

## A Biomanufacturing Enterprise for Innovative Student Training in Quality Systems & Regulatory Compliance

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### **ABSTRACT**

Biotechnology is a popular and growing science, technology, engineering, and mathematics (STEM) field that has ties to a number of industry sectors including agriculture, environmental and industrial sciences, and health care (including diagnostics, therapeutics, personalized medicine, pharmaceuticals, and medical devices). Students preparing for a career in biotechnology usually complete a considerable amount of STEM-related coursework that provides them with a solid and relevant technical knowledge base. However, they are usually not ready to work within a quality system and regulated environment because they lack training in these areas. Food and Drug Administration (FDA) regulations require companies to address this gap. This training is typically provided in-house and on-the-job, but it is often inefficient and may jeopardize the organization's productivity. Thus, there is certainly enormous value in teaching quality and regulatory concepts to college students, to round out their career preparation efforts. Such subject matter is best learned through application. At Salt Lake Community College (SLCC), a student-run biotech manufacturing (biomanufacturing) business enterprise is being established to provide students with a supportive, real-world, and contextual hands-on training environment in which they can learn and put to practice quality and regulatory concepts and skills, as well as reinforce their biotech-related STEM knowledge.

Keywords: Teaching Quality; Community College Programs in Quality; Hands-on Learning

The Biomanufacturing Program at SLCC was developed to serve the local biotechnology manufacturing industry by preparing individuals for entry- to mid- level production positions. The program complements the well-established Biotechnology Program at the college, which trains individuals for research positions in the academic as well as industrial settings. Utah's biotechnology industry is highly diverse, comprising mainly of dietary supplement, medical device, and select pharma sectors. This diversity makes it impractical for the program to focus on providing technical expertise because such training is not applicable across all sectors. However, quality systems and regulatory compliance training is desirable expertise, and common to all biotechnology sectors. This program focus is sensible and wanted, according to local industry advisors involved in Biomanufacturing Program development. These advisors stressed that a solid foundational understanding of quality systems and federal (FDA) regulations as well as biomanufacturing-relevant critical thinking skills are two industry-essential and highly desirable qualities for employees to have. Thus, the Biomanufacturing Program has made quality systems and regulatory compliance a core focus, to the delight of local companies and their representatives.

From a student's perspective, learning and mastering key concepts and practical skills related to quality systems and regulatory compliance is challenging for several reasons. First, these are very dry topics, and even the best and most captivating of instructors would have difficulty fully engaging students. Secondly, engagement is hindered by the typical student's lack of appreciation for the educational and career-enhancing value of these concepts and skills. The "Do I really need to know this?" question is often raised, and so adds to the challenge. Third, the complexity of quality systems as well as the FDA regulations, which

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are written with considerable abstraction to allow for company-/product type- specific interpretation, makes learning, application, and retention of this knowledge and any developed skills difficult and confusing.

These challenges make project-based learning a good approach to teaching quality systems and regulatory compliance. The project-based learning strategy allows students to comprehensively learn concepts and skills by applying them to a particular question or problem. Several decades of research on the effectiveness of problem-based learning has demonstrated repeatedly that project-based learning can increase academic achievement, improve learning in STEM as well as career and technical education fields, improve skill development, facilitate long-term retention of subject matter, and better prepare students to integrate and explain concepts (summarized on the Buck Institute for Education's web page *Does PBL Work?* , [http://www.bie.org/research/does\\_pbl\\_work/](http://www.bie.org/research/does_pbl_work/)).

The SLCC Biomanufacturing Program has utilized the project-based learning strategy in many of the program's core courses, but not in an integrated and cohesive manner. If the intent of the program is to prepare students to work within a quality management system and to comply with FDA regulations applicable to the biomanufacturing industry, then there is no better way to train than to let students work in this specific environment. Such training cannot be provided through traditional internships because FDA regulations prohibit those without proper training to work in these controlled biomanufacturing environments, thereby creating a "catch-22" situation.

To provide students with a comfortable and supportive real-world learning atmosphere, we are initiating the creation of a student-run contract manufacturing organization, **STUDENTfacturED**, that will act as the desired real-world work environment. This company will engage student participants in the manufacture of various biotechnology reagents by placing them in roles typical of a biomanufacturing business. This learning-by-doing tactic should allow students to gain a deeper understanding and appreciation of these roles and to effectively develop job-related skills. The manufactured reagents will be sold as instructional supplies for use in SLCC biotechnology and biology courses, as well as at local high schools teaching these college courses for concurrent credit. Because of this product focus, **STUDENTfacturED** can offer a mentored yet real business environment that is tolerant of mistakes students might make, and be a conduit through which students can master competencies essential to biomanufacturing, such as understanding vendor qualification and supply chain management; complying with good manufacturing practices and document control policies; tracking materials and production activities; managing resources and production scheduling; performing quality control and quality assurance activities, and lean manufacturing; critical thinking for troubleshooting and problem-solving; understanding quality management systems, ISO 9001 certification, and federal regulations; providing customer service and technical support; and supporting a continuous improvement effort. **STUDENTfacturED** shall serve not only students in the Biomanufacturing and Biotechnology programs, but also those in SLCC's School of Business, thereby creating and fostering an innovative learning community between students in the STEM and business fields that provides effective, efficient, and contextualized training.

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Vivian Ngan-Winward earned a Ph.D. in Molecular Biology & Biochemistry from Wesleyan University in 1991. After nine years in academic research, she entered the biotechnology industry, working as a scientist in R&D as well as regulatory affairs. In 2008, she returned to academia, as the Biomanufacturing Program Director at Salt Lake Community College, to develop and implement a biotechnology manufacturing training program with a quality and regulatory focus. She recently earned the ASQ CQE certification.

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