Center for Life Sciences Technology

Integration of Standards, Models of Standardization and Science Policy for the 21st Century Biotechnology Workforce

Final Project Summary Report

Project Manager: Dr. Rupa Iyer, Ph.D.

Director of CLiST at the University of Houston

Program Director in the Department of Undergraduate Education at the National Science Foundation (NSF)

Abstract

With the support of the National Institute of Standards and Technology (NIST), an online standards learning course was designed, developed and implemented by faculty and staff of the Biotechnology graduate program at the University of Houston. This course entitled BTEC 6300: Standards in Biotechnology was developed in collaboration with NIST, the Houston Biotechnology industry and academic partners. Since its inception the course was intended to provide a foundation for standards education in Biotechnology. Students are first introduced to the concept of standards and the organizations that serve as standards developers, regulators and accreditors. Building on this requisite background, students study, assess and in some instances test relevant examples of both technical and non-technical standards in Biomaufacturing, Bioinformatics and Environmental Biotechnology. This provides a common baseline for group discussions and for the development of ideas for new Biotechnology standards needed in academia, industry or society as a whole. Enrolled students have consistently expressed a high degree of satisfaction of course content with over 90% of respondents indicating that the course has provided them with a comprehensive understanding of what standards are and how they are created, and also with a greater understanding of the current standards, practices, and regulations that guide bioproduct development, analysis, recordkeeping and marketing. However, the project has experienced limited enrollment of participants outside of the Biotechnology graduate degree plan. Recent promotional materials have generated interest and enrollment among of graduate students in biology, civil and environmental engineering and law, but we have yet to see industry or non-academic participation in the course. Moving forward, we view the attendance of non-BTEC graduate students and industry personnel as critical to the sustainability of standards education in our program. To meet this goal, we are considering making BTEC 6300 an integral component of a three course regulatory concentration and/or certificate program

within the BTEC graduate program. In addition, we have compiled a list of Biotechnology, pharmaceutical, oil and gas firms, and consulting companies throughout the Houston area that currently employ our program's alumni. Embedded BTEC alumni will be urged to help distribute promotional material and information amongst their colleagues and potential industry applicants to generate interest and improve industry participation in future offerings.

Rationale for Standards Education at the University of Houston

From an industrial standpoint, the addition of an easily accessible course in Biotechnology standards should be well-received. Texas ranks #2 in the nation in the employment of life and physical scientists with nearly 4000 Biotechnology manufacturing and R&D companies employing 100,000+ workers. Representative Biotechnology and pharmaceutical companies that have corporate management, research, or manufacturing facilities in Texas include industry leaders such as Bayer-Monsanto, GE Healthcare, Alcon, Sigma Life Science, Thermo Fisher Scientific, and Agilent Technologies among many others. In addition to the Biotechnology and pharmaceutical industries, Houston is also home to environmental testing and petroleum engineering companies. There are currently over 25 Fortune 500 Oil and gas companies headquartered in the Houston area alone. In nearby Sugarland, Texas is the Energy Services Headquarters for Nalco, a globally leading water treatment and process improvement services company that serves the energy, agricultural, and technology industries.

From an academic standpoint, we have a strong foundational program to build on in University of Houston's (UH) Biotechnology program, which is currently ranked #2 in the U.S. based on student enrollment. We also have support from the Center for Life Sciences Technology

(CLiST) based at UH. The CLiST is engaged in developing innovative interdisciplinary research-based education through undergraduate and graduate programs in Biotechnology. The Biotechnology degree programs provide students with strong core science concepts and an application-oriented education. Our objective is to prepare students for employment opportunities in the critically important, dynamic and growing Biotechnology industry. With an emphasis on Environmental Biotechnology, this is the first program in the State of Texas to integrate Bioprocessing, Bioinformatics and Environmental Biotechnology into an undergraduate curriculum. Two curriculum tracks: 1) Bioprocessing, and 2) Bioinformatics give students the flexibility to tailor their degree based on their interest, educational background and career goals. CLiST also supports 21st century workforce development, outreach, and cutting edge research and serves as a platform for innovation and institutional collaboration by compiling and disseminating job opportunities and career fair information to UH students. CLiST hosts local high school STEM training programs, laboratory-based research projects and summer workshops annually as part of its outreach initiatives. Lastly, support at UH includes a strong desire to incorporate standards education into our curriculum among our faculty Assessment of student competencies in both undergraduate and graduate classes has revealed that while students were satisfied with course instruction and the level of technical skill acquired through their time within the program, little thought was given to why, how and where the equipment, consumables and methodology (protocols) comprising their hands-on training were developed. Our students were highly skilled, but were lacking in the ability to proactively contribute to academic research or industry needs without direction. Our faculty believed that an introductory standards course in Biotechnology with content built through the guidance and direction of our academic and

industry advisors in the CLiST consortium would be particularly beneficial in addressing this issue and would support CLiST's workforce professional development initiative.

Taken together, student need and the presence of a growing industrial presence in and around the Houston metropolitan area made the University of Houston's Biotechnology 30 hour graduate curriculum an ideal platform for dissemination of Biotechnology standards and models of standardization content. To meet this untapped potential, with the support of the National Institutes of Standards and Technology (NIST), this project was developed to successfully implement an online standards course to our graduate curriculum (**Table 1**).

Table 1. M.S. Degree Plan in Engineering Technology – Biotechnology Track

Course ID	**Core Courses (ALL Required)**	**Credits**
ELET 6360	Experimental Design and Analysis	3
TEPM 6301	Project Management Principles	3
	CORE TOTAL	**6**

Course ID	**BTEC Courses Options**	**Credits**
BTEC 6100	Seminar in Biotechnology	1
BTEC 6101	Advanced Biotechnology Techniques and Methods	1
BTEC 6300	**Standards in Biotechnology**	**3**
BTEC 6302	Introduction to Regulatory Affairs	3
BTEC 6303	Protein Engineering Technology	3
BTEC 6304	Computational Methods in Biotechnology	3
BTEC 6401	Bioprocessing in Biotechnology	4
BTEC 6397	Special Topics in Biotechnology	3
BIOL 6307	Advanced Cell Biology (course only option)	3
	BTEC COURSES TOTAL	**See above**

Course ID	**Research courses (not applicable to course only option)**	**Credits**
BTEC 6399-1	Master's Thesis in Biotechnology	3
BTEC 6399-2	Master's Thesis in Biotechnology	3
BTEC 6396	Master's Project in Biotechnology	3
	RESEARCH TOTAL	**See above**
	TOTAL CREDIT HOURS FOR MS	**30**

Our Approach for Implementing a Graduate-Level Standards Course

Creation of our online class portal

When designing BTEC 6300, an online instructional mode was chosen to allow for broader dissemination of standards knowledge to as large of an audience as possible. This audience was expected to primarily be composed of College of Technology (CoT) graduate students, graduate students from comparable areas of study to Biotechnology, and industrial representatives looking to refresh or enhance their understanding of standards relevant to their chosen field. As an online course, all content was delivered through the UH online learning management system, Blackboard Learn 9.1. The Blackboard management system included several tools designed to enhance participant learning and encourage engagement and interaction. As part of our project design we opted to use a class discussion board and web conferencing tool, Blackboard Collaborate, for group meetings and discussion of course content and weekly research topics between the course instructor, support faculty/staff and students. The discussion boards are structured thematically and work very well for soliciting feedback from students or engaging them in debate, such as our weekly lecture topic, or to formulate ideas for needed technical standards that do not yet exist.

Course content in BTEC 6300: Standards in Biotechnology

We drafted BTEC 6300 - Standards in Biotechnology as an introductory course that would focus on how different technical standards guide the business, safety, regulatory, and ethical policies of the biotechnology industry. We would also explore how standards development is often the product of collaboration between regulatory agencies, representative experts within the biotechnology industry, and/or standards developing organizations (SDOs) following a common standardization procedure to ensure consumer demands are met while maintaining a safe, healthy environment. Upon successful completion of the course participants were expected to be able to

(1) compare and contrast the different types of technical standards at work in the Biotechnology industry. (2) Explain how the development and implementation of Biotechnology standards is accomplished. (3) Identify local, national, and global SDOs and describe the roles that they play in communicating modern policy over the Biotechnology industry. Course material was divided into blocks beginning with an introductory block detailing the types of standards, SDOs and the process of standardization. Content following the midterm focuses on representative national and international standards covering specific areas of Biomanufacturing, Bioinformatics and Environmental Biotechnology (**Table 2**).

Table 2. BTEC 6300 Syllabus: Subject to Change at Instructor's Discretion.

#	**Lesson**	**Assignment Due**
1	Introduction	N/A
2	Standards Development and Introduction to SDOs	#1 Due
3	National SDOs	N/A
4	International SDOs	N/A
5	International SDOs cont.	#2 Due
6	Standards Implementation	N/A
7	Midterm	
8	Standards in Biomanufacturing	N/A
9	Standards in Environ. Biotech	#3 Due
10	Standards in Bioinformatics	N/A
11	Quality Control	N/A
12	Regulatory Compliance	#4 Due
13	Data Reporting	N/A
14	Careers in Standardization	N/A
15	Final Exam	#5 Due, Final Project Due

Course Assessment and Grading Metrics

All course assessment as part of this proposal is to be undertaken through a combination of graded lecture materials, surveys and the integration of online working materials including group discussion tools. A final paper is written over 1 of 2 topics of interest, either a critical thinking

exercise in drafting a new technical standard or an exercise in data analysis/reporting of biological sequence data. The final grade breakdown for this course is seen below (**Table 3**).

Table 3. BTEC 6300 Grade Assignments

#	Graded work	% of final grade
1	Assignments	20
2	Final project	20
3	Midterm	25
4	Final exam	25
5	Class participation	10

Graded assessment include weekly quizzes, reports, or homework assignments, a major research project, a midterm, and a comprehensive final exam. A weekly forum for discussion is provided to participants and relevant talking points are initiated by the instructor to encourage discussion and collaboration between students on lecture topics, assignments, and final project. These discussions are closely monitored by faculty for content and participation between sessions. Lastly, each participant completes anonymous pre-and post-class surveys at the end of each session. Project staff assess this information to determine what student expectations were before and after taking the course; if they were satisfied with how the course material was designed and presented; did they find supplemental information, activities and speakers to be helpful; what they would change and would not change in the course material. From this information faculty introduce the necessary course corrections prior to the start of the next session.

Project Outcomes and Lessons Learned

The course BTEC 6300 – Standards in Biotechnology was developed as a 3 hour course for the M.S. in Engineering Technology – Biotechnology track program and has to date been offered three times, in Fall 2016, 2017 and 2018. The creation of this course in itself represents a success in the short term. For this project to be effective in the long-term beyond NIST's funding

duration, diverse student participation in the course is critical. We therefore evaluated our project through its capacity to sustain itself and grow beyond its original constraints as part of this grant proposal. The number of participants enrolling in the standards course overall and the representation of different participating graduate institutions and industry organizations were key evaluation criterion. Our initial class enrollment was low (3 students), partially due to the recent introduction of the graduate program, but also due to a lack of visibility and incentive outside of the graduate program. Promotional flyers were therefore distributed in the Spring and Summer sessions across the UH system including UH main campus, UH-Clear Lake, UH-Downtown, UH-Victoria, and five off-campus centers including the UH System at Sugar Land, UH System at Cinco Ranch, UH System Northwest, UH System Texas Medical Center, and the UH System of Clear Lake-Pearland. A master list and contact information for Biotechnology, pharmaceutical, oil and gas firms, and consulting companies throughout the Houston area including 30+ companies that currently employ our alumni was also compiled for outreach purposes. As a result of our most recent efforts BTEC 6300 course enrollment for Fall 2018 has effectively doubled from a class of 5 students in Fall 2017 to 10 students with students and professionals from varied fields of study including Biology, Biomedical Engineering, Civil and Environmental Engineering and Law. This increase in both numbers and diversity represents a significant gain in a key evaluation criterion for this project's success. We plan to continue to disseminate project results, including this summarization of project, and all promotional materials across the UH system through the CLiST web portal.

Course content for BTEC 6300 developed by the Project Manager, Dr. Rupa Iyer, the Faculty Program Manager and other project stakeholders includes powerpoint lectures, supplemental materials, announcements from standards developing organizations, homework assignments,

discussion board topics, online exams and a class project. As enrollment grew and we were able to compile feedback we learned that students were not fully engaged with the online content. They were learning conceptually, over 90% of respondents to the post survey expressed high satisfaction with course outcomes (**Table 4**), but they did not have much opportunity to practice what they had learned.

Table 4. BTEC 6300 Post-Course Student Survey Fall 2016-2017

	Strongly Agree	Agree	Disagree	Strongly Disagree	Don't Know
I am familiar with the different types of standards both technical and non-technical.	95%	5%	0%	0%	0%
I understand the basic process of standards development as it applies to the biotech industry.	91%	9%	0%	0%	0%
I feel confident that I can collect, analyze and report biological data as specified by industry standards.	90%	9%	0%	0%	1%
I can identify representative SDOs at the national and global scale and their role in the standardization process.	94%	6%	0%	0%	0%
I would recommend this course to others based on my experiences.	94%	6%	0%	0%	0%

As such, our priorities shifted towards providing additional content that engaged students' in various STEM data-driven activities. Given the online nature of the course, it was decided that bioinformatics data (genomic, metabolic and kinetic) would be optimal choice for this task. In Fall of 2017, we added additional lecture materials covering standards in biological data nomenclature, analysis and data reporting, while in Fall 2018 we will continue expanding bioinformatics related work through an alternative option for a class project that uses a combination of whole genome and metagenomics sequencing data procured from strains isolated by the Iyer laboratory and bioinformatics analytical software (Geneious, Blast2Go) purchased with NIST funding. Genomic reports on three of the bacterial strains (*Pseudomonas nitroreducens* DF05, *Klebsiella aerogenes* PX01 and *Microbacterium* sp. AIS03) that will be

used for student projects have been published in the journal Genomics Data (now Data-In-Brief). Fall 2018 will also see an expansion of archived webinars detailing the various actions taken by SDOs, governmental agencies and industry reps such as ISO, NIST, NSF and BioRAD that cover their contributions to Biotechnology standards. As part of supplemental video material for lecture presentations, links to the webinars will be included where appropriate. Students will also write a 1 page synopsis on the presentation that will be included as part of their participation grade starting in Fall 2018.

Project Sustainability

We expect that student tuition for enrollment in BTEC 6300 will help to maintain and grow our CLiST web portal allowing for continued promotion of course materials and our associated Biotechnology program. As our visibility increases so should the opportunity for further student enrollment and collaboration efforts. The Biotechnology M.S. program has already made significant strides in increasing program visibility through the creation of an accelerated track that allows current undergrads to take graduate level courses for credit prior to enrolling into the graduate program. It is believed that this should significantly increase enrollment into the graduate program as it incentivizes undergraduate students to continue their studies with us.

As a vital piece of our graduate degree core, we have not only planned to sustain this course indefinitely as part of our program, but ultimately to expand upon its current implementation as part of a three course regulatory concentration and/or certificate that would include BTEC 6300, 6302 and 6304 (See Table 1) that could be used to incentivize industry participation. The structure of BTEC 6300 is broad and flexible and can readily be used to institutionalize standards

course content and assessment metrics for online courses in Biotechnology throughout the UH system as well as collaborating academic members of the CLiST consortium.

At its inception CLiST created an Advisory Board composed of representative industrial companies and organizations to shape and form its undergraduate BTEC program. Industrial members of the CLiST Advisory Board include BioHouston, a non-profit corporation devoted to fostering collaboration between academic and research institutions and the biotechnology industry, individual pharmaceutical and bioremediation companies, GlycosBio, PLx Pharma, Lonza Therapeutics and Nalco, as well as oil and gas corporations, ExxonMobil, Shell, and Chevron. This network of industrial collaborators acted as consultants assisting our faculty in building our online standards course. However, in early 2017, the CoT at UH had the Engineering Technology department, of which our Biotechnology program is a part of, to disband and reform their Advisory Boards, which is a process that is currently ongoing. This may now prove to be particularly beneficial move for us at this juncture. Several participants at the 5th Standards in Education workshop in Gaithersburg, MD back in 2017 noted that members of our Advisory Board should include at least one active standards development committee member, something that it had lacked previously. Our program is now using the ongoing process of developing a new Advisory Board to seek out potential candidates with this experience in standards development and to renew ties with our old partners and their commitment to supporting a quality program in the training of their current and future employees.