

A Cross-Disciplinary Educational Model in Biomanufacturing to Sustain a Competitive Workforce Ecosystem

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Abstract—Biopharmaceuticals manufacturing is one of the major economic activities worldwide. Ninety-three percent of the workforce in a biomanufacturing environment concentrates in production-related areas. As a result, strategic collaborations between industry and academia are crucial to ensure the availability of knowledgeable workforce needed in an economic region to become competitive in biomanufacturing. In the past decade, our institution has been a key strategic partner with multinational biotechnology companies in supplying science and engineering graduates in the field of industrial biotechnology. Initiatives addressing all levels of the educational pipeline, from K-12 to college to continued education for company employees have been established along a ten-year span. The Amgen BioTalents Program was designed to provide undergraduate science and engineering students with training in biomanufacturing. The areas targeted by this educational program enhance their academic development, since these topics are not part of their traditional science and engineering curricula. The educational curriculum involved the process of producing a biomolecule from the genetic engineering of cells to the production of an especially targeted polypeptide, protein expression and purification, to quality control, and validation. This paper will report and describe the implementation details and outcomes of the first sessions of the program.

Keywords—Biomanufacturing curriculum, interdisciplinary learning, workforce development, industry-academia partnering.

I. INTRODUCTION

THE biopharmaceutical industry represents one of the world's major economic activities, where its products are actually worth 10% of the \$800 billion global pharmaceutical market [1], [2]. The annual growth of biopharmaceuticals ranges from 11–16% [2], [3], twice as much as the increasing rates of pharmaceutical products sales [1], [2]. Compared to pharmaceutical products, biopharmaceuticals are more complex in terms of product and processes: products are higher molecular weight compounds synthesized by genetically modified cells, and are difficult to characterize in terms of chemical structure, biological activity, stability, and

therapeutic effectiveness; processes require knowledge and careful handling of the biologically active molecules [2]. On a global context, biomanufacturing is growing worldwide by the demand of new therapeutic products and biosimilars, requiring access to technologies, education and training, expertise in bioprocessing, availability of a well-trained local labor workforce and a sustained educational development for long-term operations [4]. Ninety-three percent (93%) of the workforce in a biomanufacturing facility concentrates in production-related areas [5]. As a result, strategic collaborations between industry and academia are crucial to ensure the availability of workforce needed for a country or region to become competitive in biomanufacturing [6], [7]. It is also known that bringing the workplace to the academic learning environment is important in meaningful learning [8]. The global transformation of developing biopharmaceutical industries can be highlighted by the establishment of industry-academia partnerships, such as three-week internships of students from Osaka University, Japan in the R&D laboratories of GE Healthcare Life Sciences located at Uppsala, Sweden [9]. Another significant international partnership is that of a Russian company (R-Pharm) that trained their new biopharmaceutical staff in a two-year internship with the Biomanufacturing Education and Training Center at Worcester Polytechnic Institute in close collaboration with Xcellerex (GE Healthcare), from where the biomanufacturing facility will be shipped and installed at Yaroslavl, Russia [4].

Under a local context, Puerto Rico has been a major site in global biomanufacturing and a center of excellence in manufacturing activity [10]. The biopharmaceutical industry in Puerto Rico is the leading industrial sector in economic development, generating close to 25% of the island's gross domestic product, with sales of biopharmaceutical products of \$2.8 billion in 2011 [10]. The majority of the world's leading pharmaceutical companies has established manufacturing sites in Puerto Rico. This is mainly because of the island's tax-advantage condition [1], but mostly due to the availability of well-educated, science-based professionals in chemistry, biology, chemical engineering and industrial biotechnology. The University of Puerto Rico, Mayagüez Campus has been a key strategic partner along with multinational biotechnology companies in supplying science and engineering graduates to the workforce in the field of industrial biotechnology. A series of initiatives addressing all levels of the educational pipeline, from K-12 to college to continued education for company

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employees have been established along a ten-year span [11]-[13]. Some of these initiatives include the Biotechnology Summer Camp for High School students; the Industrial Biotechnology Learning Center for company employees and personnel transitioning from pharmaceutical manufacturing towards a biotechnology manufacturing environment; and the BioMINDS Program to promote undergraduate research of science and engineering students in biotechnology-related areas [14]. These programs have nurtured the professional profiles required in the biomanufacturing industry.

A key area not been addressed yet was to complement academic curricula in sciences and engineering with knowledge and profiles in the field of industrial biotechnology. General managers from multinational biomanufacturing companies have expressed their interest in providing engineering and science graduates with curricular experiences in industrial biotechnology. The interdisciplinary nature of a biopharmaceutical process creates the need and challenges of having engineers and scientists to work as a team and to communicate concepts from their respective areas of expertise to implement, validate and operate biomanufacturing processes with precision and effectiveness.

The Amgen Biotechnology Training and Learning Enhancement for Students (Amgen BioTalents, ABT) initiative was established to strategically enrich undergraduate science and engineering students with knowledge and skills in industrial biotechnology, while these topics are not necessarily targeted in the academic and professional profile of their curricula. Through ABT we demystify the biomanufacturing workplace for students, exposing them early in their career paths to the industry environment by learning about the biomanufacturing processes fundamentals and their applications. ABT expectations are that the participants' learning process will result in science and engineering graduates that will experience a smaller adaptive phase and a quicker learning curve if recruited in a biopharma industry.

II. THE ABT PROGRAM DESCRIPTION

A. Objective

The overall objective of ABT is to provide hands-on knowledge and skills in biotechnology manufacturing to non-biotechnology students who normally do not learn in their traditional curricular courses the specific topics covered through this initiative. The training involved 30 hours in the process of producing a recombinant protein from the genetic engineering of cells to the expression of the protein, its purification and characterization, to quality control, and validation. The training was designed to mimic a biomanufacturing process (Fig. 1). Science and engineering students from the University of Puerto Rico system, as well as from private universities were recruited and assigned to interdisciplinary and multicampus teams during the training.

Scientific concepts such as DNA and genetic transformation of bacteria to produce a recombinant protein were taught to engineering students; engineering concepts such as bioreactor oxygen mass transfer and automated process control were

transmitted to science majors; while topics in biomanufacturing like good manufacturing practices (GMP) were delivered to all participants. The program aimed to provide training all across the interdisciplinary skills in a coherent, interrelated fashion that is not typically found in a traditional academic program, where students learn concepts exclusively within their field.

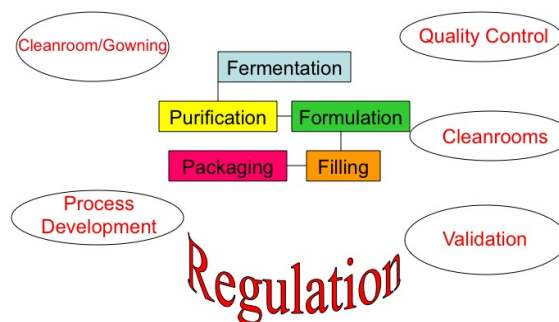


Fig. 1 Overview of a biomanufacturing process

B. Implementation: Recruitment and Participants Profile

The program targeted upper level science and engineering students. The criteria for selecting ABT participants included: GPA, a letter of recommendation from faculty in their field, and a written essay addressing "biomanufacturing as a career path in my future."

Four sessions of 30 students each were offered during the period of two academic years. The impacted population of 120 students consisted of 63% female and 37% male students, with a distribution of 64% science and 36% engineering students. Analysis of student background in biomanufacturing was performed at the beginning of the training. Eighty-seven percent (87%) of the participants had not taken biotechnology courses throughout their curricula. Table I shows that student previous curricular experience in learning about professional careers, working in interdisciplinary teams, understanding industrial applications of biotechnology and visiting a biotechnology company was limited to an average of 33% of the participants. Key areas in biomanufacturing, such as fermentation and purification of recombinant proteins, and process control, were experienced only by less than 15% of the population. Areas such as regulation, quality control (QC), cleanrooms and validation were reported as previous experiences by less than 25% of the participants.

Faculty used cooperative-learning, one-minute papers, hands-on experiences, and all concepts were presented with regards to applications to the industrial setting of a biomanufacture site to address learning styles diversity. Formal teams of students were established at the beginning of their participation in the program using as criteria diversity in learning styles and disciplines. As a result, diverse interdisciplinary teams with representation of engineering, biology, microbiology and chemistry were formed. Team building activities were incorporated in the training. Among them selection of team names related to the biomanufacturing process, as well as oral presentations throughout the training

with regards to their conceptual understanding of the biomanufacturing process.

TABLE I

STUDENTS PREVIOUS EXPERIENCES IN BIOMANUFACTURING-RELATED AREAS

Students having curricular experiences in ...	Percent
Economic development and professional careers	37
Working in interdisciplinary teams	37
Reflecting about courses relevant to professional careers	46
Industrial applications of biotechnology	27
Plant trip visit to a biotechnology company	20
Students with previous courses or workshops in ...	Percent
Regulation	23
Quality control	34
Environmental monitoring	15
Cleanrooms	24
Validation	32
Fermentation	13
Purification of recombinant proteins	9
Process control	17

C. Implementation: Curriculum

The ABT curriculum was designed in partnership with industry [6], [15] and it was a logical outcome of academia collaboration with multinational biotechnology companies. Faculty participating in the initiative had as requirements industrial experience and excellent teaching qualifications. The designed curriculum resembles the industrial process to produce a recombinant protein (Fig. 2).

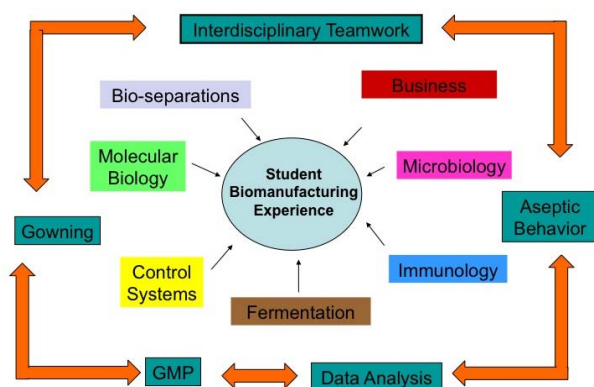


Fig. 2 The ABT workshops profile

The core of the curriculum involved an overview of industrial biotechnology from the business perspective, genetic engineering of cells to produce especially targeted biomolecules, large-scale fermentation with monitoring and control strategies, and recombinant protein purification. Since biomanufacturing occurs in a controlled and regulated environment, the training included workshops in quality control, validation, clean rooms, environmental monitoring, and regulation. The core curriculum was embedded in technical skills such as current Good Manufacturing Practices (cGMP), aseptic conduct, gowning, follow standard operating procedures (SOP), data analysis, and documentation. Soft skills across the curriculum involved working in an

interdisciplinary team, oral presentations, and teamwork. Overall, all activities involved 20% lecture and 80% hands-on.

The experience was rounded-up by providing a plant trip to a biotechnology manufacturing facility to validate the workshop experiences. The industrial visit allowed the students to interact with the management staff of the company that shared with them their career paths in the field, as well as the business component of the company.

III. ASSESSMENT

Program outcomes were assessed using a combination of strategies that include pre- and post-tests, an overall evaluation, and student testimonies. The pre-test assessment strategy provided information about previous experiences and knowledge that students had on the curriculum targeted by ABT. Data established the base-line for the delta in knowledge as a result of the student's learning after the training.

On an average, pre-test data shows that 17% of the population had knowledge in biotechnology. Post-test data indicate a 90% overall improvement in biomanufacturing knowledge. It must be remarked the delta in knowledge acquired by the students in the areas of fermentation (7 to 95%), purification (2 to 83%), and gowning (5 to 99%).

The second assessment strategy involved an overall evaluation of the training process by the students. Data in Table II, using 27 criteria with a scale from 1 (strongly disagree) to 4 (strongly agree) indicated a participant's evaluation of 4.0 on an overall basis. It is important to point out that all students would recommend ABT to peers, considering that the training enriched their academic profile, it was conceived as relevant to the workforce environment, and strengthened their teamwork skills. All ABT participants indicated that the training was representative of the biotechnology plant facility visit.

The third component of the evaluation process was assessing individual workshops using a scale from 4 (outstanding) through 0 (poor). Overall, participants assessed the workshops as outstanding.

An informal assessment strategy used to determine the student's learning consisted on assigning each team the preparation of a drawing where the understanding of the biomanufacturing process by team members was sketched. This exercise was performed before and after completing the ABT training. As part of the program closure event, each team compared their drawings and explained them to the rest of the group. This strategy allowed the visual and global learners to conceptualize the training and provided an excellent opportunity at the end of the training to clarify any misconceptions. Another informal assessment strategy consisted on the preparation by the teams of an open exit essay in which they expressed their impression about the program. All of the testimonials were extremely positive.

TABLE II
OVERALL ABT EVALUATION SCALE: 4-STRONGLY AGREE, 3-AGREE,
2-DISAGREE, 1-STRONGLY DISAGREE

Criteria	Score
The workshop was well organized	4.0
Time was distributed effectively	4.0
The objectives were clearly presented and accomplished	3.9
My previous knowledge was taken into account	3.9
There were diverse opportunities to learn	4.0
I was persuaded to put in practice the theory	4.0
I had the opportunity to reflect on my own learning	3.9
The active participation of the participants was promoted and valued	4.0
The trainers were knowledgeable in the subject matter	4.0
The trainers shared their industrial experience	4.0
The workshop provided a theoretical component of the subject	4.0
The workshops provided hands-on experiences	4.0
The workshops are relevant to the workforce environment	4.0
The training enriched my academic profile	4.0
The workshops provided the industrial perspective to the subject presented	4.0
I would recommend BioTalents training to other fellow students	4.0
The experience will be invaluable in my professional career	4.0
The training provided an innovative approach to traditional Science and/or Engineering curriculum	3.8
I would recommend this innovative approach as part of my Science and/or Engineering courses	4.0
It was an enrichment experience to have faculty and peers from various disciplines	4.0
I value the interdisciplinary nature of training	4.0
The workshop helped me strengthen my teamwork skills	4.0
My previous knowledge in biomanufacturing was integrated in this training	3.9
The workshop allowed me to reflect about economic development and professional careers	3.8
The workshops were representative of the field trip to industry	4.0
After completing the training I have a complete idea of processes associated to biomanufacturing	3.9
The training enriched my profile in knowledge and skills	4.0
Overall average	4.0

IV. DISCUSSION

It is crucial to engage science and engineering students early in their education in experiences that provide them with meaningful learning and networking with career paths in their fields. The ABT Program was instrumental in providing science and engineering students with the opportunity to enhance their curricula in biomanufacturing. A key element of success was the partnership with industry. This partnership allowed the development of a program that provides real-world applications to the students and opened the door to validate the experience by visiting a biotechnology company.

An extremely value-added learning experience is the interaction of students with senior-level industrial staff that were able to convey to students additional knowledge and skills that must be pursued during their academic experience and will allow them to become more competitive upon graduation.

Learning in this training was promoted by theory, hands-on, and teamwork; applying the approach of designing a meaningful learning through a learning-style profile and understanding student's previous experiences in biomanufacturing. This was also another key element of

success.

The best assessment of the success of the program can only be expressed by a testimonial of one of the program participants: "Amgen BioTalents has been one of the most gratifying experiences that I have had through my career as an undergraduate student. Completing the 30-hour training process and learning so much knowledge is a treasure. Personally it helped me to decide that I will continue graduate studies in biotechnology. Thanks to this program, I discovered my passion for biotechnology and my academic perspectives made a 180-degree turn."

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