About the Team Master’s Project

The Team Master’s Project (TMP) is the capstone activity for students in the Master of Business and Science, Master of Science in Medical Device Engineering, and Master of Science in Applied Life Sciences (TMP concentration) programs at KGI. In accordance with KGI’s mission of translating the potential of the life sciences into practice, the TMP offers a rigorous and experiential learning opportunity which immerses students in the type of work many will pursue after graduation. TMPs are supported by interdisciplinary teams made up of four to six students who work with sponsoring companies to address real world company objectives.

Replacing the traditional master’s thesis work found in standard programs, these projects provide students with the opportunity to apply their business, regulatory, engineering, clinical, and scientific training to state-of-the-art corporate challenges. Our teams are advised by both KGI faculty and expert industrial liaisons to ensure that academic rigor is paired with pragmatic focus. TMP teams also include students from KGI’s Master of Engineering in Biopharmaceutical Processing program, as well as selected undergraduates from The Claremont Colleges.

TMP activities emphasize problem-solving, project management, productive teamwork, and effective communications skills that will be critically important to KGI graduates as they pursue careers in the applied life sciences industries. Representing a substantial portion of a student’s academic workload, these projects are designed to produce valuable deliverables for the sponsoring companies.

For more information, please scan the QR code or contact Corporate Partnerships at partnerships@kgi.edu.
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Alexion: Waste Minimization & Digital Optimization within Alexion Pharmaceutical’s Clinical Supply Chain

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Corporate Liaisons: Mark Swift, Russell Marshall, Ian Hargadon, Imran Shakur, Ahmed Shoieb

Faculty Advisor: Anna Hickerson

Alexion Pharmaceuticals, a subsidiary of AstraZeneca, is dedicated to revolutionizing the lives of individuals affected by rare diseases through groundbreaking medicines, innovative technologies, and comprehensive healthcare solutions.

Positioned within the Product Development and Clinical Supply (PDCS) department, the TMP team has been tasked with spearheading a project aimed at optimizing resource utilization, scalability, and waste reduction along the clinical supply chain continuum. This initiative is pivotal as Alexion gears up for sustained growth in its clinical pipelines, underscoring the critical role of digital optimization throughout the supply process.

The team conducted a thorough analysis of Alexion’s clinical supply chain, mapping the end-to-end process while identifying key internal and external stakeholders to pinpoint areas of waste. Additionally, the team has quantified these factors, providing valuable insights that form the basis of recommendations for waste minimization and optimization. Literature review and engagement with subject matter experts has garnered insights into industry-used digital tools and waste management techniques, ensuring alignment with best practices.

Key recommendations include implementing additional key performance indicators (KPIs) and a scorecard system that enhances transparency of the clinical trial design dynamics that drive waste. Additionally, a proposal for a series of multi-stakeholder meetings led by dedicated project managers could foster greater levels of collaboration and knowledge sharing. Key favorable outcomes would be total stakeholder buy-in, informed protocol development, and optimized trial execution.

Completion of this project will provide Alexion Pharmaceuticals with an implementation plan that addresses key challenges and leverages solutions to drive efficiency within its clinical supply operations.
**Alphinity: Evaluation of a Novel Impeller-free Mixing Pump**

**Students:** David Guthary, Matthew Kirschbaum, Nicholas McGuire, Paola Pinto, Nigel Reed, Skyler Santos

**Corporate Liaisons:** Craig Vincze, James Yeary

**Faculty Advisor:** Shiva Abdolrahimi

Alphinity, a bioprocessing industry leader, introduces PIXER®, a new impeller-free pump-mixer hybrid tailored for precision fluid delivery and mixing in bioprocessing. Powered by Polymorphic Pump Technology® (PPT®), PIXER® offers unparalleled adaptability, featuring configurable setups tailored to meet the unique demands of various bioprocessing applications. Its primary focus lies in minimizing shear and pulsation, thus optimizing product yield and quality.

As part of its commitment to innovation and advancement, Alphinity has sponsored the development of PIXER®, which is now poised for an initial launch. However, recognizing the importance of comprehensive data in demonstrating its efficacy, Alphinity aims to gather quantitative insights into PIXER®’s performance across a variety of operational parameters.

The Alphinity TMP is dedicated to assessing PIXER®’s performance under varied conditions, with a specific focus on the effects of solution viscosity, working volume, and pump speed on mixing efficiency. Leveraging methods such as real-time conductivity measurements following salt spike injections, the TMP team has correlated PIXER®’s conductivity homogeneity to mixing time.

Through rigorous experimentation and data analysis, the Alphinity TMP team aims to provide invaluable insights into PIXER®’s capabilities. By quantifying its performance metrics with respect to different variables, this project not only showcases PIXER®’s capabilities but also equips Alphinity with crucial information for strategic decision-making and marketing.

By contributing to a better understanding of PIXER®’s functionalities, the Alphinity TMP paves the way for its position in bioprocessing workflows. With the TMP’s findings, Alphinity is primed to lead the industry toward greater efficiency, reliability, and quality in bioprocessing mixing.
Amgen: Business Impact Analysis and Continuity Plan for Process and Product Development at Amgen

Students: Gerardo Blanco, Adrian Chiu, Wyatt Hennig, Karina Lalwani, Hannah Rosenthal

Corporate Liaisons: Andy Sundberg and Eileen Engelberg

Faculty Advisor: Jim Sterling

We determined the impact of a catastrophic event like a natural disaster or a cyber-attack on Amgen’s Process and Product Development (P&PD) group. To help the company respond to such an event as quickly and efficiently as possible, we developed a return-to-normal operations plan. We created three main documents: a Business Impact Analysis (BIA), a Global Business Continuity Plan (BCP), and a Location Business Continuity Plan (LBCP).

The BIA summarizes a disaster’s impact with respect to four main areas: financial, reputational, operational, and regulatory. Through a set of representative interviews aimed at capturing the impact on these four functions, we generated an estimate of the return to operations (RTO) time.

The BCP covers the recovery strategies that could be used in the event of a business disruption to minimize the impact in the three following P&PD subprocesses: Drug Substance/Drug Product Process Design, Device Design Controls, and Packaging and Labeling Development.

Time permitting, the team is also tasked to complete a location-specific BCP (LBCP). The LBCP specifically details the dependencies and contingencies of individual sites and outlines a more site-specific plan for RTO.
Amgen: Developing Dynamic Tableau Dashboard for Driving Business Decision-Making

**Students:** Vahe Akopyan, Hannah Chum, Guarina Garcia-Delgado, Kaya Hano, Evan Villano

**Corporate Liaisons:** Julie Matheny

**Faculty Advisor:** Haibo Liu

Amgen, a leading developer of pharmaceutical products, focuses on advancing healthcare through innovative research and development. Its business operations encompass three main functions: Research and Development, Operations, and Commercial. Operations at Amgen are composed of five core areas: Global Supply Chain, Process Development, Manufacturing, Quality, and Engineering.

For this project, the team focused on Process Development (PD), which is accountable to deliver on an exceptionally large and dynamic portfolio. Aiding in the analysis of that portfolio is the Business Strategy Integration (BSI) team. The BSI team is responsible for the development of financial assessments for PD teams to advance Amgen’s pipeline portfolio. BSI works across Process Development functions to assess the impact of new product advancement, product lifecycle management, and the introduction of new processes and technology for development.

The goal of this project is to create a searchable database of BSI’s business case (BC) financial assessment data in Tableau, an automated data visualization tool, to enable dashboards for monitoring BSI’s financial assessment portfolio. These visualizations will inform the impact of projects on PD business and contribute to product strategy decisions.

The TMP team was tasked with creating a dynamic Tableau dashboard that could display a variety of visualizations of financial data derived from business cases and rapid assessments that are analyzed by the BSI team. To accomplish this objective, the team used Alteryx to aggregate the business cases so that a compatible output can be utilized for Tableau. To better understand the needs of this project, the team engaged in stakeholder interviews to outline and define user and data requirements. In addition, the team created a data process flow map to outline how data was being extracted, manipulated, and presented for a dynamic dashboard. User stories were also created from the perspective of business analysts and business leaders to aid in the development of the Tableau dashboard so that meaningful insights could be made from the visualizations. Completion of this project can empower BSI with a new capability to rapidly analyze business case data to support more efficient and informed business recommendations to drive decision-making regarding PD budget data, resource allocations, development pipelines, etc.
Boehringer Ingelheim: Downstream Facility Capability Model

Students: Edgar Baldeon, Samuel Claesson, Emiko Ito, Kevin Pizarro, Justin Scoggins

Corporate Liaison: Shengchun Guo

Faculty Advisor: Sue Behrens

Boehringer Ingelheim (BIFI) is known for its commitment to innovation and has a strong pipeline of drugs in various stages of development. In addition to pharmaceuticals, Boehringer Ingelheim also produces animal health products, including vaccines, parasiticides, and pharmaceuticals for pets and livestock. Boehringer Ingelheim has a location in Fremont, California focused on the production of large-scale biologics.

This Team Master’s Project aims to build a digital model of BIFI’s downstream manufacturing facility for process development and facility fit purposes. Apart from performing facility fit exercises, the model should also be used to aid development scientists to proactively optimize the process to avoid gaps and identify areas for improvement to better position the site for future projects. Also, this model can be used to create a Process Description (PD) or can be used to scale up an existing process. Additionally, this tool provides access to all downstream manufacturing equipment and parameters that are stored in a secured Equipment Database, allowing the user to select the most suitable equipment for the process analyzed.

Additionally, we developed a User Guide for the model. This guide will be used for training and onboarding new employees to build their ability to apply the software tools developed for the Downstream Process (DSP) area. It defines standardized procedures for the software tool to maintain consistency and accuracy in data processing and analysis. Inevitably, users may encounter issues or have questions while using the software tool. A well-documented user’s guide includes troubleshooting tips, FAQs, and contact information for technical support, facilitating timely resolution of issues and minimizing downtime.
Boehringer Ingelheim: Utilization of Advanced Modeling Software to Simulate Biopharmaceutical Manufacturing Facility and Identify Potential Process Bottlenecks to Improve Manufacturing Capacity

Students: Bryce Fitzwilson, Mara Girgis, Mohd Islam, Sean Ko, Natasha Matti, Ahmed Srass

Corporate Liaisons: Johnny Lam

Faculty Advisor: Michael Koeris

The project’s objective is to simulate the biopharmaceutical manufacturing floor at the Boehringer Ingelheim facility using the Real-Time Modeling System (RTMS) software. Our task is to enhance the existing model of the upstream and downstream processes, which was created last year, by incorporating essential utilities. These utilities include water for injection (WFI), clean steam generation (CSG) capacity, and waste capacity. Additionally, our team aims to complete the facility model by modeling the drug product fill line. This comprehensive computer model provides invaluable insights into improving Boehringer Ingelheim’s manufacturing capacity.
Gilead: Data Verification to Support CMC Submissions

**Students:** Krithika Balakrishnan, Sorinna Buo, Armaana Chawla, Eva Fernandez, Brigitte Vazquez

**Corporate Liaisons:** Yannie Meletopoulos, Laurinda Cunha

**Faculty Advisor:** Larry Davis

Gilead Sciences is a research-based biopharmaceutical company headquartered in Foster City, California with offices worldwide. Gilead is focused on therapeutics for HIV/AIDS, liver diseases, hematology and oncology, inflammatory and respiratory diseases, and cardiovascular conditions.

With a wide portfolio of drugs in their pipeline in various stages for commercialization, there is a need for a process that can manage its Chemistry, Manufacturing, and Controls (CMC) data for their respective sections of the regulatory submissions to Health Authorities. The Gilead KGI Team Master’s Project (TMP) team was tasked with the development of a data verification process that ensures the traceability of the data in CMC regulatory submissions.

The TMP team was able to identify areas of opportunity for improvement in the data verification processes. The team is also conducting ongoing literature reviews and interviews with subject matter experts to identify best practices and software platforms as potential options for implementation. The requirements for the process include completing data verification without compromising time to submission, maintaining flexibility for use across all drug and data types (in-house and external), and with consideration given to the evolution of data.
Kite Pharma: Innovative Cost Analysis Model for Quality Control Test Methods of CAR-T Therapies


Corporate Liaisons: Kyle Carter, Tam Soden, Jennifer Joseph

Faculty Advisor: Alan Rothfeld

Kite Pharma, a Gilead Sciences company, has been a leading pioneer in the immune-oncology space. Kite was acquired by biopharma leader Gilead Sciences in October 2017. Kite’s notable CAR-T therapies are Yescarta® (axicabtagene ciloleucel) and Tecartus® (Brexucabtagene autoleucel). Yescarta is designed to treat large B-cell lymphoma (DLBCL), while Tecartus treats mantle cell lymphoma (MCL) and acute lymphoblastic leukemia (ALL). These medications function by genetically modifying a patient’s own T-cells to express a chimeric antigen receptor (CAR), enabling them to recognize and attack cancer cells.

The Kite Pharma TMP team was assigned the task of developing a user-friendly standardized cost analysis model for evaluating the expenses associated with quality control (QC) test methods in CAR-T therapy. This tool will be utilized within Kite Pharma to assess the financial impact of assays in their current portfolio and make informed business decisions. To achieve this objective, the Kite Pharma TMP consulted and interviewed various subject matter experts (SMEs) and gathered data to address pertinent areas of concern. The resulting tool serves as a model for input of qualitative and quantitative data that would automate cost analysis for QC test methods. Successful completion of this project will provide Kite Pharma with a practical tool for evaluating and mitigating potential financial burdens.
MacroGenics: Identification of Clinical Supply Chain Management Trends and Future Outlooks Within the Industry

Students: Maithili Dhawale, Andrew Jones, Edith Ruiz, Benjamin Smith, Mayur Upparapalli, Morris Vasser-Campbell

Corporate Liaisons: Lisamarie Georgen, William Franklin

Faculty Advisors: Ed Arnheiter, Yun Liu

MacroGenics is a leading biopharmaceutical company specializing in the discovery, development, and manufacturing of intricate biologics tailored for combating cancer and other disorders. Founded in 2000, the company has consistently pushed the boundaries of innovation. With an extensive pipeline of product candidates undergoing meticulous evaluation in clinical trials, MacroGenics harnesses proprietary antibody-based technology platforms to craft six immune-oncology programs. Collaborating synergistically with Eversana, MacroGenics has successfully commercialized MARGENZA (margetuximab), a groundbreaking therapeutic agent indicated for metastatic HER2-positive breast cancer treatment, underscoring the company’s unwavering commitment to addressing critical medical needs.

Guided by a set of core values emphasizing patient-centricity, innovation, and inclusivity, MacroGenics remains at the forefront of scientific advancement. Leveraging innovative antibody-based platforms, including multi-specific, Fc optimization, and antibody-drug conjugate (ADC), the company strategically balances in-house capabilities for discovery and manufacturing with strategic partnerships with leading contract research organizations.

Within its Technical Operations and Clinical Operations departments, MacroGenics adeptly navigates the complexities inherent in managing the clinical supply chain. Recognizing the multifaceted nature of supply chain management, the company has identified an opportunity to further enhance efficiency and streamline operations. This TMP project aims to meticulously analyze and address existing bottlenecks, optimize forecasting methodologies, refine secondary packaging processes, and explore industry best practices across various dimensions of the clinical supply chain. With completion of this project and through the joint effort with MacroGenics, our team has provided the necessary information to transform clinical supply chain management to ensure life-saving therapies reach patients worldwide without interruption.
Medtronic: Development and Deployment of Marketing Strategy for Internal Laboratory Services

Students: Kusha Bidasaria, Matthew Chan, Kaitlyn Hohl, Alazea Serrano, William Thomas

Corporate Liaisons: Paul Shipley

Faculty Advisor: Maxim Polonsky

Medtronic is a global medical device company founded in 1949. Its mission is to use technology to alleviate pain, restore health, and extend life. It has developed technology that treats over 70 health conditions across four portfolios: cardiovascular, diabetes, medical-surgical, and neuroscience.

Over the past two years, Medtronic has centralized and standardized its internal lab services, resulting in Global Lab Services (GLS). GLS serves and supports 20 operational units and 65 manufacturing sites at the global level. Furthermore, GLS provides lab testing services across six functions: Chemical Characterization, In vitro, Microbiology, Chemistry, Product Stability, and Pharma.

The Medtronic TMP was tasked with developing and implementing a marketing strategy to identify and engage with potential customers to increase internal revenue and customer satisfaction. To achieve this goal, the team undertook five vital steps: 1) completing and verifying the customer and opportunities map; 2) deploying a survey to all existing and potential customers; 3) conducting Voice of Customer (VoC) sessions; 4) evaluation of the current value proposition; and 5) curating a long-term sustainable marketing strategy. The team stratified customers by functions, organizational employment level, and operating unit. Furthermore, a tangible plan was provided for each of the groups. The completion of this project has provided Medtronic and GLS with important information to guide customer engagement and retention.
Merck: Leveraging Digital Risk Management Platforms to Build a Resilient Supply Chain Framework

Students: Ashley Barraza, Pavithra Shekhar, Umit Suri, Nicole Tan, Liya Yemaneberhane

Corporate Liaisons: Renan de Assis Torres, David Jimenez

Faculty Advisor: Meghana Joshi

Through bold and transformative science, Merck is driving innovation that continues to prove its strength as a veteran company at the forefront of the industry. The past decade has introduced the fourth industrial revolution, Pharma 4.0, wherein the industry has seen changes in manufacturing and other areas brought about by digital technologies.

One such area, and the focus of this project, is how digital technologies can be leveraged to improve Merck’s supply chain network and resilience. Due to the increasing number of disruptions that impact supply chain, Merck has found that its current risk identification, analysis, and management processes are not sufficient. The Digital Supply Chain Value team aims to develop digital capabilities that address current process gaps and ensure a resilient supply of Merck’s life-saving products.

The primary objectives of this TMP were to identify the pain points in the current processes specifically concerning suppliers and to build a business case on how implementing more automated and robust risk management platforms can provide value to supply chain on an enterprise-wide level. To accomplish these objectives, the team performed primary and secondary research, engaged in interviews and surveys with key stakeholders across the company, and performed gap analyses. After establishing the business needs, the team was tasked with mapping how a risk management platform would affect the various teams and how best to implement it. This took the form of a comprehensive change management plan highlighting timelines, key personnel, potential challenges, and additional applications to other risk management functions.
Pfizer: Leveraging Mechanistic Chromatography Modeling for Process Characterization Studies

Students: Franchesca Crevani Ore, Emmanuel Mensah, Nahir Rojas-Rivera, Farnoush Sohbati, Leonardo Tavormina

Corporate Liaisons: Shilpa Ananthakrishnan, Arch Creasy, Leo Kutlowski

Faculty Advisor: Saurav Datta

Pfizer is one of the world’s premier biopharmaceutical companies. The corporation has a diverse portfolio of medicines, including small molecules, biologics, and vaccines, which make them one of the leaders in the life sciences industry. Pfizer’s main purpose involves introducing scientific and commercial innovations that change patients’ lives for the better and those around them.

Within Pfizer, the Bioprocess Research and Development (R&D) group develops and implements new technologies to support the manufacturing of biotherapeutics from early stage through commercial launch. The Bioprocess R&D group has tasked the Pfizer TMP team with using GoSilicoTM, a mechanistic chromatography modeling software, to accelerate the process characterization of a polishing step used in the purification of a monoclonal antibody-like molecule. Digital twin chromatography models were created using wet lab data and simulations were conducted to compare model predictions with real-life experimental results. This work aimed to help Pfizer understand the limits of current mechanistic model and develop a verification and validation strategy to support the model in a regulatory filing.

The team was also responsible for developing templates and tools that could facilitate late-stage process development efforts. These tools are designed to support robust process control and aid in regulatory interactions, ensuring that optimization strategies are effective and compliant with regulatory standards. The aim is to establish a streamlined and efficient process, from modeling and experimentation to discussion and regulatory approval, enhancing the overall efficiency and reliability of biopharmaceutical manufacturing.
Pfizer: Investigating Barriers to Optimize Inflammatory Bowel Disease (IBD) Clinical Trial Recruitment

**Students:** John Ayad, Sophia Carigo, Deborah Omosalewa Ife-Tugbiyele, Claudine Ignacio, Sabrina Smadi

**Corporate Liaisons:** Martin Summers

**Faculty Advisor:** Jeniffer Hernandez

Pfizer, is a leading American multinational pharmaceutical corporation known for its innovation in healthcare. The company’s mission centers around advancing therapeutics in areas such as Anti-Infectives, Oncology, Inflammation and Immunology, Internal Medicine, and Rare Diseases. Driven by a commitment to research and development, Pfizer is dedicated to creating breakthroughs that improve patient care and address significant unmet medical needs.

The TMP student team is tasked with addressing the challenges of patient recruitment for inflammatory bowel disease (IBD) clinical trials. Despite the availability of new treatments over the last decade, there remains a significant unmet need among the global IBD patient population. The declining recruitment of patients into clinical trials is a major barrier to introducing new therapeutic options.

The team’s objective is to explore and understand the barriers to IBD clinical trial recruitment by focusing on patient perception and experience. This initiative seeks to understand the IBD patients in their decision to participate in clinical trials through comprehensive research, including interviews with patients, physicians, and investigative site staff. Following this understanding, the project aims to refine clinical trial protocols, enhance patient-centricity, and ultimately increase patient “recruitability”. The overarching objective is to expedite the introduction of new therapeutic options for IBD by ensuring efficient and effective trial participation.
**Synedgen: Radiation Countermeasures**  
**Therapeutic Development**

**Students:** Karina Lalwani, Wyatt Hennig, John Ayad, Adrian Chiu, Gerardo Blanco  
**Corporate Liaison:** Shenda Baker  
**Faculty Advisor:** Jim Sterling

Synedgen, Inc. (Claremont, CA) is a biopharmaceutical company founded in 2009. As pioneers in the novel field of glycomedicine, the Company has developed a proprietary drug platform called the Multivalent Innate Immune Signaling Target (MIIST), with therapeutics that target human glycobiology to unlock new therapies. The Company's lead pipeline asset is MIIST305, a drug for Ulcerative Colitis (UC) and Acute Radiation Syndrome (ARS). MIIST305 is a non-absorbed, cationic biopolymer that targets modulates the human innate immune response to lower gut hyperinflammation, promote the repair and regeneration of gut tissues, and promote microbiome homeostasis. In preclinical models, the drug has shown efficacy in treating GI injury that is the hallmark of both UC and ARS. Synedgen has conducted pre-Investigational New Drug (IND) meetings for both indications with the FDA without any significant hurdles.

The TMP team was directed by Synedgen to investigate four different areas: ulcerative colitis clinical endpoints, mini-pigs biomarkers for ARS, production scale-up, and enterprise cost. We identified the unmet needs in the UC disease space, and potential primary and secondary clinical endpoints.

Through discussions with numerous research companies we were able to identify specific companies to support the Synedgen biomarker assessment effort. We also characterized the lab time to develop biomarker kits for ARS specifically designed for rodents and mini-pigs in order to test the samples in their labs. We have provided a list to Synedgen of companies that have the capabilities to specifically handle Synedgen pre-clinical and biomarker testing needs.

Finally, we provided a financial analysis for the scale-up of manufacturing necessary for the proposed effort. This included the bioreactor and purification technologies required, as well as the laboratory facilities needed at different scales of production of pre-clinical product.
Upside Foods: Literature and Product Information from Vendors for Cell Separation Technologies

Student Team Members: Victoria Apodaca, Eduardo Hernandez, Amarjot Mann, Gopi Patel, Madhumitha Senthilkumar, Sarah Vue

Corporate Liaison: Kesav Reddy

Faculty Advisor: Gargi Ghosh

Upside Foods (formerly Memphis Meats), headquartered in Berkeley, California, pioneers real meat production by cultivating animal cells instead of raising animals. The Manufacturing Science and Technology Development (MSAT) department spearheads introducing new processes and products, technology transfer, validation, and manufacturing support. They collaborate with process development, engineering, manufacturing, sensory, and product development teams to cultivate, scale up, implement, and commercialize cultivated meat products.

The Upside Foods Literature Review and Vendor Evaluation project seeks to analyze and compare different cell separation techniques used in cultivated meat production, alongside evaluating potential vendor options. The objective is to gain a comprehensive understanding of how the cultivated meat industry leverages cell separation techniques and identify opportunities for Upside Foods to optimize its manufacturing process. Ultimately, a user requirement specification report will be delivered, outlining potential vendors and recommended cell separation techniques.
Keck Graduate Institute would like to thank all our sponsors for their generous support of the Team Master’s Project.

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