Thesis Project Portfolio

Design of an Amgen Trastuzumab Manufacturing Facility in Thousand Oaks, California to Continuously Produce Kanjinti, a HER2+ Breast Cancer Treatment Biosimilar

(Technical Report)

A Critique of the Drug Development System in Relation to Orphan Drugs

(STS Research Paper)

An Undergraduate Thesis

Presented to the Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Fulfillment of the Requirements for the Degree

Bachelor of Science, School of Engineering

Morgan Pellegrin

Spring, 2021

Department of Chemical Engineering

Table of Contents

Sociotechnical Synthesis

My STS research paper and technical capstone project assessed two different contexts of drug development: the manufacturing process of monoclonal antibodies and the political and economic structure in the pharmaceutical industry. The technical capstone is the full design of a manufacturing facility for Kanjinti which is a HER2+ breast cancer treatment biosimilar which is owned by Amgen. The STS research went beyond the manufacturing process to discuss how the current political and economic system of drug development is inadequate in driving innovation, especially in the specific case of orphan drugs. Researching the two topics simultaneously presented the obvious disconnect between the motives of large pharmaceutical companies and the need for therapeutics for patients who are struggling from rare diseases.

The technical portion of my thesis was designing a pharmaceutical manufacturing facility for the production of the monoclonal antibody trastuzumab that is a HER2+ breast cancer chemotherapy therapeutic. The facility is located in Thousand Oaks, California on the Amgen headquarters. This facility was designed to operate continuously and with single-use technologies. Continuous operation allows for a more efficient and flexible process, so the drug can be priced lower and made more accessible to the thousands of individuals suffering from this specific type of cancer. Similarly, single-use technologies work to reduce costs and eliminate waste to promote a more environmentally friendly process. The capstone project involved defining the specifics of multiple unit operations, from mammalian cell culture to purification of the product to the point at which it is ready for injection. While designing a more a efficient manufacturing process for Kanjinti was to benefit the thousands of patients with HER2+ breast cancer, there are also 20-25 million patients who suffer from approximately 5,000 rare diseases that have no drug treatment options.

My STS research discussed the history of the drug development process and specific events that shaped the political and economic structure of the for-profit nature of the pharmaceutical industry. Drugs for rare diseases often are never developed or reach a stagnant point in clinical testing because they are too costly to produce or the revenue margins are too small. These drugs are deemed “orphan” drugs. In the 1970’s The Orphan Drug Act (ODA) was passed to provide incentives for pharmaceutical companies to produce these much-needed therapeutics. In my STS paper, I discuss the successes, failures, and what’s next in the progression of the Orphan Drug Act. Throughout my research I found that the very nature of orphan drugs encourages us to think about what innovation occurs and what drugs are developed when profit is considered more important than public health.

Both my technical project and STS research gave me a better understanding of the nuances of the pharmaceutical industry. My technical project was successful in designing a fully operational manufacturing facility that is feasible both economically and physically. My STS research was insightful in describing the successes and shortcomings of innovation in the pharmaceutical industry.