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Office of Apprenticeship
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Employment and Training Administration
United States Department of Labor

**Registered
Apprenticeship
Trends in
BIOTECHNOLOGY**



Registered Apprenticeship In Biotechnology



Registered Apprenticeship training plays an important role in developing skilled workers. With the combination of on-the-job learning, related instruction, mentoring, and incremental wage increases, the apprenticeship model can be an effective system for addressing human resource issues and skill shortages that many industries and businesses face. Registered Apprenticeship can provide the expertise and knowledge individuals need to do their jobs effectively and advance in their careers.

Twenty-first century apprenticeship allows for a flexible, competency-based training strategy that enables apprentices to move through a program at her/his own pace, benchmark the achievement of each set of core competencies and build a portfolio of skills and interim credentials that validate the acquired knowledge and ability. Additionally, the related instruction is articulated with many two- and four-year colleges, allowing apprentices to work toward a degree. This is good news for biotechnology because it meets many of the industry's human resources and skills training needs. Workforce challenges faced by biotechnology companies are complex. The core of the problem is that there are not enough skilled workers to fill the projected job openings. There are few educational programs addressing the need for laboratory science

workers. Enrollment in existing programs is low and a large number of current biology students lack the hands-on laboratory skills needed for employment. There is also a clear gap between the readiness of students entering community colleges and the demands of bioscience coursework as evidenced by the high number of entering students who need remedial math and science.

The Registered Apprenticeship model is addressing these and other issues in biotechnology firms and should become part of their human resources and training strategy. The model offers an efficient, flexible training system that is responsive to new technology to keep workers up-to-date on skills they need to do their jobs.

The U.S. Department of Labor (DOL), Employment and Training Administration (ETA), Office of Apprenticeship (OA) has made a strategic decision to introduce the model to the biotechnology industry. "Advancing the Apprenticeship System" is one of the department's key initiatives, with investments of more than \$15 million to fund apprenticeship programs in new industries through the President's High Growth Jobs Training Initiative. They include-

- Advanced Manufacturing
- Biotechnology

- Geospatial Technology
- Health Care
- Information Technology
- Military-Indiana National Guard
- Transportation

The following case study looks at results of investments and training efforts in biotechnology. Even though the project is in its early stages, there are promising trends that point to the value of apprenticeship:

Benefits to Employers

- Greater competence of employees
- Greater employee retention
- Lower investment in recruitment
- High productivity
- Improved quality of products
- More diverse workforce

Benefits to Apprentices

- Nationally recognized and portable credentials
- Improved skills and competencies
- Increased wages as a result of mastered competencies
- Ability to advance in career
- Higher self-esteem based on enhanced skills and certifications

Industry: **BIOTECHNOLOGY**

The biotechnology industry can be defined as the use of biological processes (particularly cellular and molecular) to solve problems and make useful products. The biotechnology industry includes firms that use cells and biological molecules for applications in medicine, agriculture, and environmental management.

The biotechnology industry, with a workforce of nearly 750,000, is expected to grow at a steady pace over the next decade. Biological technicians are expected to grow by 19.4 percent by 2012 and biological scientists are projected to grow by 19 percent.

The industry has more than tripled in size since 1992 with U.S. revenues increasing from \$8 billion in 1992 to \$39.2 billion in 2003.

The industry is currently concentrated in a number of specific geographic areas around the country, although additional regions are building biotechnology infrastructures:

New England
Raleigh-Durham
Washington-Baltimore
New York
Philadelphia
San Francisco
San Diego
Los Angeles
Seattle

Source: Bureau of Labor Statistics, 2005

U.S. Biotechnology Industry Statistic: 1994-2003

Critical Skills Shortages Prompt Shift in Training Approach

Project Overview

The U.S. Department of Labor awarded a \$5 million grant to a consortium of five community colleges across the nation to support development of the National Center for a Biotechnology Workforce. Each community college is responsible for developing a specific sector of the biotechnology industry. This overview focuses on the New Hampshire biomanufacturing pilot project which is integrating the apprenticeship model (on-the-job learning) with traditional classroom instruction.

The biomanufacturing sector is rapidly growing as more biotechnology companies move into manufacturing, particularly in the Northeast and Mid-Atlantic states. This growth is making demands on educational institutions to prepare highly trained, entry-level technicians. With 155 biopharmaceuticals already in production and 370 in the pipeline waiting for approval from the Federal Drug Administration (FDA), existing and new facilities need personnel.

Dr. Sonia Wallman is Director and Chair of the Northeast Biomanufacturing Center and Collaborative and in addition, chair of the department at the New Hampshire Community Technical College (NHCTC). She has been nurturing the industry and educational development since 1994. Wallman has secured a number of federal grants which have helped equip a 5,000 square foot laboratory where students learn the fundamentals of growing cells and harvesting proteins. The state-of-the-art facility simulates actual labs and operating procedures found in biomanufacturing companies. Students learn how products are taken from the research and development phase to large-scale production, tested and approved by the FDA and then prepared for mass consumption. With this grant, Wallman worked with industry and education to identify biomanufacturing industry skill needs, develop training curricula and support the first apprenticeship program in the field. A team of educational institutions and employers have developed skill standards for 10 occupations.



They have identified the knowledge, skills and abilities necessary for each job. They have also developed research protocols and standard operating procedures to train biotechnicians. Now they are working on developing the needed curriculum.

NHCTC currently has 60 students working on a certification or towards a degree in biomanufacturing and many are taking the apprenticeship path. Apprenticeship offers students a partial scholarship and paid on-the-job learning with leading biotech manufacturers. Participating employers give entry-level technicians the opportunity to do the procedures and experiments that they need for the profession. Students come from a variety of educational backgrounds. Some students come directly from high school while others are adults making career changes. Students' starting salaries in the field range from \$40,000 to \$70,000 and this is before they complete their Associate's degree.

NHCTC has partnered with the Seacoast School of Technology in Exeter, NH, a unique high school biotechnology program that feeds into college-level programs. By the time students graduate high school, they have taken several college course requirements including microbiology.

Northeast Biomanufacturing Collaborative

Out of the initial grant, Wallman helped form the Northeast Biomanufacturing Collaborative, a group of community colleges from Northeastern states including New Hampshire, Massachusetts, Rhode Island, New York, Pennsylvania and Maryland (see page 6). The community colleges are working with DOL's Office of Apprenticeship to implement the apprenticeship model with the biotechnology companies in their areas.

Role of Registered Apprenticeship

Registered apprenticeship is a key component in the project. It fits naturally into a field like biomanufacturing with its emphasis on related instruction combined with hands-on laboratory work. Students work towards their Associate's degree in Biotechnology and work 2000 hours to complete an apprenticeship in biomanufacturing. They take classes their first two semesters at NHCTC in subjects such as biology, chemistry, writing technical documents, and computers. During the summer between freshman and sophomore years, students apprentice with a biomanufacturing firm. They earn an incremental wage based on the full salary of an entry-level

Workforce Challenges

Recruitment and Retention

- Biotechnology firms need more skilled workers than are available and are projected to need more workers than are currently enrolled in training programs.

Skills Competencies and Training

- Lack of nationally-recognized articulated skill competencies and career ladders, as well as sources of training. Additionally, secondary and postsecondary science and math curricula need to be updated to meet the skill requirements identified by the biotechnology industry.
- Few educational programs address the need for laboratory science workers; a low enrollment in existing programs; and a large number of current biology students lack the hands-on laboratory skills needed for employment.
- Gap between the readiness of students entering community colleges and the demands of bioscience coursework as evidenced by the high number of entering students who need remedial math and science coursework.

Image and Outreach to the Public

- Youth, educators, and job seekers lack clear information about career options within the biotechnology industry, therefore limiting the number of individuals attracted to the industry.

*Sources: DOL/ETA Environmental Scan;
DOL/ETA High Growth Industry Profile*

Employer Profile

The Lonza Group, headquartered in Switzerland and founded in 1897, is a leading manufacturer of biotechnology products with 22 production and Research and Development facilities worldwide. The company has five sites in the United States in Pennsylvania, New Jersey, New Hampshire and Illinois. Lonza's business model centers on "custom manufacturing" in life sciences, and provides a range of technologies and capabilities in biomanufacturing, including screening, process development, scale up, production and regulatory support.

The company has implemented a registered apprenticeship training program at the Lonza Biologics Inc. plant in Portsmouth, NH, a facility that is completing expansion as a result of strong customer demand for its products. According to Mike Ciccio, Production Manager, and Tara Meulenbroek, Human Resources Generalist, the apprenticeship model is appealing because it helps the company build a foundation for their growing workforce. "The community will get a better understand of the industry," explained Ms. Meulenbroek. They hope to use the apprenticeship program to build a pipeline of workers from the surrounding area.

In the program that Lonza sponsors, apprentices learn the fundamentals of a biomanufacturing technician. Even though this is an entry-level position it takes a substantial amount of training to prepare for this occupation which encompasses four levels. Mr. Ciccio learned about the apprenticeship program as an advisory board member of the New Hampshire Technical Community College. Mr. Ciccio explained that the model has helped Lonza reach out to the community. Because of its association with the community college and now the apprenticeship program, Lonza is now more connected to high schools and grassroots organizations.

Mr. Ciccio and Ms. Meulenbroek describe some worthwhile efforts in undertaking an apprenticeship program: it takes greater commitment and time for the existing Lonza staff to teach new individuals and trying to get the biotechnology industry involved in outreach efforts to the community which will lead to more recruitment. Lonza Biologics, Inc. is committed to this effort because they know an apprenticeship program will lead to a better prepared workforce.

biotechnician in one of the apprenticeable occupations described in this case study. During the second year, students continue their courses and may elect to work and study simultaneously or wait until their sophomore year is complete before apprenticing in a biomanufacturing lab. The courses are difficult; so many students just focus on their studies. Second year courses include bioinformatics, genomics and proteomics. After their Associate's degree is complete, apprentices have the option to work full-time, or go on to obtain a Bachelor's degree in chemical engineering or bioengineering at the University of New Hampshire or a combination of full-time work and further education at another educational institution.

Apprenticeship staff from the U.S. Department of Labor worked closely with the NHCTC team to develop and pilot the apprenticeship program. Now a group of community colleges from the Northeast and Mid-Atlantic States and DOL staff are in the process of expanding the apprenticeship model to additional employers.



Role of Community Colleges

Community colleges are playing a pivotal role in this effort. They are coordinating all of the work to develop industry standards and curriculum along with employers and industry experts. Additionally, they are working with high schools and other partners to recruit candidates to their programs. NHCTC has worked with several high schools to develop a “feeder” program that starts high school students in the biotech field as early as 10th grade. By the time students have completed their first year in the community college, the schools organize recruiting events where employers come in to talk to students about job prospects.

Apprentice Profile



Katrice Jalbert
Apprentice
Lonza Biologics, Inc
Portsmouth

Katrice Jalbert just completed her first year of course work at the New Hampshire Community Technical College (NHCTC) in biomanufacturing and is doing the on-the-job learning portion of her apprenticeship. Katrice came from the Seacoast School of Technology where she focused on the sciences. While still in high school, Katrice wanted to see what biotechnology was all about so she took a course. She fell in love with it and was then recruited for the NHCTC apprenticeship program. Katrice didn't have the funds to attend a full college program and needed to stay close to home to help her family, so the apprenticeship program was ideal for her. Katrice explained, “You learn so much more by working in a place rather than just reading about it in a book.”

Katrice will do two week rotations over the summer in each department at Lonza Biologics, Inc. in Portsmouth, NH, so she will learn the entire business of biomanufacturing. She first worked in the dispensing department which processes outside orders and has just moved into the glass wash and autoclaving department which sanitizes equipment and purifies the product. When the school year begins again in August, she will continue perfecting the skills she learned at Lonza in the NHCTC state-of-the-art lab while completing her course load. Katrice will finish her Associate's degree and then continue at Lonza because they will pay for the rest of her college in return for working for them for a given time period. Katrice's goal is to work in cancer research but as she explains, “You need to see and understand the manufacturing side of the business to understand the entire process.” Her dream is to go to France and study the healing aspects of aroma therapy as essential oils can kill bacteria.

Apprenticeable Occupations

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).

Manufacturing Technician-Downstream: Responsible for setting up area operations, performing according to Standard Operating Procedures (SOPs). Follows electronic work instructions in accordance with a Good Manufacturing Practices (GMP) environment to manufacture biopharmaceutical drug substances.

Chemistry Quality Control Technician: Tests samples for internal and external customers; analyzes, communicates results; reviews, validates, troubleshoots procedures; monitors environment, equipment, instrumentation.

Microbiology Quality Control Technician: Performs routine microbiological testing of raw materials, in-process samples, and finished products. Monitors manufacturing areas, equipment, and processes. Calibrates and maintains equipment.

***Facilities Technician:** Performs daily monitoring, repair, and preventive maintenance activities on critical systems and equipment; troubleshoots, installs, evaluates and modernizes new and existing systems.

***Environmental Health and Safety Technician:** Monitors water and air; calibrates and maintains scientific monitoring equipment and performs routine analysis of all environmental and monitoring systems; processes permits.

***Instrumentation/Calibration Technician:** Maintains, calibrates, tests, troubleshoots, and repairs circuits, components, analytical equipment, and instrumentation. Performs validation studies. Requests purchase of components.

***Process Development Technician:** Evaluates, improves, and assists with scale-up manufacturing processes and technologies in order to improve product yield and reduce overall costs of production.

***Quality Assurance Documentation Technician:** Provides administrative support related to documentation systems. Audits all documentation manuals to assure accuracy, timelines, and availability. Maintains and archives all master documents.

***Validation Technician:** Develops, recommends strategies, and designs studies to validate and document effectiveness of systems, equipments, methods, or processes. Conducts processes and qualification programs.

** Pending DOL Approval.*



Preliminary Observations

Although the Registered Apprenticeship model is still in its infancy in the biomanufacturing industry, there are a few observations about its impact.

Competency-based Skills Development

The industry has developed skill sets needed to work in a biomanufacturing company. The apprenticeship model has incorporated these skill sets and apprentices must show mastery of tasks to move on to the next level. This approach is proving highly effective. In particular, with the structured on-the-job learning component, apprentices develop hands-on skills needed to produce bio products. This contrasts with the traditional university model where students don't learn the important hands-on laboratory skills.

Worker Pipeline

Biomanufacturing employers who are using the Registered Apprenticeship model are going beyond their traditional source of talent trained in universities and reaching out to community colleges, dislocated workers and others who are being trained in a new way to do the work. This approach is helping to address the worker shortage.

Apprentices Have a Better Understanding of Career Paths

By integrating employment and studies, apprentices get a real world picture of working in the industry which will help them make informed career choices. They also see the various occupational paths available from the entry-level laboratory technician to mid- and higher-level professions.

Participating Employer Sponsors:

- Amgen Inc., West Greenwich, RI
- Biogen Idec, Cambridge, MA
- Genzyme, Corp., Framingham, MA
- GlaxoSmithKline, King of Prussia, PA
- Lonza Biologics, Inc., Portsmouth, NH
- Vaccinex, Inc., Rochester, NY
- Wyeth Biopharma, Andover, MA

Northeast Biomanufacturing Collaborative Participating Community Colleges

- New Hampshire Community Technical College, Portsmouth, NH
- Finger Lakes Community College, Canandaigua, NY
- Community College of Rhode Island, Warwick, RI
- Montgomery County Community College, Blue Bell, PA
- Community College of Baltimore County, Catonsville, MD

Participating High School

- Minuteman Regional High School, Lexington, MA

For More Information

Office of Apprenticeship
Employment and Training Administration
U.S. Department of Labor

www.doleta.gov/oa
1.877.872.5627

Biotechnology
Northeast Biomanufacturing Center & Collaborative
www.biomanufacturing.org
<http://biotech.nhctc.edu>
<http://www.bio-link.org>



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