

## Project Summary

The proposed QA Certificate will serve as a “bridge” program recruiting the unemployed, the underprepared/underemployed, minority High School Students who might not consider college, and NJ’s large foreign born population for employment into High Tech Bio/Chem Manufacturing and higher technological education.

The immediate focus of the project is to train and place individuals into jobs in the regulated industries of New Jersey. Classroom instruction is designed as a workplace environment – not lecture/lab and is inquiry based – and there are no prerequisites to enter the program beyond a HS diploma. QA credits will count towards a BCC Associates in Science and we are in the process of developing Articulation agreements with programs at 4 year colleges (NJIT and Stevens). The 3 main tasks are:

1. Development of course material for the 5 courses that comprise the Certificate. This includes outfitting a dedicated Technology Laboratory in our Manufacturing Facility, developing modules and BCC & HS Faculty development.
2. Recruitment of students by development of science based curriculum with the local High Schools; training of HS teachers by utilizing them as assistants in BCC programs and making course materials available to them; accepting credit for QA course taught at the HS level; establishment of BCC summer camp courses in Biotechnology; working with NJworkforce to provide training to the unemployed and providing training for employees of local industries.
3. Developing a job pipeline : Forging close relationships with the diverse Bioscience Industries of NJ in order to assess their needs in an ongoing fashion, to establish externships and jobs, to develop sources of instruction and funding and to establish a basis for monitoring program success during internships and employment.

**Intellectual Merit.** The BCC QA project is that it is tailored to meet the needs of the extremely diverse mix of high tech industries in NJ<sup>3,34</sup> and teaches all the essential skills identified by NJ Bioscience Industry<sup>3,34</sup>. In addition the 75 instructional modules that we propose to develop, will provide interactive activities that teach through practice 80% of the technical skills required in Biomanufacturing as reported by an NSF. The program will utilize NotebookMaker’s electronic laboratory notebook **ELN** loaded onto an external hard drive which also will hold all the course material developed and adapted (from NSF and other available sources) for the courses, thus obviating the need for costly text books and providing the student with a 3 oz portable computer lab that he can use anywhere he can find a computer

**Broader Impacts.** The materials developed in this program as well as those previously developed by others, will be disseminated regionally and nationally through Notebookmaker and presentations at Conferences. It will strengthen the partnership between BCC, industry and the K-12 system enabling integration of quality assurance and biotechnology into training of technicians from many fields. It broadens participation of underrepresented groups. The modules will employ the newest techniques in inquiry based learning and information technology.

## **Motivating Rationale**

NJ is not educating a workforce for its Bioscience Industries as evidenced by the fact that >25% of the jobs in this rapidly expanding industry are filled by foreign born workers<sup>33</sup>. While overall manufacturing employment in NJ has decreased 0.7%, employment in the large Pharmaceutical and Research Testing industries of NJ has grown vigorously and is predicted to grow 2.7% annually and that of medical laboratories devices and equipment to grow 0.6% annually<sup>34</sup>. But in fact much of the growth of these industries has been fueled by immigration – 1.6 million of NJ's 8 million residents are foreign born and 250,000 entered between 2000 and 2004<sup>19</sup> because NJ is not producing enough graduates to fill these jobs: Only 25% of NJ HS graduates will finish college, despite the fact that 33% of our jobs require a college degree<sup>34</sup>. Further only 19% of those that proceed to the 2<sup>nd</sup> year of college but do not graduate are left to fill the 36% of jobs that require some post-secondary education<sup>24</sup>. In addition more than half of the 1.6 Million foreign born in NJ have less than a HS diploma<sup>17</sup>

The BCC QA program proposes to recruit students to the bioscience industries by developing Bridge courses with our HS and by crafting a program that bridges the educational gap that leads to failure for so many CC students: 82% of the students entering Bergen require remediation and only 11% graduate from BCC<sup>24</sup>. Discouragingly, students do not receive college credit for these remedial courses. We believe that we can remediate by teaching basic math and English in the context of this program. Thus there are no prerequisites for this certificate program. However we will administer the Accuplacer Test at the beginning and end of the program in order to evaluate how well we have succeeded. The certificate will consist of 18 credits that will train students in many of the techniques and methods used in the technical industries while introducing them to the workplace expectations of the regulated industries and the scientific principles behind the techniques they are learning while preparing them for work and/or an AS degree that will transfer to a 4 year college<sup>4,28,32,33,34,35,36,37</sup>. We will recruit through an ambitious program at the local High Schools to excite students about the opportunities in the biosciences field and through the State's One Stop Program for retraining of the unemployed.

The bioscience sector of NJ is unique in its diversity. In 2007 NJ "Ranked first in Breadth of Biosciences and 2<sup>nd</sup> in Depth"<sup>2</sup>. It "is the only state with specialization in all 4 bioscience sub sectors" i.e. 1. Pharmaceuticals, 2. research testing 3 medical laboratories, devices and equipment, and 4. chemicals<sup>2,34</sup> and as such preparing Technicians for NJ jobs requires a generic approach. Our program is based on developing the skills that NJ Bioscience employers identified as critical<sup>35</sup>. (It is notable that the employers do not identify any particular technical skill or skill set and that they emphasize that the skills listed below are required at every level of employment in the industry<sup>35</sup>).

**"Adaptability"** defined as, "critical thinking/problem solving, lifelong learning skills, flexible role orientation"

**Information Management and Communication/relationship building skills..** especially prioritizing information, cultural understanding, the ability to communicate ..using .. written, verbal .. and presentation skills"

**Interdisciplinary skills** especially multiple sciences and mixtures of science and business skills.. project/product management and entrepreneurship skills"

**Math/science/engineering/technology skills**, especially the ability to use and understand new technologies.

The skill set outlined in the Heldrich report<sup>35</sup> cannot be taught in the passive environment of a traditional classroom but must be taught in a workplace styled inquiry based environment that we wish to create. It also our belief that an active inquiry based learning environment will be an attractive option for non traditional bioscience students.

### **Goals and Objectives**

**Goals.** This QA Certificate program is designed to 1. recruit 2. educate and 3. set students on a career track for employment in the diverse Bioscience Industries in Northern New Jersey

**Objective 1. Recruit students.** Preliminary efforts to recruit students has revealed that the 2 populations we intend to serve require at least 2 separate approaches. The mature prospective student I have interviewed want career opportunity specifics – salaries, DOL data etc; the recent HS graduate is turned off by “a good solid job” opportunity and is seeking an exciting future i.e. despite enjoying and succeeding in their HS science courses they major in journalism, business, art. We plan to recruit mature students through NJworkforce programs including one-stop as well as advertisements in areas that attract adult education seekers. We will develop a WEB Page that contains the information and information sources that our mature students require. See Appendix ?. Recruitment of HS students will require working with the area HS implementing some of the programs that others have reported to be successful e.g. running summer camps in biotechnology and medical diagnostics; preparing programs that we can take into the HS classes that give us an opportunity to present the glamorous and interesting side of bioscience. Introducing some of our programs into the HS curriculum for college credit: HS teachers will assist us in teaching the course at Bergen and then we assist in adapting the course for teaching in the HS by the trained HS teachers. It is expected that many of the modules we will develop can be used as stand alone HS modules for our HS workshops.

In year 1 we will

- Enroll 18 students in the QA program and place 9 in jobs/internships/AS programs
- Develop the WEB Page
- Develop advertisements and distribute them
- Train 2 HS teachers in Intro to QA
- Assist 2 HS teachers to teach Intro to QA Spring Semester
- Establish a biotechnology Summer Camp – enroll 10 students for summer 2010 and utilize 2 HS teacher as assistant in order to train them in methods of biotechnology
- Take the popcorn project into 5 Hackensack HS classes (expose 100 students x% black, x% Spanish)
- Train 1 BCC faculty member to teach in the QA program – by utilizing them as assistants in teaching

In Year 2 we will

- Enroll 42 students in the QA program and place 21 in jobs/internships/AS programs
- Expand the biotechnology camp program to engage 30 students – Train 4 HS teachers as assistants in the camp and train them in methods of biotechnology
- Adapt 2 of the QA modules for use in HS class and present to 10 classes (200 students)
- Train 2 more HS teachers in Introduction to QA

Train 1 additional BCC faculty member to teach in the QA program

In year 3

Enroll 66 Students in the QA program and place 30 in jobs/internships/AS programs  
Expand the biotechnology camp to engage 60 students – Train 6 HS teachers as assistants in the camp and train them in methods of biotechnology  
Adapt 2 more of the QA modules for use in HS class and present workshops to 20 classes (400 students)  
Offer Project Management in the Spring QA Curriculum and Train 2 HS teachers  
Arrange to have Project Management taught in High School for College Credit.  
Train 1 additional BCC faculty member to teach in the QA program

Objective 2. Prepare students for employment in the regulated industries of NJ.

We propose to teach the skill set articulated by NJ Bioscience companies<sup>34</sup> i.e. **Math Science and Engineering** skills are the basis of all the QA courses and will be learned as students master common laboratory and QC techniques such as centrifugation, protein purification, immunoassay, pH and ionic measurement, HPLC, simple statistical methods used in manufacturing, spectrophotometry and metrology: **Information and management skills** will be acquired through using an Electronic Laboratory Notebook for all tasks will ensure that students are familiar with computer skills Word and Excel, can summarize data, draw conclusion and are familiar with electronic documentation under 21CFR section 11 requirements; All activities will be conducted in workplace environment that includes time clocks, and strict adherence to SOPs, GMP/GLP, and OSHA & ECRA guidelines. Training will include extensive training in job application and handling of issues such as reporting failure: The final course “Protocol Writing,” will hone **interdisciplinary skills and Adaptability Skills**, students working independently in groups will write the protocols for, develop, manufacture, QC, package and label and prepare for shipping a solution of 3% H<sub>2</sub>O<sub>2</sub>. At least 1 of every 5 hours of class time, students will discuss and critique their work -- with emphasis placed on problem solving.

Year I.	Develop 75 interactive modules (Appendix 2) that will teach interactively the skills and knowledge addressed in the curriculum.
Year II.	Refine and expand the interactive modules Develop 2 additional faculty members that can teach the programs
Year III	Prepare the modules for publication Prepare 2 more faculty members that can teach the programs

Objective 3. Students will enter the workforce and/or continue into an AS in science program. Students who complete the program may remain at Bergen and earn an AS in Science which will be transferable to regional 4 year colleges (Appendix 3). Students who wish to work will be placed in internships or employment. The companies that have promised internships all support employee job related training so students would not have to choose between work and education.

Year I	Place 9 students in internships or employment and monitor Establish an AS in Science that accepts all QA credits Develop articulation agreements with NJIT, Stevens and Paterson
Year II	Place 18 students in internships or employment and monitor See at least 1 student go on for an AS in Science

Develop articulation agreements with 2 other colleges  
Year III Place 30 students in internships or employment and monitor  
Have at least 3 students continuing on for an AS in science

#### **Objective 4. Evaluation**

1. The ability of the program to improve basic math and English Skills will be measured by administering the Accuplacer Test at the beginning and end of the program. Our goal is that all students will place high enough on the Accuplacer by the end of the Certification to place out of remedial courses.
2. Acquisition of mathematical and scientific skills will be ascertained by classroom practical examinations, observation, evaluation of ELN and employer reports.
3. Adaptability to the workplace will be ascertained by ELN maintenance, Time Clock and attendance and program utilization of standard employee evaluation forms that rate work habits and ability to work on a team. .
4. Success of HS programs will be ascertained by
  - Evaluate Camps by increase in the #s of students attending the camps
  - Evaluate success of HS class presentations by increase in the
    - # of Hackensack students entering the BCC Biotech and QA programs
    - # of Hackensack students enrolling in the HS QA College Credit Course:
5. The efficacy of Job training will be ascertained by
  - Employer 3 month, 6 month and/or 12 month evaluations
  - The number of requests we get for graduates i.e. the numbers of our students employed
  - The number of employees from firms where we have placed a students who decide to attend BCC
  - Evaluation of program by students on 1 year followup
6. Job Interviewing skills.
  - The BCC job training advisor will interview all students during the last semester and grade them.
7. Efficacy of training of HS teachers by survey of participating teachers to ascertain how much of the new material has been incorporated into the classroom teaching.

**Objective 5 Dissemination of Materials.** Notebookmaker, the developer and manufacturer of the ELN that we are using has agreed to collaborate with us on adapting our materials as well as relevant NSF developed materials to disseminate with a special edition of the ELN for colleges. This Text will be modifiable by the teacher using the ELN in their class so that the Text can be added to or modified as their specific needs dictate. See letter of agreement in Appendix 2. We will prepare to present at Bioman and BioLink Conferences. We plan to video some of the QA classroom modules and make the video's available for conferences as well as for viewing by teacher's wanting a more graphic demonstration of the interactive teaching strategy.

#### **PROJECT OUTCOMES**

**Recruitment.** We will run programs for over 800 students of which we estimate >60% will be minority students, engage/train over 35 teachers and recruit a total of 126 students over the 3 years of the grant and be attracting students at the rate of 66/year through the strategies listed below .

1. We will develop a web site that contains the bioscience career choices with skills and compensation and gives information about internships and jobs as well as listing financial aid sources for the program.
2. We will develop advertising that can be distributed through the High and through Ciarco Center and NJworkforce programs.
3. We will establish a Biotechnology Summer Camp that will train 30 students/summer and train 4 HS teachers/year. Many report that HS teachers trained at college camps become recruiters, but I know of no data.
4. We will establish a summer medical diagnostics Camp that will develop a test for smoking.
5. We will develop or adapt 4 different interactive programs that we can take into HS classes. Over the course of the grant we will contact 700 students
6. We will train 6 HS teacher to teach Introductin to QA at the High School level for College Credit.

**Modules:** We will develop 75 modules (Appendix 2) that teach students the following

1. Recognize the critical importance of Quality Assurance and understand the various organizations and methods that are used to insure Quality
2. document in accordance with GMP/GLP
3. follow, critique and write SOPs
4. Use Excel to analyze data and convert it into graph form
5. Understand and be able to use simple statistical tests to analyze data
6. Implement all safety regulations
7. Make and quality control chemical solutions
8. Understand the principles behind and perform electrophoresis, Elisa testing, centrifugation, protein purification, HPLC, PCR
9. Utilize spectrophotometry to track and identify chemicals
10. Use Word and Excel facily
11. Solve appropriate problems appropriately
12. Work effectively on a team
13. Understand the structure of a Bioscience Company and the critical role SOPs form in communicating between divisions.
14. Read a manual for an instrument and following instructions install it, validate it and utilize it for testing
15. Identify and report failure
16. Interview for a position
17. Pass the accuplacer test and continue onto an AS
18. Develop the skill to understand, validate and operate the scientific instruments listed in Appendix (2)

**Graduate.** We will prepare students 63 students for employment

**Job Placement** We will assist all graduates in gaining employment by implementing the following

1. We will visit Human Resources at 40 Companies in North and Central Jersey and maintain contact with them via email

2. We will maintain contact with graduates by email and by inviting them back to talk to students and attend conferences.
3. We will host 5 Conferences that are attractive to our targeted industries and provide certified training for their employees
4. We will continue membership in ASQ, GMPTEA and NJBiotech
5. Our advisory Board have each promised 2 internships.—we will seek more
6. We will arrange for students to complete the course while on the job so that we can place students during their education

#### **Bridge to further education**

1. Establish QA AS in Science
2. Demonstrate via the Accuplacer that the program improves the basic math and English skills
3. Articulate our program with at least 4 Four year NJ Colleges

#### **Dissemination**

1. Publish our results through BioLink and BioManufacturing
2. Publish the 75 modules through NotebookMaker
3. Make our materials through the BioMan/BioLink Websites
4. Present at BioLink, BioMan and other appropriate Conferences

#### **Program Deliverables and Activities**

Our QA Certificate holder would develop 80% of the skills required to fulfill the biomanufacturing jobs listed in Fig 1 as estimated by Northeast Biomanufacturing Program, leaving only 20% of the skills unaddressed. Many of our prospective students already have these specialized skills; some of these skills are so specific to a company that they need to be acquired on the job, and some through job specific training in a technical area at BCC or an area college.

#### **Program Activities and Deliverables**

**The Starting Point.** The QA Certificate curriculum has been approved and is currently listed in the college catalogue in the Science and Technology Division. Currently the courses are not being taught, although we are hopeful of starting a small class in Spring 2008. Interviewing of over 20 students and njworkforce applicants in an effort to start a Saturday program in Fall 2008 indicated that these consumers, because they are job oriented need an intensive one semester program that gets them into the workforce quickly. Currently the QA courses are not part of an AS degree program that would articulate transfer to a 4 year college, but the Science and Technology Division expects no problem with these courses being accepted towards an Associates and Science and Dr. Ranky an incoming member of our Advisory Board and Prof at NJIT is currently working with us on articulation with NJIT See letters of support. We will also work on articulation with Stevens and Paterson and other schools in our district.

**Recruitment/Marketing.** The STEM Pathway. The PI spent a considerable part of her time this summer on recruitment. BioLink and BioMan Conferences confirmed the observation of all that we need to strengthen the STEM pathway and we need to make HS students aware of what a career in Bioscience would be like so that they enter college at least willing to consider what science has to offer.

We have agreed to collaborate with Hackensack on 3 different levels (Appendix 3)

**Train High School Teachers in Classroom Biotechnology/Bioscience techniques (total of 17)** by utilizing teachers as paid classroom assistants in the Quality Assurance Classes and in the Summer Camp Programs. .

**Bring Interactive half day workshops to the High School Science Classes exposing 825 students and 35 teachers to career opportunities and real life science endeavors.** The Popcorn project that I participated in at BioMan is the first one that I plan to bring to the HS and I would hope to develop or learn of several others that are just as participatory. Since I am planning all classes to be as interactive as the popcorn project is, I believe that I can modify some classes for HS and hope to use students to present. The PI has already planned for her Disease of the Month Club students to bring their presentations and to discuss their career plans with the science classes during Fall and Spring 2008.

**Offer college credit QA courses at Hackensack HS.** BCC has been asked to offer the Intro to QA program in the HS *Letter*.

**Summer Biotechnology Camps (>60 students)** would be offered at the end of the first year. We expect that using HS teachers as assistants in the camps at a ratio of 1 teacher to 10 students would be desired, so training of HS teachers should be sustainable from tuition. In addition we would be training HS teachers in Biotechnology techniques that they could introduce to their classrooms and developing an information pathway between the college and the HS.

**Industry:** We will establish relationships with 40- 60 local industries/organizations that would be interested in QA trained students. We will set up a mailing list with especial attention on smaller biotech employers and keep these companies aware of our graduates and conferences. Industry should be able to provide us with students, with employment opportunities for students, with faculty and with the ability to keep our course materials current. We will make an average of >20 visits/year.

**Unemployed/underemployed/ambitious.** Working with Mr. Larry Greenberg, Director of BCC Web Sites we will expand the outlined WEB site (Appendix 1). We will work with NJ workforce (Appendix 3) to structure the courses in such a manner as to maximally accommodate their needs –a 1 semester course and we are willing and able to offer this when our science laboratory renovations are completed in Fall 2009.

## **Curriculum Development and Course Structure**

**Curriculum Goals.** Appendix 2A outlines what students will accomplish in each course but it does not address how to teach these subjects interactively. Appendix 2B provides an outline of the manner in which we hope to approach the course material in the 1<sup>st</sup> two weeks of Introduction to QA and QC in Biotechnology I. These modules were developed for a Saturday Worksession that runs from 8 am to 4 pm with 30 minutes for lunch – there is no effort to separate the 2 courses and there is no lecture and laboratory rather, the tasks for the day are designed to teach the concepts while training students in problem solving. In response to the many reports of employers that they need workers who can comply with GMP/GLP, we will try to make the class and grading reflect anticipated job performance, thus there will be no lecture/lab and no multiple choice exams: 10 % of class grade will be promptness – there will be a timeclock. Another 10% will be attendance (there will be 1 excused absence/semester). 10% will be appropriate behavior towards others, 10% adherence to safety guidelines (1% will be

subtracted for every infraction; 10% presentations. 30% will be the laboratory notebook and 30% practicals. The thrust of the courses will be to make students realize that they cannot perform the given tasks without understanding the basic scientific principles behind their task and the instrumentation required for the task, GMP/GLP regulations, and the business goals, and without the ability to work and communicate with their team and with the rest of the company. The ELN will be downloaded onto a portable external hard drive which will be provided to all students all text materials developed and adapted by BCC will be available for download to the disc. Hence students will not have to purchase texts and will have the ability to access the ELN license when outside the school – if we did not go this route students would not have access to the ELN or the class material when not using the laboratory PCs. Also the school can only service equipment purchased by and owned by the school – which the hard drive would be.

**Employment Skills.** In many reports *cite*, the Bioscience, Biotechnology, BioManufacturing Pharmaceutical Industry has emphasized that familiarity with the basic scientific principles and technical skills are only 1 of 5 or 6 basic skills required. The others are problem solving, team work, ability to embrace change, written and oral communication skills, understanding of the business goals of the company and the different roles of different divisions in meeting these, and ability to operate under GMP/GLP and safety regulations. We plan to address development of the soft skills through development of role playing scenarios, by having professionals come into class to discuss real life scenarios, and by utilizing the skills of our IST Team to develop team spirit and provide job application skills. At least 1 class hour and 1 assignment hour of every week will be devoted to these soft skills, i.e. for career development looking at job opportunities on the WEB, sharing leads with the class, attending ASQ meeting or conferences, visiting companies, practicing job interviews, writing resumes etc. and devoted to handling of common crisis or problem situations: i.e. what to do when your supervisor wants a false report. How to report a problem. How to handle harassment. What to do about a co-worker who does not do his share. How to handle a family emergency. How to ask for guidance if you received a less than favorable report. How to respond when you receive criticism. How to analyze what you need to do to keep moving up. What are your interests.

**The Program.** The 18 credit, 1 semester, Certificate Program comprises 28 class hours/week. Students will attend class 4 days a week from 8 am to 3 p.m. with 50 minutes for lunch and a 20 minute morning break at 10. As unemployed they will be responsible for making job applications, so that a free day for job searching makes sense. As a full teaching load at BCC is 15 credits, teaching the program will require 2 professionals. For the 1<sup>st</sup> semester, PI will be responsible for 13 teaching hours (She will carry 7 hours of release time to carry out the additional tasks of the grant/program: an instructor will take 15 credits. Both PI and Instructor will spend their mandated 3 office hours/week in the classroom this makes sense as a large part of the training is in counseling re job placement and employment skills– this will provide 6 hours/week during which time 2 instructors are in the class and PI has observed that the students who most need counseling do not attend office hours but are very easily counseled during laboratory sessions. PI will be present in the classroom or in her office nearby during >75% of total classroom hours so as to direct the program.

**Faculty Development** The instructor or instructors hired to teach 15 credits in the QA program will be trained on the job by the PI. It is our plan to involve current BCC Faculty as instructors



Distributedx1000														
QA Course taught at HS						1				2				3
# Stdnt HS QA						20				40				60
ID HS teachers for QA														
# Presentations to HS Classes		1	2		4	4	4		4	4	4		6	33
Biotech Camp enrollment					12				24				36	72
WEB Page	X	x	x	x	x	x	x	x	x	x	x	x	x	
# HS Students Exposed to Presentations*		25	50		100	100	100		100	100	100		150	825
<b>Offer 1 Semester program</b>		x	x			x	x			x	x			6
<b>Offer Sat or Eve Cert Courses</b>						x	x	x		x	x	x		
<b>Modules</b>														
Curriculum Outline	x													
# QA Modules Developed Reworked	15	20	20	20	15	60	60	15	15	60	15	60		75
QA Module to NotebookMaker							X		X		X		XX	
NBM Publishes														XXX
Modules on WEB														XXX
<b>Faculty Dev</b>														
# HS teachers trained to teach QA in HS					2				2				2	6
# HS Teachers Trained in Camp					2				4				4	10
# BCC Faculty Trained					1				1				1	3
<b>Career Development</b>														
<b>BCC QA AS Program</b>	X													
# Students Placed in					3				6				12	21

jobs/internships														
QA Conferences at BCC				1		1		1		1		1		5
# Students in AS program						1				3				4
Articulation Agreements		1			1			1			1			4
# of New Company Visited	4	3	3	3	3	3	3	3	3	3	3	3	3	40
# Companies revisited						3	3	3	3	3	3	3	3	24

- Assumes 25 students per class

### Roles and Responsibilities of the Personnel

Dr. Judith Fitzpatrick will bear the primary responsible for meeting all project goals outlined in the project timeline. She will develop the 75 QA modules and set up the QA classrooms. She will teach the first 2 programs with the assistance of a BCC instructor in training. She will deliver the popcorn experiment to the first three HS classes and supervise the program in subsequent years. BCC trained QA faculty will take over the HS program in the second year. They will use students as assistants in the HS classroom presentations. With the assistance of the then BCC faculty in training, and the Hackensack HS teacher designated as assistant for Intro to QA, she will liaison with Hackensack High School supporting their designated teachers in adapting the Intro to QA module to the HS classroom. With administrative assistance she will organize and host 5 QA symposia over the course of the program. In year 2 and 3 she will initiate relationships with Fairlawn HS and Englewood HS. She will personally visit 12-24 Bioscience companies/year and with administrative assistance keep these companies informed of our programs, send them resumes of our students that are ready for placement, monitor the progress of our students who are placed there and keep abreast of their industrial needs through involving them in our advisory board. She will serve as QA Advisory Board Coordinator. She will prepare materials for publication.

Dr. Joan Tscherne will teach the first Biotechnology Camp and remain the coordinator of the Camp program. It is projected that local HS teachers will be recruited to teach the course in future years.

Dr. Amarjit Kaur will serve as liason between BCC and Notebookmaker and will bear primary responsibility for formatting of materials for WEB access, for publication, and for formatting for Notebookmaker.

Dr. Mauro Marzocco will initiate a QC course that leads to ASQ Quality Technician Certification for engineering students. He will lead the effort to obtain AS credit for the QA courses and the articulation process. In QC for Biotechnology I and II he will teach the modules that address electrical circuitry.

Dr. Jack Waintraub. Dr. Waintraub will serve as outside evaluator for the project, conducting an ongoing formative assessment and providing quarterly feedback to assist the PI and project team in identifying and alleviating potential impediments and conduct the summative evaluation.

The Advisory Board represents the best GMP/GLPQA talents the Biosciences Industries of N.J. and will continue to advise on the curriculum and will contribute substantial resources including internships and job opportunities; see attached letters of commitment.

Hafeez Ansari, Ph.D., is former V.P. Technical Affairs for Quest International, the Mount Olive, New Jersey division of Imperial Chemical Industries. (ICI) and currently an internationally recognized consultant in the food and fragrance industry. Ernest Carabillo is a Pharmacist, lawyer, former Director of 3 FDA Agencies and founder and long term President of Expertech Associates, an internationally renowned Consortium that provides regulatory advice and strategies to the medical device industry . Steve Mottolo is V.P. of Operations of Genzyme Corporation, a Pharmaceutical and Chemical Company with Yearly Sales of over \$1 Billion Joel Lipset is Global Head of the Instrumentation Laboratory Inc, QA, Worldwide Complaint, and Product Integrity. Eugene Reilly, is Manager, Pharmaceutical Sciences Quality with the Pharmaceutical Sciences department of the Schering-Plough Research Institute. Thomas Davis, DVM, Ph.D. is former head of Toxicology at Schering Plough and currently serves an international consultant on Regulatory Affairs for Schering Plough, Ranbaxy and others.

Salvatore Mastroeni, Director One-Stop Career Center, Bergen County Technical Schools and Michael Wocjic, Assistant Superintendent, Curriculum and Instruction, Hackensack Public Schools will secondary education representatives will nominate high school faculty for certification training and facilitate the STEM pathway in the districts to the community college. At present, Michael Wocjic, Assistant Superintendent, Curriculum and Instruction, Hackensack Public Schools, is representing this portion of the committee. Mark Porto, Principal of Hackensack HS has expressed great interest in our program and initiated the initiative to offer Intro to QA at the HS. He is currently supporting the PI's Disease of the Month Club students giving their presentations about the various diseases to the HS Anatomy and Physiology Club as a way to establish links between the HS and college community.

Mr. Edward Renz, a teacher at Hackensack HS who has a masters in project management is our liaison at the HS and is scheduled to be the first to be trained to teach Intro to QA at Hackensack HS.

Faculty to be trained may be selected from existing faculty, new hires or adjuncts with appropriate credentials that are selected from the local industries.

### **Plan for Sustainability**

The Certificate and Associate in Science Degree in QA will complement the college's already successfully launched Biotechnology, Manufacturing and AS Engineering Programs and be sustained by tuition. The NJ workforce initiative has identified QA training as a high priority training area and will support it by covering tuition for the unemployed and underemployed. Our

Advisory Board has already promised 10 industry internships/year and an inside track on jobs. Bergen County is home to more than 2,500 biotech, manufacturing, and supply chain/logistics companies that require employees attuned to and trained in QA and QC. These companies employ over 40% of the county's workforce (Profile of the NJ Meadowlands Regional Economy and Workforce, 2007). We expect that establishing relationships with the bioscience companies in the region will provide us with job placements and recruits to the program. High school students will be recruited through a health and sciences pathway that already exists between the college and local school districts as well by our 3 HS outreach programs that will reach more than 1000 students: the HS workshops, the Summer Biotechnology Camps (which will be self supporting from tuition) and the College level Intro to QA course that will be self supporting, we will introduce at Hackensack and other HS. Working closely with the state's and county's economic development agencies, the college opened a new South Campus which opened Fall of 2008. The new campus construction includes a 70,000 square foot facility for classrooms and laboratories to meet the workforce education and training needs of an estimated 29,000 new positions opening up in the region. With a light rail passenger stop on the South Campus, the facility will be connected to the entire North Jersey/New York Metropolitan area. Furthermore, the South Campus, as part of the Meadowlands Redevelopment effort is actively involved in and supported by the North Jersey Economic Innovation Alliance, an eight county workforce development initiative that involves eight community colleges, five major universities, and a wide range of public institutions and private industry partners. A critical skill set targeted for development by the Alliance is QA and QC. This project will serve a vitally important purpose in moving the Alliance forward. We are members of TEA/GMP, ASQ and Biotech NJ organizations that will provide exposure and training for our students and speakers for our program. Dr. Paul Ranky a world respected leader in advanced manufacturing has agreed to serve on our Advisory Board in December 2008 and in his position as professor of Industrial and Manufacturing Engineering has agreed with Ernest Geskin his department chair to facilitate an articulation agreement with NJIT. Our acting Dean, PJ Ricatto has advised us that he will negotiate an articulation agreement with Stevens Institute with whom he has negotiated such agreements previously.

The college's modern Manufacturing facility can be utilized for teaching and meetings; BCC has access to a large community of highly educated individuals in the QA QC field who assist in teaching and in assuring that our program is continually adapted to the needs of industry, the program is expected to flourish, sustain itself, and grow in value and importance long after the NSF ATE start-up investment. It is the long term objective of Bergen Community College to become a Regional Center of Excellence for QA. Once we have successfully launched this program it is our intention to expand to offer QA in Health Services, Food Science, Engineering and Computer Sciences. We are centrally located to serve the Technological community of NJ; many of our students and faculty have close ties to the industries that this program will serve. We plan to develop programs that bring together industry our current and former students and educators from HS and College. BCC has an exceptional Media Department that will allow us to adapt the program to be shared with other regional institutions/industries. and a track record of disseminating programs. In addition, this program complements the new Biotechnology Degree program and both are actively supported by industry leaders and K-12 partners who were instrumental in their development.

## Evaluation Plan

Ongoing project monitoring and evaluation will be conducted by the Advisory Committee, the Dean of Sciences and Health, and the Academic Vice President. The budget includes \$500/module (total of \$37,500) for evaluation of module content by Industry Professionals. In addition, Dr. Jack Waintraub, PE, chair of the engineering department at Middlesex Community College and PI of the NSF funded Center for Advanced Technological Education there, has agreed to serve as external evaluator of this proposed project. Mr. Waintraub is a former Chairperson of the Engineering Department at Middlesex Community College and former Executive Director of the New Jersey Center for Advanced Technological Education. Along with the Advisory Committee, his feedback will inform development and refinement of instructional modules and he will serve a leadership role in the collection and analysis of the qualitative and quantitative data that will serve both formative and summative evaluation.

Working closely with project PI and the QA industry advisory committee, Dr. Waintraub will guide the ongoing formative assessment beginning in the first year of implementation. This will concentrate primarily on: (a) attainment of planned objectives and tasks, (b) impediments to progress, and (c) corrective actions that might be required. The project management team will also work with Bergen Community College's Center for Institutional Effectiveness and Research to develop a system to track student performance in the promised internships and facilitate development, collection and analysis of both qualitative and quantitative data on three levels. At the first level, working closely with partners on the advisory committee, the project team will collect data to facilitate formative assessment efforts. Over the first year of implementation, these will focus on the extent to which planned objectives and tasks are accomplished as well as on impediments that may arise and corrective actions that might be required. They will regularly provide the external evaluator with this information for analysis and feedback. This is concerned with ensuring the:

1. The program is consistent with identified needs of regional biotech industries and with recommendations of nationally cognizant organizations, especially the Biomanufacturing Industry Skill Standards. Dr. F is currently serving on the NJIT advisory Board of the NJ CHE Innovation Partnership Institute which is charged with evaluating the needs of NJs Advanced Manufacturing companies and required educational content.
2. The Instructional methods and materials that are being developed are inquiry based and consistent with principles of effective education as well as national standards of QA and QC
3. Student academic performance levels and program satisfaction levels are high;
4. Industry partner satisfaction concerning student and technician preparation for and performance on the job.
5. Students are afforded internship and employment opportunities.

The second level involves overall student performance and specifically concerns:

1. Enrollment, retention, and graduation rates of students in the program.
2. Student performance as indicated in logs and journals, projects and production efforts, and course quizzes and tests
3. Attendance and activity reports,
4. Interest surveys and workplace learning experience feedback.
5. Student assessments of course content, laboratory experiences, and job shadowing, and cooperative education workplace experiences.

6. Job performance as documented by teacher and supervisor ratings.

7. Aggregate student performance, including pre and post-test Accuplacer test results, course grades, completion time, rate, employment rate in manufacturing and transfer rate to four-year degree or higher programs in SMET.

With the first cohort's completion of the program as the project moves through the second year, summative evaluation data will also be collected for Dr. Waintraub, who will provide leadership in the overall analysis of qualitative and quantitative assessment.

(1) pre and post results from the Accuplacer college placement test.;

(2) program enrollment and retention;

(3) Student evaluations of course content, laboratory experiences, and co-op education;

(4) Co-op or internship performance in the workplace as documented by faculty and supervisor ratings;

(5) performance as demonstrated in course grades, proficiency assessment, work portfolios, and capstone projects.

(6) Industry satisfaction with technician performance on the job.

By the conclusion of the final project year, full documentation of the extent to which projected outcomes have been achieved will be available. Findings will be analyzed in comparison to information on previous student groups from Hackensack High School manufacturing program. A final evaluation report will be submitted to NSF at the conclusion of the project.

Evaluation will continue with data collection and analysis through the college's Office of Institutional Research in the context of the college's annual review of and report on performance and outcomes, thus providing a foundation for additional Bergen County high schools to partner in the initiative.

### Outcome and Measures

	Outcome	Instrument/Measure
Recruit	# of students	# of students
	# of inquiries	# of inquiries
HS Workshops	Stimulate interest in bioscience careers	Pre-workshop questionnaire about science workers followed by post session questionnaire.
College Credit QA	Program Attractiveness Recruitment Efficacy	# of students signed up # of these students who report that they will enter a College Science Program
Web Site	Advertises program	# of hits/ # of repeat hits
NJ Workforce	Create Skilled Worker	# of graduates who are employed in bioscience or related industry jobs within 1 year of Cert.
Program Training	Basic skills	Accuplacer
	Technological skills	Classroom Evaluation
	Workplace skills	Classroom Evaluation
	Reliability, promptness	Employer evaluation
	Communication, team work	BCC job placement interviewer eval

	Employer Satisfaction	Survey of Employers/job evaluations
	Student Satisfaction	Student Evaluations
Summer Camp	Ability to interest students	# of students enrolling after year 1
	Training of HS teachers	How much do they incorporate @ HS level by survey
Modules	Covers Critical Subjects	Industry evaluators reports On the job performance evaluations
	Educational effectiveness	Student evaluation # of students completing the program
Faculty Dev.	Effectiveness of Training	Faculty evaluation of their training Student evaluation of trained Faculty
Job Development	Job Placement	# of students placed in jobs # of students receiving high marks from employers
Bridge to AS	# of students going on the AS	# of students going on the AS
Liaisons with Industry	Adjuncts	# of adjuncts inquiries that we receive
	Jobs/Internships	# of jobs and internships
Conferences	Relevance	# of returning attendees, survey of attendee satisfaction
	Networking	# of students who make contacts with industry at the conferences

## Dissemination Plan

Project products and outcomes will be widely disseminated through a number of means:

- o Materials will be formulated for distribution by NotebookMaker
- o Adjunct faculty, all of whom are working in QA at regional companies, will bring the program as well as products to their workplaces.
- o Teachers from participating HS school districts who receive the certification or Biotechnology training will implement the introduction of the material into their classes and advertise the program
- o Delivery of presentations and poster sessions at NSF ATE conferences and workshops.
- o Participation at meetings with Manufacturing, Education, and related Interest Groups of the Bergen County Workforce Investment Board.
- o QA Advisory Committee, industry representatives as well as members area school districts, will promote the program and materials at their own organizations.
- o PIs will present at the New Jersey Department of Education's annual "Generation Next" conference for vocational and technical education professionals, at the "Best Practices" conference sponsored by the New Jersey Council of Community Colleges, and at the Technology Council of New Jersey meetings and conferences, BioLink and BioMan.
- o Bergen Community College is a member of the Northern Jersey Economic Innovation Alliance (NJEIA), an economic and workforce development initiative that includes major

industries, public and private agencies and organizations as well as all the colleges and universities in the 8-county North New Jersey region. Since QA and QC are targeted skill sets for key regional industry groups, the program and the products will serve as a vital means to further Alliance goals.

- o Project team will participate in the network of New Jersey's ATE Center at Middlesex County Community College.
- o BCC will promote the program through press releases, and announcements.
- o Materials Developed will be made available on the BCC Biotech and Biotech QA/QC website as well as Bio-links for use beyond the region.
- o The college will sponsor QA and QC symposia in cooperation with regional industry and organizational partners.

Local Industries will be visited and given program information and evaluation materials.

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## FACILITIES, EQUIPMENT & OTHER RESOURCES

**FACILITIES:** Identify the facilities to be used at each performance site listed and, as appropriate, indicate their capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Use "Other" to describe the facilities at any other performance sites listed and at sites for field studies. USE additional pages as necessary.

### Laboratory:

### Clinical:

### Animal:

### Computer:

### Office:

### Other:

**MAJOR EQUIPMENT:** List the most important items available for this project and, as appropriate identifying the location and pertinent capabilities of each.

**OTHER RESOURCES:** Provide any information describing the other resources available for the project. Identify support services such as consultant, secretarial, machine shop, and electronics shop, and the extent to which they will be available for the project. Include an explanation of any consortium/contractual arrangements with other organizations.

QA will have access to all the Science and Technology equipment and resources currently supplied by BCC. BCC is currently adding more than 5

Laboratories. It is planned that QA will occupy a dedicated up to date GMP dedicated laboratory so that all equipment in the QA lab will be maintained according to FDA guidelines and all health and safety guidelines rigorously adhered to.

Not Applicable

Not Applicable

The Chemistry department maintains 24 laptop personal computers that connect with the college's network and the Internet. These will be

used by students in the Biotechnology Quality Assurance classes. However, when the program moves to dedicated space in the manufacturing building these computers will not be available. The BCC library contains 132 computer stations for the use by students 7 days a week. All full time faculty have offices and the services of departmental secretaries. Adjunct project faculty drawn from industry partners will receive similar support. In addition while we remain in the Science department laboratories we will have use of

HPLC instrumentation in chemistry  
DNA sequencing and DNA analysis equipment  
2 Autoclaves  
3 DI water purification systems  
24 laptop computers with network connections  
Smart classrooms.

The advisory committee of industry and school district partners provide rich resources as noted in letters of commitment.

All BCC classrooms are equipped for internet access and computer based presentations.

The Center for Instructional Technology and Media Services at BCC provide technical assistance, training, and support for production of interactive instructional methods and materials.

## **FACILITIES, EQUIPMENT & OTHER RESOURCES**

### **Continuation Page:**

NSF FORM 1363 (10/99)

### **LABORATORY FACILITIES (continued):**

QA expects to utilize BT equipment (BioRad Smart Plus Spectrophotometer and Centra CL5R centrifuge) on an as needed basis. For Microbiological projects the program will utilize the renovated Microbiology Labs equipped with the following equipment: Water Distillation, autoclave, icemakers, incubators, microscopes and waterbaths. Chemistry labs possess HPLC.

### **COMPUTER FACILITIES (continued):**

week. In addition there are free-time computer laboratories in each building. Library and free-time labs have equipment as well as furniture that ensures accessibility for students with disabilities. BCC provides 24/7 service for its WEB Based programs.

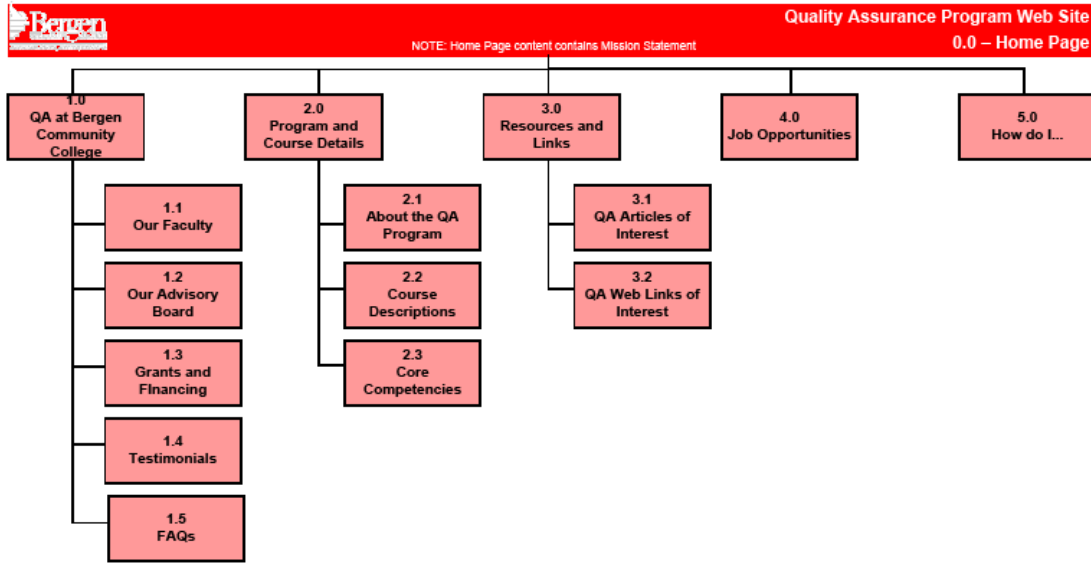
Programs available for all Faculty use include: Office, Course Management Software, Turnitin 2 for marking student writing and presentations. Globalscape Studio 4, uLead Video Studio 9, Authorware, Flash and Shockwave Players, Hot Potatoes, Respondus, Adobe Photoshop. As appropriate, students have access to these programs as well as Jaws and an extensive array of additional assistive software and technology. BCC also supports the production of all class materials in MP3 format ? PI has her A&P class on as available at

<<http://www.screencast.com/users/J.Fitzpatrick/folders/Default>>

### **OTHER RESOURCES (continued):**

Conference facilities support regional dissemination meetings and symposia for project findings and curriculum products

# Appendix I Web Page Outline



Header Legend:		Item Legend:		Office of Information Technology Web Services Department Page 1 of 2 Last Modified On: 9/2/2008						
Global Footer	Home (Parent) Page	Child Page	Existing Page		New Page	Future Page	Redirected Link	Existing Content	New Content	Future Content

## Appendix 2 A. Program Curriculum

**Bergen Community College**  
**Division of Science and Health**  
**Course Syllabus**

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**Course Title:** Quality Control in Biotechnology I

**Prerequisites:** None

**Course Description:** Introduction to Quality Control in Biotechnology I is designed to familiarize students with the instrumentation and methods commonly used to insure QC in the Biotechnology, Pharmaceutical, Personal Care, Food and related Industries. Students will become familiar with the safety standards, documentation methods, instrumentation and regulatory agencies that set the standards. Students will learn to evaluate processes for adherence to industry safety and quality standards and to maintain a Laboratory notebook that meets FDA standards.

**Contact Hours/Credits:** 2 lectures 4 labs, 3 credits

**Textbook:** Basic laboratory Methods for Biotechnology, Lisa A Seidman and Cynthia J. Moore Prentice Hall

**Specific Objectives:**

1. Students will be familiarized with the Methods and Applications of Biotechnology and the organization of Biotechnology Companies. Students will be evaluated by periodic notebook collections and peer and instructor assessment in laboratory and class of written procedures.
2. Students will learn; how to identify Hazards and Risks, who in the corporation is responsible for workplace Safety, the Regulatory Agencies governing Safety, the Labeling and Housekeeping, requirements for compliance and the handling of Emergencies. Safety Training programs will be examined in detail. Students will be evaluated by periodic notebook collections and peer and instructor assessment in laboratory and class of written procedures.
3. Students will be familiarized with the Regulatory Agencies governing Medical and Food Products and the historical background of the Regulatory Agencies. Students will be introduced to the technical issues of stability and contamination in Production Systems. Students will be evaluated by periodic

## **Appendix 2 B. Sample Classes**

QA Curriculum: The curriculum to be developed is inquiry based. There will not be lecture or laboratory and the core of the program will be the electronic laboratory notebook. In the Fall, Students will take, TEC 145 Introduction to Quality control and TEC 150 QC in Biotechnology I. Class will run from 8 AM to 4 P.M. An example of the 1<sup>st</sup> day is provided

### **Unit 1 – Sept 6**

8 am Clock in using the classroom time clock

8- 8:45 Introductions and students articulate what they want out of course

8:45 Assign computer, lab coat and external hard drive. Students load the electronic laboratory notebook following instructor doing it on screen.

9-10:15 Assign each group of 2-4 a section of the lab notebook to explore, learn to operate and prepare to explain to class. Provide walk around assistance during this period.

10:15 – 10:30 break

10:30 – 12 Presentations by groups that include students.

12-12:30 lunch break

12:30 – 2:00 Job investigation. Students looking at similar type jobs will be paired up: the pair will go to industry and government sites and investigate jobs that might be of interest. Each pair will identify at least 1 job of interest. Week's assignment will be to continue this search and create an employment favorites site that lists the web sites of interest. Next week each pair will present their findings and group will discuss, salaries job requirements and strategies for interviewing.

2-4:30 Students will use data on Salary and education level to become familiar with Excel program in their laboratory notebooks. They will

1. go to assigned web site to obtain data – not supplied here because sites/info changes
2. transfer data into Excel -- demonstration on classroom screen
3. convert to graph using wizard
4. play around making different types of graphs
5. Select the graph that best illustrates the correlation between salary and educational level.

Week's assignment will be to enter a set of data into excel, convert to graphs, articulate conclusions, write 4 questions that one could ask. Next week each student will take 5 minutes and present his graph, conclusion and questions to the class.

### **Unit 2 Sept 13 Introduction to Quality Control**

Pre 8 am Clock in

8-9 Student presentations of their Excel graphs and results of job searches

9- 12:00 Preparation for Popcorn experiment.

Introduction to Experiment -- 15 minutes

Forms and instructions will be in the lab notebook – students will access and print out forms as needed

Students will be in 4 groups: Material Control, Production, Quality Control, QA

Each group will read the instructions for that group and prepare a diagram of the flow of material with the task and group responsible labeled.

Each group will discuss standards for raw material and for popped popcorn and what tests will be used to determine quality. Each group will present and the class will select the criteria and tests. The forms in each lab notebook will be altered to contain the protocol.

12:00-12:30 lunch

12:30 – 2:30 p.m. Run popcorn experiment.

2:30 – 3:30 Discuss results with emphasis on changes that they would make to improve quality

3:30 – 4:30 Enter popcorn data into Excel and graph. Write a summary

Week's assignment

### **Unit 3 Sept 20 Regulation**

Safety. Emphasis will be placed on identification of Hazards and Risks, Who is responsible for Safety, the Regulatory Agencies, Labeling and Housekeeping, work habits and Emergencies. Safety Training programs will be examined in detail.

Discuss why businesses need to care about safety . Use News Story [about toxic sealant sold through Home Depot to illustrate.](http://www.nytimes.com/2007/10/08/washington/08consumer.html?ei=5087&em=&en=49027b303063b262&ex=1191988800&pagewanted=all)

<<http://www.nytimes.com/2007/10/08/washington/08consumer.html?ei=5087&em=&en=49027b303063b262&ex=1191988800&pagewanted=all>> <<http://sns.vanosteen.com/>>

Workplace. Discussion of why Safety is an issue in the workplace. Liability, cost of loss of time, morale

1. Community – release of hazardous materials
2. Beyond Community – acid rain, global warming
3. Product – Discuss China.

### **Laws governing Compliance**

1. Local
2. State
3. Federal

**Enforcement of Compliance – Students with guidance will look up info on computer**

Local level – town inspectors, fire department  
State level -- Need to know -- look up NJ regulations  
See sheets that need to be filled out

Federal Reg

MSDS Sheets

Shipping regulations

EPA

FDA

USDA

### **Penalties -- student assignments on computer by group**

1. Local
2. State
3. Federal

12:30 – 3:30 Root Cause Analysis Invited speaker Jim Hewlett of NBC2

Assignment:

### **Unit 4 Sept 27** The Organization of Technology Companies.

8 -9 Presentations of last week's assignment

9-9:30 The Organization of Technology Companies. Brief Presentation of Corporate Structure

9:30-12:30 Exercise. Set up a company with 8 friends. The purpose of the company will be to develop and sell cookies. Describe the tasks of the President, Financial Officer, Marketing, Development, Production, Quality Control, Quality Assurance, Sales, Shipping and Receiving. Make a diagram that shows the order in which tasks must be accomplished in order to get a product to market.

A partial list of questions I will provide as guidance.

Who should make the decisions regarding

- What product to develop?
- How much the product will cost? Hint think about what features the cooky must have. Who will buy it?
- The theme of the products? The type of cooky
- How long does it need to stay fresh

## Appendix 3 Letters of Support



### Schering-Plough Research Institute

2015 Hatteras Hill Drive  
Kenilworth, New Jersey 07033-3333  
Telephone: (908) 289-4136

October 09, 2007

Dr. Judith Fitzpatrick  
Bergen Community College  
400 Paterson Road  
Paterson, NJ 07652

Dear Dr. Fitzpatrick,

Congratulations on the launch of the Bergen Community College Quality Assurance Certificate program. This program will yield immense benefits to your students and to the science-based industries of New Jersey. There is a continuing need for people who understand the fundamentals of quality control and quality assurance in the pharmaceutical, biotechnology, food, nutrition and environmental sciences industries, and the Bergen Community College program should help educate the next generation of students who will take over the critical quality positions in these industries.

The program syllabus covers the core issues and final competencies required to manage quality in today's highly regulated, global pharmaceutical and biotechnology environments. Beyond these industries, the skills that will be developed in the Bergen Community College program are transferable to all high technology industries and thus will provide its students with a broad, lifelong preparation for working in the valuable high-technology sector.

A global pharmaceutical company like Schering-Plough continually seeks informed, skilled quality assurance professionals whose education, training and experience suit them to manage and lead quality control and quality improvement efforts in its commercial manufacturing, clinical supply, and research and development operations to assure the continual production and development of safe and efficacious drug products that serve the needs of our patients and their healthcare providers.

For my part, I will be happy to continue my participation on the advisory committee, and further to advocate for Schering-Plough's support of the Bergen Community College program, which could include overall program support, and individual student support through one or more internships in our in-house program.

Sincerely,

A handwritten signature in blue ink that reads "Eugene E. Reilly".

Eugene E. Reilly  
Manager, Pharmaceutical Science Quality  
Schering-Plough Research Institute



October 9, 2007

Mr. G. Jeremiah Ryan  
President, Bergen Community College

Dear Mr. Ryan

In the knowledge gained within my capacity as Director of Quality Assurance for Instrumentation Laboratory (IL), as well as prior positions within operations management, I can certainly support the contention that the Quality Assurance Certificate Program is a valuable addition to your curriculum. Within the In-Vitro Diagnostics manufacturing, quality control and quality assurance disciplines (where my expertise resides), the need for GMP and GLP trained personnel is a constant factor.

In general, an applicant with such a quality certification (even without an MLT) would be significantly more likely to be employed for entry or minimal experience required positions, than an applicant without.

I will continue, if so desired by your offices, to serve in a capacity as Dr Fitzpatrick and I consider appropriate, while realizing that my knowledge base is within the above disciplines. Further, I could minimally help by fast-tracking any applicants for summer internships within my firm, or applicants with certifications, for employment opportunities should such openings arise. This commitment is not made by the company, but by me. I have apprised IL management that I will support this program as appropriate. I will also discuss with top management the possible preferential support for intern applicants, and will keep Judy informed.

Best wishes,

Joel Lipset  
Director of Quality Assurance  
Instrumentation Laboratory  
526 Route 303  
Orangeburg, NY 10962

[JLipset@ob.ilww.com](mailto:JLipset@ob.ilww.com)

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**Ernest A. Carabillo, Jr.**

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October 9, 2007

G. Jeremiah Ryan  
President  
Bergen Community College  
400 Paramus Road  
Paramus, NJ 07652-1595

Dear President Ryan:

The importance of Quality in the Health Care Industry has been extensively written about in the literature yet, the availability of pragmatic courses which prepare people for this profession is unusually sparse. While self study courses are available from national organizations they are no substitute for student involvement with professional instructors. Our nation is at a disadvantage with other countries with significantly lower wage scales in providing trained individuals with college level background skills in this respect. A few years ago I was advised that a degreed engineer in China would be happy to do the work that we have technicians do here in the US for \$ 15,000 per year. While we really don't require degreed engineers to accomplish technician level manufacturing activities the growing requirements for more sophistication do demand a higher level of entry level knowledge specific to the Industry.

I have been involved in healthcare for forty years. First, as a pharmacist attorney defending the Industry, then ten years in the Federal Government starting in the FDA and ending in the Office of Drug Abuse Policy in the Executive Office of the President. From there I spent my time in the Medical Device/Pharmaceutical Industry in senior level positions responsible for Quality and Regulatory programs. I have seen the effects of poor training first hand as my area of focus was crisis management and correction. Too often problems arose because of lack of proper basic knowledge at the technician level due to improper training. I believe this course will go a long way in mitigating this type of issue.

I have committed myself to assist Judith Fitzpatrick Ph.D. in any way that I can, consistent with my experience and network. I will serve on her advisory committee and provide input when asked to the programs and potential speakers.

I applaud you for your foresight to establish a program like this in the heart of the Healthcare Industry in New Jersey.

Ernest A. Carabillo, Jr.

Dr. Judith Fitzpatrick  
Bergen Community College

Paramus, NJ

Dear Dr. Fitzpatrick,

I am writing to support the development of the Quality Assurance Certificate Program at Bergen Community College, and to confirm my agreement to serve on the Advisory Board for the program.

The primary experience and expertise I bring to the program are related to Good Laboratory Practice (GLP) compliance. In my previous position as Director of Toxicology at Schering-Plough, and my current work as a consultant in toxicology for many large and small pharmaceutical companies, I have been required to conform to GLP regulations and to direct the activities of professional and technical staff in GLP compliance. Part of my responsibilities at Schering-Plough was to assure that all staff was properly trained in GLP requirements. From that experience, I am a strong advocate of the Quality Assurance Certificate Program at BCC. In the heavily regulated pharmaceutical industry that is a large part of the New Jersey economy, proper training in Quality Assurance principles and procedures is an essential step in developing a staff and a corporate culture that are committed to quality and the proper documentation of that quality. Training at the college level, in a program that is not directly conducted by specific employers, will give students a broad appreciation of the benefits of thinking and acting on the principles necessary to assure quality performance, and will make those students more generally employable than those with similar technical training but no training in Quality Assurance.

I am willing and able to serve on your Advisory Board. My participation may add experience and emphasis on GLP procedure, and thereby supplement the expertise of those other members of the board who have experience mainly in the area of GMP compliance.

Sincerely,

Thomas Davis DVM, PhD  
President  
PreclinPharma

9 Oct 07

**Dr. Judith Fitzpatrick**  
**Bergen Community College**  
**Paramus, NJ 07652**

Dear Dr. Fitzpatrick,

**Re: Quality Assurance Certificate Program**

**This is to express my strong support for renewing the Quality Assurance Certificate Program at Bergen Community College, and to confirm that it would indeed be an honor to serve as a member of the Advisory Committee for the program.**

**My own responsibilities as Vice President Technical Affairs for Quest International Flavors & Fragrances involved directing a large number of technical staff, including quality assurance and product safety and regulatory personnel to serve food and cosmetic industry clients. Conformance to GLP requirements were absolutely essential yet there was not a single community college in the state that provided the required training to the young people seeking a career in quality assurance. Most of the training was acquired on the job. It must be noted that more than 90% of the Flavor & Fragrance companies essential to cosmetic and food products manufacturers are actually based in New Jersey and contribute substantially to the state economy. I have carefully reviewed Bergen Community College's Quality Assurance Certificate Program and believe that it would serve New Jersey's biotechnology industry and its GMP workforce extremely well. This is a win/win proposition for both NJ workforce and the industry. I have no doubt that industry would make its own contribution in the long run by providing financial support and internship opportunities for students in the program once the course gains traction and becomes known to companies in businesses such as pharmaceuticals, cosmetics and food in New Jersey.**

**In my current work as a technical consultant to the above mentioned industries, I am in a better position to participate in your advisory committee and give something back to the community that has rewarded me generously for my expertise over the years. I believe your program provides some of us an opportunity to make a valuable contribution to the professional lives of many young NJ residents who are seeking a career in quality assurance.**

**With best wishes.  
Sincerely,**

**Dr. H. Rahman Ansari, PhD, MRIC  
President  
Avisina Research, LLC**

Dr. Fitzpatrick  
Bergen Community College  
Paramus NJ

Dear Dr. Fitzpatrick

I am writing this letter in support of Bergen Community College's grant submission to the National Science Foundation. I understand that an approval of grant monies will launch a certificate program for the professional development of a quality assurance technician program for the Pharmaceutical/Biotech community.

This can be a very important program for the state of New Jersey and the many medical device/pharmaceutical industries within the Garden State. As an employer in Bergen County, it has become increasingly more difficult identifying trained technicians to staff our quality control and operations departments. New Jersey is the home state for the pharmaceutical/health care industry and as a result, competition exists for "industry" trained technicians. A certified technician program from Bergen Community College should provide employable technicians to the New Jersey health care industries. I believe that Bergen Community College with the guidance from local health care employers and the experience from the proposed board should provide an excellent program to its students and industry.

Genzyme provides tuition reimbursements to its employees for curriculums that are mutually beneficial to the employee and the company. This program will certainly qualify and be applicable for the current and future technical staff at our Ridgefield facility.

I look forward to the initiation of this program and can support the program through service on the advisory committee

Regards

*Steve*

Stephen Mottola MBA  
VP Operations  
Genzyme Biosurgery

## **Appendix 4 HS Workshop Questionnaire**

Rank each question as

- a. All the time
- b. A lot of the time
- c. Not so much
- c. Very little

1. How much do scientists talk at work?
2. Scientist work alone
3. Scientists use math
4. Scientist laugh
5. Scientists need to use common sense
6. Scientists need to know a lot about people
7. Scientists are not very practical
8. Scientists are not concerned about money
9. Scientists are not involved in business
10. Scientists have to be much smarter than I am.

**Appendix 5 QA Brochure**

Publication QA Brochure.pub