Thesis Project Portfolio

Production of Adalimumab: A Humira® Biosimilar

(Technical Report)

Understanding the Need for Public Assistance to Overcome Obstacles in the Biosimilar Sociotechnical System

(STS Research Paper)

An Undergraduate Thesis

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Sociotechnical Synthesis
(Executive Summary)

Increasing Access to Medicine with Generic Drugs

Due to the high cost of medicines, many patients are not able to afford needed and life improving treatments. One solution to this problem is the introduction of generic medicines, which are drugs designed to mimic existing and expensive therapeutics. Generic medicines have the potential to increase access to medicine by being sold at a lower price than the originator drug and increasing market competition. One therapeutic of particular interest is Humira® as it is consistently the top grossing pharmaceutical product with no generic on the market. Therefore, for my technical project, my capstone team designed a manufacturing process to produce a generic version of Humira. In order to determine if this design would be effective in increasing patient access, my STS research analyzed the success of generic drugs at lowering the cost of medicine and penetrating the market.

The manufacturing design details the steps required to produce 60 kg of a generic version of Humira in 7 months, which would occupy approximately 10% of the current Humira market. Our team designed the process to be continuous and to implements single-use equipment. These manufacturing techniques increase process productivity by producing large cell densities and decreasing downtime between batches. The designed upstream process produces 12.8 kg of product during 30 days of continuous processing in a 500 L perfusion bioreactor. The solution produced in the bioreactor is then purified in a downstream process with a product recovery of approximately 79%. The downstream process was designed to have 11 steps including filtration, chromatography, and viral clearance methods. Although our team is selling our product for 30% less than Humira, our results show that implementing this process would be highly profitable.

However, in my STS research, I found that generic versions of biological medicines, such as Humira, have not been as effective as small molecule generics in reducing the cost of originator drugs. Biologics have many unique characteristics that makes manufacturing, regulation, and marketing more complex. Therefore, I used Mesthene's framework on political and economic organizations to determine how the public and private domains of the pharmaceutical system could better work together to meet the unique needs of biologics. My analysis revealed that private organizations need more public support in order to have the funds and information required to make it through patent proceedings and clinical trials. Additionally, the public domains should ensure that approved generics are used by doctors and patients through granting interchangeability and increasing education.

Through completing these projects simultaneously, I learned that designing a viable and profitable manufacturing process will not be beneficial unless the product is being used by consumers. In the case of Humira, reducing the cost by 30% will not be enough to overcome challenges facing medicine accessibility. With technical expertise, engineers have the potential to greatly impact society, but they will not be successful if they cannot ensure that there are organizational and cultural institutions in place to ensure the success of technical projects. Therefore, it is vital for engineers to consider more than just the technical components of an engineering project and to understand the sociotechnical system of which they are members.