrounds in biology/chemistry who seek to focus on skill development. MWCC projects that the individuals

most likely to participate in the biotech/biomanufacturing programs will be those seeking career enhancement or retraining as a result of unemployment or nonqualified status. Many biotech students in other programs nationally have advanced degrees in computer science, mathematics, medicine or biology/chemistry. Many are also foreign born with professional licenses yet are unable to be licensed (physicians, pharmacists, etc.) in the United States. This projected pool of applicants offers a track record of success in college- level mathematics and science-related coursework. A second group would include those who are seeking a second career. Those directly out of high school and whose backgrounds in mathematics and science (biology/chemistry) may vary are likely to comprise the smaller third group of applicants.

RESOURCES AND BUDGET (Attachment C)

Human Resources

Organizationally, the proposed program will be located within the Division of Mathematics, Science and Technology. The Division Dean is a 34-year employee of MWCC, serving both as faculty member in biology and as interim dean of faculty.

Currently, the College employs a variety of full and adjunct faculty capable of instructing foundation courses. Two adjunct faculty, currently teaching biology, maintain current employment in the biotech industry in research and development and biomanufacturing. An interim program director, who is a full-time faculty member at MWCC, will be appointed in September to organize the program and integrate the curriculum into the Biology Department. As the program matures and student enrollments grow, the College anticipates adding another faculty member who will specialize in biomanufacturing.

Beginning in January 2007 MWCC will employ a full-time permanent program director at the department chair level who will initiate a local advisory board, further develop syllabi, implement plans for laboratory renovation, and recruit students. The permanent chair will also undertake substantial outreach activities, including the following:

- Meet with BMS officials to develop courses (especially workshops) for employees moving to the Devens area—spring 2007

- Lecture on public access TV on topics in biotechnology/biomanufacturing as a means to educate the regional community—spring 2007

- Publish a series of articles on biomanufacturing in general and careers in particular to further educate the populace on potential jobs in the immediate area—spring 2007

- Visit selected regional high schools for career discussions with upper-level science students—spring 2007

- Meet with program faculty of Minuteman Regional Science and Technology's Biotechnology program to develop a seamless transfer of credits to avoid redundancy—spring 2007

Physical Resources

MWCC recognizes that biotechnology specific courses need to be situated in dedicated laboratory space and supported by faculty, staff, and equipment. Through internal resources, grants, and legislative funding, the College intends to establish a “Biomanufacturing Center” at or near its Devens facility that will continuously improve through connections to the Northeast Center for Biomanufacturing Consortium.

Budget

Year One Costs reflect continued employment of the department chair-instructor and instructional materials for initial BTC and biology/chemistry courses. Year Two Costs (Level II coursework) reflect potential laboratory renovation, the bulk of equipment purchases and increased needs for supplies to support day and evening, degree or certificate courses. Year Three Costs show continuing purchases of equipment; as well as a greater need for expendable supplies. Year Four Costs reflect an additional staff member and additional supplies to support greater enrollments.

Mount Wachusett will be submitting grant requests to the National Science Foundation/Advanced Technological Education and Department of Labor for funding. The College has recently closed its Computer and Electronic Technology program due to declining enrollments and a weakened job market. Approximately \$90,000 which formerly covered faculty salaries, will be allocated to support staff/supplies/ equipment for the proposed program. The College recognizes that additional support will be required through grants/donations (from Bristol Myers Squibb), tuition, and possibly legislative appropriation.

EXTERNAL REVIEW

An external review of the proposed program was conducted by Dr. Maureen Harrigan, Program Director, Industrial Biotechnology, Moorpark College, Moorpark, California; and Dr. Sonia Wallmann, Chair of Biotechnology and Director of the New Hampshire Biotechnology Education and Training Center, New Hampshire Technical Community College, Portsmouth, New Hampshire.

Reviewer Findings

Overall, the reviewers wrote in support of the program and agree that the curriculum is sound and carefully planned in all aspects. They agreed that there is high demand for biotech graduates and that graduates of the proposed MWCC program “will be highly competitive within the workplace and be valued by employers as knowledgeable and skilled scientists.”

The reviewers also recommended setting up a system for obtaining feedback and input from the supervisors or plant managers on the preparedness and on-the-job performance of program graduates and suggested that the College should expect influence of industry advisors to result in some tweaking of the curriculum.

In response, the College provided a timetable of steps that it will take to further develop the program over the next three years, including the recruitment of industry advisors and development of curricular enhancements.

From the reviewers' point of view, the northeast region, state and federal employment outlooks for employment in biomanufacturing are substantial: "Not only will we see expansion of biopharmaceutical biomanufacturing facilities throughout the region, but also the growth of the bio-based economy where the need for the same competencies will grow for the biomanufacture of biofuels, such as ethanol and various industrial enzymes to support the pulp and paper, plastics, and other industries."

STAFF ANALYSIS AND RECOMMENDATION

Following thorough review of all documentation provided, staff recommendation is for approval of the Associate in Science in Biotechnology/Biomanufacturing and the Certificate in Biotechnology/Biomanufacturing at Mount Wachusett Community College.

One year after graduating the program's first class, the institution shall submit to the Board a status report addressing its success in reaching program goals, as stated in the application, and in the areas of enrollment, curriculum, faculty, resources, and program effectiveness.

Attachment A

10 Targeted Biomanufacturing Job Descriptions

Process Development Associate

Responsible for evaluating, improving, and scaling-up manufacturing processes in order to improve product yield and reduce overall costs of production. Executes small-to-medium scale production work, which may involve cell culture, fermentation, purification, and/or chromatography. Additionally, assists with maintenance of production equipment. May research and implement new methods and technologies to enhance operations and may assist in validation of production processes.

Validation Specialist

Responsible for developing and recommending validation strategies and designing studies for the purpose of providing documented evidence that a system, equipment, method, or process has been validated. Conducts and processes qualification programs, writes detailed protocols and reports to document the validation of systems/equipment, and provides validation support for facility and utility expansion, compliance upgrades, etc. Develops and implements solutions to validation issues. Knowledge of current industry practices and GMP requirements related to validation tasks is required.

Manufacturing Technician-Upstream

Responsible for assisting manufacturing in specific product-related operations in cell culture and growth. Operates and maintains production equipment as it relates to cell culture (i.e., cell harvests and separation operations). Also performs fermentation. Operates and maintains production equipment related to fermentation (e.g., fermenters, bioreactors, centrifuges). Weighs, measures, and checks raw materials to assure proper ingredients and quantities. Prepares media and buffer components. Maintains records to comply with regulatory requirements and assists with in-process testing.

Manufacturing Technician-Downstream

Responsible for setting up area operations, performing according to SOPs, and following electronic work instructions in accordance with a GMP environment to manufacture biopharmaceutical drug substances. Responsibilities include cleaning-in-place (CIP) and sterilizing-in-place (SIP) of equipment, column chromatography, ultrafiltration, diafiltration, conducting protein purification operations, monitoring control devices, and executing any other related operations pertaining to the process area. Also maintains records to comply with regulatory requirements and assists with in-process testing.

Instrumentation/Calibration Technician

Maintains, tests, troubleshoots and repairs a variety of circuits, components, analytical equipment and instrumentation. Calibrates instrumentation and performs validation studies. Specifies and requests purchase of components. Analyzes results and may develop test specifications and electrical schematics. Performs continuous monitoring of equipment status, condition and location. Prepares required documentation for the recording and notification of events and changes related to equipment such as calibration certificates, deviations, out of tolerances and installation reports. Knowledge and understanding of measurement parameters and experience working in a GMP environment is preferred.

Chemistry QC Technician

Performs a variety of inspections, checks, tests, and sampling procedures for the manufacturing process according to standard operating procedures (SOPs). Performs in-process inspection and documents results. Monitors critical equipment and instrumentation.

Writes and updates inspection procedures and checklists as necessary. Requires knowledge of current good manufacturing practices (GMPs).

Microbiology QC Technician

Performs routine microbiological testing of raw materials, in-process samples and finished formulations according to Standard Operating Procedures (SOPs). Conducts routine environmental monitoring of GMPs, manufacturing areas, equipment and processes according to established procedures. Calibrates and maintains microbiology laboratory equipment. Compiles and analyzes data for documentation of test results and prepares related reports. Revises and updates SOPs as necessary.

Environmental Health and Safety Technician

Responsible for water and air sampling and monitoring, processing permits, calibration and maintenance of scientific monitoring, data collection and routine analysis. Installs and services recording instruments, maintains physical stations where data are collected, inspects stations records to ensure quality assurance and preventative maintenance procedures are conducted properly. May conduct special studies, such as toxic water monitoring, biological monitoring, and air/water pollutant investigations and recommend corrective actions. Records and maintains periodic data logs and information files. Typically works from drawings, specifications, diagrams, schematics, and specific verbal and written instructions. Working knowledge in sampling, data collection and analysis, pollution complaint investigations, instrument calibration, and environmental law, or experience in assessing environmental conditions is desirable.

Quality Assurance Documentation Coordinator

Responsible for providing clerical and administrative support related to documentation system requirements/maintenance. Audits all documentation manuals to assure they are accurate and up-to-date, and available to appropriate personnel. Maintains filing of all master documents and assists in all microfilming and archiving activities.

Facilities Technician

Performs daily monitoring, repair, and preventive maintenance activities on critical systems and facility equipment. Troubleshoots, installs, and modernizes new and existing systems, including refrigeration equipment, water systems, HVAC systems, and electrical systems. Documents repairs, adjustments, and replacement of equipment and/or components per GMP standards. May also provide input and corrections to SOPs and assist engineering in the evaluation of new equipment or technology. Knowledge of major trades, such as carpentry, electrical, plumbing, and HVAC refrigeration, including the ability to interpret blueprints, technical manuals, and specifications, is required.

* **Source:** Massachusetts Biotechnology Council's Overview of Biotechnology Industrial Jobs from the Massachusetts Biotechnology Directory at <http://www.bio-link.org/issuesWorkforce.htm>

Attachment B – Curriculum Outline
 Mount Wachusett Community College
 Associate in Science Degree in Biotechnology/Biomanufacturing

Semester 1	Course Title	Credits	GE or CR*
BIO 109	General Biology	4	GE
BTC 101	Introduction to Biotechnology	4	CR
BTC 102	Basic Solution and Media Preparation	2	CR
CHE 107	General Chemistry I	4	CR
ENG 101	English Composition I	3	GE
Semester Total		17	

Semester 2			
BIO 205	Microbiology	4	CR
CHE 203	Introduction to Biochemistry	4	CR
ENG 102	English Composition II	3	GE
CIS 127	Computer Technologies	3	GE
	General Elective	3	GE
Semester Total		17	

Semester 3			
BTC 110	Biotech Exper. I: Concepts and Procedures	5	CR
HUM 212	Medical Ethics	3	GE
MAT 143	Probability and Statistics	3	GE
PER 126	Fitness and Wellness	2	GE
	Social Science Elective	3	GE
Semester Total		16	

Semester 4			
BTC 120	Biotech Exper. II: Biomanufacturing	5	CR
BIO 130	Plant Science	4	CR
BTC 200	Biotech. Practicum and Seminar	5	CR
Semester Total		14	
Total Credits		64	

Of the above, five of the courses would be new: BTC 101, BTC 102, BTC 110, BTC 120, and BTC 200.

*GE=General Education; CR=Curriculum Requirement

Certificate in Biotechnology/Biomanufacturing

Course Number	Course Title	Credits
CHE 203	Intro. To Biochemistry	4
MAT 124 (or 143)	Inter. Algebra(or Statistics)	3
BTC 101	Intro. To Biotechnology	4
BTC 102	Basic Solutions & Media Preparation	2
BTC 110	Biotech Experiences I: Concepts and Procedures	5
BTC 120	Biotech Experiences II: Biomanufacturing	5
BTC 200	Biotech. Practicum & Seminar	5
Total Credit Hours		28

Attachment C – Budget

BIOTECH/BIOMANUFACTURING BUDGET PROJECTIONS

One Time/ Start Up Costs		Annual Expenses			
		Year 1	Year 2	Year 3	Year 4
(10/1/06 – 6/30/07)	Cost Categories				
\$36,400 (.5 Academic Year)	Full-Time Faculty (Salary and Fringe)	\$72,800	\$ 75,000	\$ 75,000	\$158,000*
	Part-Time/Adjunct Faculty (Salary and Fringe)		\$ 8,000	\$ 12,000	\$ 8,000
	Staff				
	General Administrative Costs		\$ 2,000	\$ 3,000	\$ 4,000
	Instructional Materials, Library Acquisitions	\$ 6,000	\$ 12,000	\$ 20,000	\$ 20,000
	Facilities/Space/Equipment		\$341,130	\$ 40,000	
	Field and Clinical Resources				
\$ 3,000	Marketing	\$ 3,000	\$ 3,000	\$ 3,000	\$ 2,000
	Other (Specify)				
\$39,400	TOTALS	\$81,800	\$441,130	\$153,000	\$192,000

One Time/Start- Up Support		Annual Income			
		Year 1	Year 2	Year 3	Year 4
	Revenue Sources				
	Grants**		\$200,000	\$200,000	\$150,000
	Tuition/Fees	\$ 65,000	\$119,880	\$130,000	\$130,000
	Departmental				
\$36,400	Reallocated Funds (from Electronics program)	\$ 53,600			
	Other (specify)				
\$36,400	TOTALS	\$118,600	\$319,880	\$330,000	\$280,000

Reflects addition of second full-time instructor.

**Approximations

Projected Lab Costs

ITEM	QTY	UNIT COST	TOTAL
Anaerobic incubator	2	10,000.00	\$20,000.00
Autoclave	1	11,000.00	\$11,000.00
Centrifuges, micro and refrigerated micro	2	8,200.00	\$16,400.00
Chemical fume hood	2	2,000.00	\$4,000.00
Computers and printers	4	1,600.00	\$6,400.00
Deionizer, for water	1	1,630.00	\$1,630.00
Distiller, for water	1	10,000.00	\$10,000.00
Environmental growth chambers	2	2,000.00	\$4,000.00
Fermenters/bioreactors (0.5-2 L)	4	21,000.00	\$84,000.00
Freezers	2	1,800.00	\$3,600.00
Incubators (20°- 95° C)	2	4,100.00	\$8,200.00
Micropipettes (0.1-1000 um ranges)	100	25.00	\$2,500.00
Microscopes, brightfield	24	1,400.00	\$33,600.00
Microscopes, inverted	2	3,500.00	\$7,000.00
Microscopes, phase-contrast	6	2,900.00	\$17,400.00
Refrigerators	3	1,000.00	\$3,000.00
Spectrophotometers, 20/21	2	9,000.00	\$18,000.00
Spectrophotometers, UV	2	15,000.00	\$30,000.00
Thermal cycler system	2	20,000.00	\$40,000.00
Transilluminator, UV	1	9,800.00	\$9,800.00
Shaker water baths	4	1,900.00	\$7,600.00
Horizontal/Vertical Electrophoresis units, power supplies	6	500.00	\$3,000.00
	TOTAL COST		\$341,130.00