

**Design of a Pembrolizumab Manufacturing Plant Using Continuous Bioprocess
Technology and Single-Use Bioreactors**
(Technical Report)

A Care Ethics Analysis of the Piper Alpha Oil Platform Disaster
(STS Research Paper)

An Undergraduate Thesis Portfolio

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Socio-technical Synthesis

Cancer is a life-threatening illness that has invaded and stolen the lives of billions of people, making cancer drugs such as pembrolizumab critical in the fight against this disease. However, manufacture of such drugs must be carried out such that all parties involved remain unharmed. Examining the ethics surrounding the Piper Alpha oil explosion can apply broadly to any engineering application, including my technical project of designing a pharmaceutical facility for a cancer drug. Pharmaceutical companies are not only responsible for providing safe and accessible medications to society, but they are additionally responsible for their personnel, the environment, and the surrounding community directly affected by the pharmaceutical facilities. Although there is no overlap in technologies between the two projects, the ethical lessons that can be learned from the Piper Alpha disaster can and should be utilized in the context of any technical design, such as a pharmaceutical facility, in order to ensure that those involved with the technology learn to act ethically for the good of the greater whole.

The technical report includes the full design of a Merck pharmaceutical facility producing the cancer drug Keytruda, also known as pembrolizumab. This process encapsulates the drug production process beginning with the inoculation of a master cell bank and ending with a 99.9% purified product ready for intravenous injection. Our capstone team designed the facility to implement a fully integrated, continuous process, in addition to using single-use technology. Making the process continuous offers advantages of higher yield, purity, and efficiency, thus allowing us to drive production costs down, leading to lower drug prices in an effort to make the drug more accessible. Implementing single-use technology indicates that several components of the process will be disposable after a single use, which will decrease the environmental and social impacts of hazardous cleaning chemicals. Overall, the goal of this project was to further

our understanding of pharmaceutical processes, while analyzing the feasibility and economics of implementing new pharmaceutical technologies.

The STS research paper analyzes the morality of various members involved in the Piper Alpha oil rig explosion. I use the theory of care ethics, developed by Carol Gilligan and Nel Noddings, which focuses on the duty of care two parties owe each other in a relationship, especially when the power dynamic is asymmetrical. My claim is that Occidental Petroleum, the company that owned the Piper Alpha oil rig, was immoral due to their failure to provide adequate care for their personnel, and should therefore be held accountable for the resulting casualties. Specifically, I use evidence from the Piper Alpha investigation to prove how Occidental Petroleum continuously failed to provide care to its personnel. By examining this case study, I hope readers can understand that proper engineering design compliance with rules and regulations should arise naturally when designing from a moral standpoint, rather than forcing design specifications to meet the required standards.

Working on both the technical design of a pharmaceutical facility and the Piper Alpha disaster analysis simultaneously has given me tremendous insight into the immense responsibilities engineers carry within society. It is crucial that engineers design with those they owe a duty of care to in mind, such that the final design does not put these parties in harm's way. When working on the pharmaceutical facility design, I was awestruck at how many opportunities there were for failure, such as the personnel getting injured, the drug not meeting quality control standards, or environmental contamination. As the pharmaceutical company owes a duty of care to its personnel, customers, and environment, simultaneously analyzing morality within the context of the Piper Alpha disaster certainly shed light on the weight our technical design decisions would carry within society.