About the Team Master’s Project

The Team Master’s Project (TMP) at Keck Graduate Institute (KGI) is a degree requirement and capstone activity for students in the Master of Business and Science (MBS) program 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 typically 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 marketing, business, financial, and science training to state-of-the-art corporate challenges. Importantly, our teams are advised by both expert KGI faculty and industrial liaisons to assure that academic rigor is paired with pragmatic focus. Members of TMP teams often also include other KGI students in our postbaccalaureate programs, Master of Engineering in Biopharmaceutical Processing, Master of Science in Applied Life Sciences, Master of Science in Medical Device Engineering, as well as senior undergraduate students from The Claremont Colleges.

TMP activities emphasize problem-solving, project management, new business opportunity, 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 about 35 percent of a student’s final year of academic work, these contract research projects are designed to produce valuable deliverables for the sponsoring companies.

Learn more about TMP by visiting kgi.edu/tmp.
TMP Virtual Public Presentations
Friday, April 29, 2022

8:00–8:15 a.m. . . . . . . Welcome by Sheldon Schuster, KGI President
Shannon Braun, Senior Director of Corporate Partnerships
Ken Gruys, TMP Program Director

8:20 a.m.–12:10 p.m. . . Team Presentations
Zoom Group A and Zoom Group B | Register at kgi.edu/event/tmp22

<table>
<thead>
<tr>
<th>Time</th>
<th>Zoom Group A</th>
<th>Zoom Group B</th>
</tr>
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<tbody>
<tr>
<td>8:20 a.m. Start</td>
<td>Pfizer</td>
<td>Development of Global Clinical Development Plans and Medical Strategies</td>
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<td>8:30 a.m. Q&amp;A</td>
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<td>8:40 a.m. Start</td>
<td>Pfizer</td>
<td>Process Development of Non-platform molecules using Mechanistic Modeling</td>
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<td>8:50 a.m. Q&amp;A</td>
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<td>9:00 a.m. Start</td>
<td>Catalent Pharma</td>
<td>Process Approaches for mRNA–LNP Products</td>
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<td>SanBio, Inc.</td>
<td>Investigation of Human Mesenchymal Stem Cells through Growth Kinetics and Product Characterization</td>
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<td>9:30 a.m. Q&amp;A</td>
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<td>9:40 a.m. Start</td>
<td>AstraZeneca</td>
<td>Identifying and Proposing Solutions for Warehouse Operations Optimization</td>
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<td>9:50 a.m. Q&amp;A</td>
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<td>10:00 a.m. Start</td>
<td>Gilead Sciences</td>
<td>Reporting Tool for the Analysis of Equipment Parameters During the Lyophilization Step in the Manufacturing of AmBisome®</td>
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<td>10:10 a.m. Q&amp;A</td>
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<td>10:20–10:30 a.m.</td>
<td>Break</td>
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<tr>
<td>10:30 a.m. Start</td>
<td>Promex Industries</td>
<td>Expansion of Medical Device Electronics Manufacturing Services</td>
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<td>10:40 a.m. Q&amp;A</td>
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<td>10:50 a.m. Start</td>
<td>Boehringer Ingelheim</td>
<td>CFD Modeling of Downstream Hold Tanks</td>
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<td>11:00 a.m. Q&amp;A</td>
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<td>Boehringer Ingelheim</td>
<td>Characterization of Available Scale Down Models using Computational Fluid Dynamics, and an Economic Analysis</td>
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<td>11:30 a.m. Start</td>
<td>Orbillion Bio, Inc.</td>
<td>Serum-Free Media Development and Cell Line Suspension Adaptation for the Cultivated Meat Industry</td>
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<td>11:40 a.m. Q&amp;A</td>
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<td>11:50 a.m. Start</td>
<td>Analytik Jena</td>
<td>Design and Prototype of Automated, Cloud-based Imaging System</td>
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<td>12:10 p.m.</td>
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</tbody>
</table>

10 minute presentation, nine minutes of Q&A, and a one-minute transition to the next team
Innovators Start Here
## Contents

About the Team Master’s Project ................................................................. 2
Clinical Supply Chain Network Optimization ............................................. 6
Digital Neurology Landscape Analysis ...................................................... 7
Recommendation for a Commercially Viable Multispecific Protein Therapeutic Manufacturing Process ...................................................... 8
Optimizing CMC Regulatory Submissions ............................................... 9
Design and Prototype of Automated, Cloud-based Imaging System .............. 10
Reclassification of Regulatory Depository Files to Increase Accessibility and Efficiency ................................................................. 11
Identifying and Proposing Solutions for Warehouse Operations Optimization ................................................................. 12
Applying Innovation to Goal Keeping & Daily Huddles ............................... 13
CFD Modeling of Downstream Hold Tanks .............................................. 14
Characterization of Available Scale Down Models using Computational Fluid Dynamics, and an Economic Analysis ........................................ 15
Process Approaches for mRNA–LNP Products ........................................ 16
Investigating the Future of Regulatory Affairs ......................................... 17
Reporting Tool for the Analysis of Equipment Parameters During the Lyophilization Step in the Manufacturing of AmBisome® ........................................ 18
Survey of Electronic Batch Record Options for Clinical GMP ...................... 19
Determining Entry Points to Integrate Hologic BCI Test into the NCCN-Designated Cancer Centers ................................................................. 20
1) Creation of a Predictive Shipping Analytics Tool ................................. 21
2) CGT Autologous Competitive Intelligence ........................................ 21
Serum-Free Media Development and Cell Line Suspension Adaptation for the Cultivated Meat Industry ................................................................. 23
Developing Global Clinical Development Plans and Medical Strategies ........ 24
Process Development of Non-Platform Molecules using Mechanistic Modeling ................................................................. 25
Expansion of Medical Device Electronics Manufacturing Services .............. 26
Investigation of Human Mesenchymal Stem Cells through Growth Kinetics and Product Characterization ................................................................. 27
Supply Chain Analysis for MTO vs. MTS .................................................. 28
Clinical Supply Chain Network Optimization

Students: Andrew Dionson, Sophia Montoya, Mandavi Oberoi, Adnan Syed, Jonathan “Ojo” Ventura

Corporate Liaisons: Jeff Heckler, Chris DiAndreth, Anamika Jha

Faculty Advisors: Jim Sterling, Joel West

The Amgen Thousand Oaks Site Supply Chain organization supporting this project is responsible for all aspects of supply planning, manufacturing scheduling, capacity planning, risk mitigation and raw materials planning/sourcing activities for manufacturing and supply of clinical and commercial therapeutic drugs. This project focused on Amgen’s clinical supply chain operations at the ATO (Thousand Oaks) and ABR (Netherlands) sites that support packaging and labeling of clinical finished drug product (FDP) for clinical studies. As the capabilities at these sites grow and clinical trials become more complex and global, there is a new opportunity to reoptimize how Amgen performs site selection analyses.

The Amgen team sought the help of the KGI student team to establish a new framework for decisions that enable the company to optimize its clinical network in terms of product and supply risk, speed to patient, inventory management, and material and operational costs. The team achieved this objective by first conducting industry benchmarking research to gain insight on how other companies design optimized supply chains. We then interviewed subject matter experts (SMEs) and key opinion leaders (KOLs) at Amgen and KGI to better understand the current state of the clinical supply chain and site selection process. We then used this background knowledge to build a decision tool to aid the Amgen team with making optimized site selection decisions and demonstrated its utility using a real-world business case.
Amgen Inc., headquartered in Thousand Oaks, California, is one of the largest biopharmaceutical companies in the United States. The company was founded as Applied Molecular Genetics in 1980 with the goal of manufacturing innovative medicines for seriously ill patients. Riding off successes of keys assets like Enbrel® (etanercept), Neulasta® (pegfilgrastim), and Prolia® (denosumab) in recent years, Amgen now consistently brings in over $20B in revenue annually. The TMP students will tackle a digital neurology landscape analysis to provide Amgen's commercialization team with a full breath analysis of the external digital neurology space. This project supports Amgen’s Commercial Insights team focusing on their migraine drug Aimovig® (erenumab-aooe).

Aimovig® is a preventative migraine medication administered through injection (SC). In the broad neurology space, it is common for neurologists to treat a variety of conditions, such as, migraines, Alzheimer's, strokes, Parkinson's, multiple sclerosis, epilepsy, and others. Broadly researching the digital behavior of neurologists could help identify potential market opportunities for any of these conditions.

The digital neurology analysis consists of three simultaneously conducted phases: investigating the prevalence of digital prescriptions, external companies’ social media initiatives, and other digital media streams being utilized to target patients and healthcare professionals. As graduate and undergraduate students, we were uniquely positioned with generational knowledge to delve into these topics and provide maximum value to Amgen.
Recommendation for a Commercially Viable Multispecific Protein Therapeutic Manufacturing Process

Students: Julia Carreon, Rozhin Naghdi, Gianhu Nguyen, Harshpreet Suri, Jessica Toledo

Corporate Liaisons: Christopher Borths, Janine Tom, Ed Wong

Faculty Advisor: Animesh Ray

A biotechnology leader, Amgen is a global biopharmaceutical company founded in 1980 with a deep commitment to serving patients through discovering, developing, manufacturing, and delivering innovative therapies to address human disease. The therapeutic areas include cardiovascular disease, oncology, bone health, neuroscience, nephrology, and inflammation.

Amgen is currently exploring novel biologics development and manufacturing for multispecific protein therapeutics. With its wide range of applications, including delivering payloads to targeted sites and redirecting T-cells to tumor cells, multispecific therapeutics have been shown to be effective for various clinical indications such as oncology. However, due to the likelihood of aggregation, potential immunogenicity, among other issues, this area of therapeutics development remains an active, ongoing research challenge.

The Amgen Evaluation of Bioconjugation Technologies TMP Team was tasked with the construction of a state-of-the-art bioprocessing and conjugation chemistry process model, based on the evaluation of protein production options and suitable chemical conjugation technologies for commercial manufacturing. To fulfill these objectives, the Amgen TMP team reviewed and analyzed published literature on current, emerging, and future-forward technologies for the production and conjugation of relevant classes of proteins. Additionally, the team estimated projected yields, analyzed process feasibility, and conducted a Cost of Goods Manufactured (COGM) analysis on production and conjugation methods for large scale manufacturing based on determined criteria. Completion of this project is expected to provide Amgen with insights on the technologies and production of multispecific protein conjugates that have the potential for a broad application to future therapeutics through modular molecule design and site-specific control.
Optimizing CMC Regulatory Submissions

Students: Micaela Arambel, Vishakha Jain, Nita Kumar, Jizel Snow

Corporate Liaisons: Mike Abernathy, Jill Beierle, Nina Cauchon

Faculty Advisor: Rajesh Parti

This project focuses on evaluating the implementation of automation processes for Chemistry Manufacturing and Controls (CMC) data which will enable streamlining of regulatory submissions to a health agency through transforming burdensome word and data documents into digitization forms leveraging modern technology.

Assumptions of automation efforts include modernizing by digitizing CMC data driven sections for the regulatory filing process which will allow for the potential of faster review of products in not only one region of the world, but multiple regions in coordination between sponsors and regulatory agencies when seeking approval for Amgen’s therapeutic products.

The scope of this project focuses specifically on FDA. The project resulted in the development of a tool that quantifies both time and cost savings with automation. In addition, a manuscript for publication and a script for social media were also developed.

In the near future, automation will make the data-entry process less burdensome and modernize regulatory filings. Regulatory professionals can spend more time working on ensuring the quality of the data discussions provide appropriate regulatory and scientific rationale and less time on verifying the information, as data integrity remains intact. Automation will also ensure that multiple stakeholders within the other functions, such as a quality function of the company can view the same data and give their feedback in real time. The benefits of the time and cost savings due to automation can potentially streamline submission and review processes in accelerating access to therapies for patients.
Design and Prototype of Automated, Cloud-based Imaging System

Students: John Gomez, Tristan Jaeger, Maria Jose Melo De la Carrera, Michael Gonzalez, Christopher Moore

Corporate Liaison: Sean Gallagher

Faculty Advisor: Anna Hickerson

Our TMP client company, Analytik Jena US LLC, is located in Upland, California and is a subsidiary of Endress + Hauser, a Swiss-based globally operating process and laboratory instrumentation and automation supplier. Analytik Jena continually strives to develop state of the art products to further science and technology.

Analytik Jena operates in designing and manufacturing analytical instruments. These products include: Elements Analysis, Molecular Spectroscopy, Liquid Handling & Automation, and Sample Prep Consumables. The Upland Analytik Jena office we worked with specializes in designing, manufacturing, and servicing gel electrophoresis imaging systems. Their gel imaging products are used for Western Blot Analysis, Colony Counting, Gel Electrophoresis, and Chemiluminescence. The products include automation for optical controls, filter selection, epillumination (lighting from around the sample) and transillumination (lighting from underneath the sample) lighting selection, and built-in image analysis software, VisionWorks, to streamline the research process.

Existing imaging systems, with all the necessary components, are usually complex and very expensive, and because of this are more often purchased by research companies with sizable funding. As such, there is a problem of accessibility of these instruments to the educational and personal market sectors. This project created a new compact gel imaging system leveraging a cloud-based component. The intention of this project was to allow the system to become a cost-effective option for high schools, college research institutions, and research labs with limited funds.
Reclassification of Regulatory Depository Files to Increase Accessibility and Efficiency

Students: Maria Hammett, Pablo Meza, Jamie Lyn Pacada, Julie Tobar-Sosa, Nahomi Yewhalashet

Corporate Liaisons: Yvonne Coffey, Laura Smith, Anaia Davidson, Mary Wilhelm, Gary Kirk, Liam Curran

Faculty Advisor: Kate Choi

Ascendis Pharma is an innovative technology company that’s building to become a leading, fully integrated global biopharmaceutical company making significant differences to patient’s lives. The company was founded in 2007 and have established themselves in the industry through their innovative TransCon (transient conjugation) technology platform to meet unmet clinical needs for various populations.

As with any leading pharmaceutical company, regulatory affairs are an integral part of day-to-day operations. Ascendis Pharma is interested in the reclassification of its Veeva Vault documents to increase overall accessibility and efficiency of the company. In order to accomplish this, the team was tasked with completing a careful analysis of Standard Operating Procedure trainings and the standardization of Veeva documents to deliver a recommendation for future document management. Through learning about the regulatory affairs of Ascendis, our team was able to assist in organizing these documents so as to increase the efficiency of future file requests.

As we have become more familiar with various regulatory documents, we have moved into the analysis of different Health Authority questions and responses. Our team hopes to present our final results showing how these processes are critical for an efficient regulatory strategy team. We hope this work will allow the Regulatory Team at Ascendis to search and retrieve documents in a more efficient manner as they continue to grow and expand.
Identifying and Proposing Solutions for Warehouse Operations Optimization

Students: Gabriela Estupiñán, Janette Keola, Rachael Magill, Nathalie Pham, Daniel Saucedo

Corporate Liaisons: Pranav Patel, Steven Sachar, Matthew Barr

Faculty Advisor: Sukumarakurup Krishnakumar

AstraZeneca is a leading biopharmaceutical company with locations across the globe providing both clinical discovery and commercial scale production of various life changing pharmaceuticals. Through decades of growth and market success, millions of patients worldwide utilize their innovative medicines. In 2020, AstraZeneca had a 70,000+ workforce and produced $25.9 billion in sales. The Biologics Manufacturing Center in Frederick, MD primarily focuses on commercial manufacturing of company products on both a large and small scale.

AstraZeneca has noted operational stress being placed on their supply chain due to warehouse storage capacity. In order to optimize their warehouse capabilities, they directed our TMP team to identify areas for improvement through the expansion of existing technologies.

Our KGI TMP team was tasked with selecting opportunities presented by AstraZeneca to better protect their supply chain and improve warehouse operations. To accomplish this, the KGI Team traveled to the Frederick site to assess the situation and identify where rapid impact could be realized. Two major projects arose from the site visit. The first being the creation of a reverse logistics solution for asset tracking that operates both on-site and externally to limit potential asset loss. The second being an evaluation of materials handling from warehouse to manufacturing with reduction of manual events and optimized digital reporting. Completion of these projects will provide AstraZeneca with solutions to better monitor assets and material management with potential application across multiple sites globally.
Applying Innovation to Goal Keeping & Daily Huddles

**Students:** Kate Blanding, Lizeth Rivas, Sofia Shimizu, Cecile Vazquez

**Corporate Liaisons:** Daniel Lee, Lily Ramirez

**Faculty Advisor:** Ed Arnheiter

Atara Biotherapeutics is a biotechnology company developing groundbreaking off-the-shelf allogenic T-cell immunotherapies for patients suffering from cancer, certain autoimmune diseases, and serious viral infections. Atara’s mission is focused on transforming the lives of patients with serious medical conditions through pioneering science, teamwork, and commitment to excellence.

Atara’s TMP team has focused on two project applications. Project application one is based on Goals Cascades. This project is to identify and determine if there is a better way to track and manage annual team goals. We will investigate how updates are generated, integrate a cascade visibility to the Organization/Corporate goals, propose an enhanced methodology to track and manage goals, and utilize technology demos to create an innovated cascade system. The goal cascade system will help Atara understand the overall flow of projects.

The second project application is based on program/project-based work center teams (Daily Huddles). For this project we intend to determine what is the best way to facilitate Work Center Teams (WCTs), also known as Daily Huddles for Program/Project based teams. As a team we will utilize the research gathered from the White paper and playbook to further research on a variety of features and components of best practices tool to further improve communication, workflow, and project progress.

Atara’s TMP team aims to provide essential resources to Atara Biotherapeutics to advance the company’s cross functional team communication, collaboration and success by creating features of continuous improvement strategies and frameworks, and project management.
Boehringer Ingelheim (BI), founded by Albert Boehringer in 1885, is the largest privately-owned pharmaceutical company in the world. Headquartered in Ingelheim, Germany, BI is widely known for creating pharmaceutical products for application in both humans and animals, including focus on critical cardiometabolic, respiratory, nervous, and oncology diseases. BI prides itself on revolutionizing medicine by developing novel therapies and treatments for these conditions, as well as collaborating with an extensive network of partnerships.

The BI TMP team was tasked to investigate the mixing for portable hold tanks used in various stages of the downstream manufacturing process through the use of computational fluid dynamics (CFD). ANSYS software was used to build the geometries for hold tanks of different sizes. Additionally, CFD was used to construct meshes for each tank, perform mesh-independent studies, analyze flow patterns and velocity profiles, and run mixing studies within each tank. The models ultimately allowed for the characterization of mixing in all tanks, which is vital in ensuring that pool homogeneity is achieved. Completion of this project will allow BI to better understand tank mixing behavior and will aid in determining the accurate power numbers for impellers. The team is dedicated to enable model-based troubleshooting for BI in the event of mixing deviations, as well as implement more sophisticated models in their facilities.
Characterization of Available Scale Down Models using Computational Fluid Dynamics, and an Economic Analysis

Students: Kyle Mendaros, Karina Park, Chase Pasos, Rebecca Ross, Tayfun Tanir

Corporate Liaisons: Dominique Monteil, Brendan Lianoz

Faculty Advisor: Michael Koeris, Adrin Gharakhani

Boehringer Ingelheim (BI) is a privately-owned pharmaceutical company founded in 1885 by Albert Boehringer. BI is a research-driven pharmaceutical company with the aim of improving the health and quality of life in humans and animals by developing innovative treatments for diseases with no or few satisfactory existing treatments. They are a world-leader in biopharmaceutical contract manufacturing. Therefore, finding the most optimal Scale Down Models (SDMs) that match the large scale is helpful for their success in production of biopharmaceuticals.

SDMs are a miniaturized representation of commercial scale bioreactors that are utilized to evaluate upstream process. These reactors are also used in process characterization studies, which at large-scale is not practical in most cases due to economic and time constraints. In addition to the aforementioned benefits, SDMs help to enhance the process understanding, investigating the process deviations, improve process robustness, and reducing the cost and time from R&D to commercialization of the therapeutic molecule.

BI has engaged KGI’s TMP team to explore potential candidates for a benchtop bioreactor for their SDM. The team has explored commercially available benchtop bioreactors and developed a ranking strategy to finalize a list of potential candidates. The BI TMP team is looking into the chosen SDM candidates and performing characterization studies using CFD to determine their fit as SDMs for BI’s large scale bioreactors. The team is also conducting technoeconomic analyses in parallel to further support final business decisions.
Process Approaches for mRNA–LNP Products

Students: Alex Ceballos, Dominique Trio, Sarah Sambolich, Max Zocchi

Corporate Liaisons: Victor Vinci, Thierry Nguyen, Kathleen Berth, Jingtao Zhang, Morgan Gillies

Faculty Advisor: Sue Behrens

Catalent Pharma Solutions is one of the world’s largest contract development and manufacturing organizations (CDMO), providing integrated technological solutions for the pharmaceutical industry. This allows Catalent’s clients to use pre-existing facilities and technology to generate product material, allowing clients to save both time and money while focusing on drug discovery and marketing. Catalent’s success is attributed to a strong diversification approach which has allowed them to build a robust portfolio of technology platforms.

During the COVID-19 pandemic, messenger RNA (mRNA) in lipid nanoparticle (LNP) vaccine products were established as safe and effective methods of preventing the spread of the disease. This method of delivering nucleic acid in the human body has proven to be reliable and has thus sparked the interest of several companies to bring more mRNA-LNP based therapeutics to patients. Catalent wants to place itself at the helm of these transitions into mRNA-LNP medicines and the best way to do so is to offer a standardized platform approach that can be used by Catalent’s clients to more rapidly take their products from the lab scale to the production scale and deliver them to patients.

The KGI Team has been working with several Catalent sites in the United States. The main tasks for the project are to create an up-to-date review of all available literature, including papers, books and patents, as well as obtaining equipment and raw material data from manufacturers. All of this knowledge will allow for the creation of a platform approach to mRNA-LNP products as well as the potential for licensing or partnership deals with companies holding relevant patents in a particular area of interest. The ultimate deliverable of the KGI Team is to compile and summarize these findings into review articles for publication.
Eli Lilly & Co. is a leading pharmaceutical company with a diverse product portfolio including small molecules, biologics, injectables, oral tablets, and medical devices. Founded in 1876, Eli Lilly continues to focus on five disease areas and is committed to their core values of integrity, excellence, and respect for people. Eli Lilly & Co.’s Global Regulatory Affairs Department (GRA) advises internal Eli Lilly teams engaged in development, clinical, manufacturing, and commercial activities, on the regulatory expectations to develop and obtain regulatory approval for the commercialization and distribution of prescription drugs and medical devices. GRA also leads the interactions between Eli Lilly and global regulators around the world.

The global regulatory environment is constantly changing to match the advancements in science, medicine, and technology to address the needs and requirements of health authorities and regulators. Companies must be aware of these changes to keep up to date and comply with pharmaceutical and biotechnological industry regulations. The Eli Lilly TMP team was tasked to identify the current regulatory landscape and assess its future trajectory in order to develop long-term strategies that may help GRA to better adapt to the future regulatory environment. The team identified key findings and themes from its secondary literature research and conducted interviews with key opinion leaders and subject matter experts within Eli Lilly. The four major goals of the project were to identify global regulatory environment scenarios, assess their anticipated impact and likelihood, determine commonalities, and inform Eli Lilly of the strategies identified. By the completion of the project, Eli Lilly hopes to gain an expanded knowledge and understanding of the future regulatory space, with insights as to how to better prepare for that future.
Reporting Tool for the Analysis of Equipment Parameters During the Lyophilization Step in the Manufacturing of AmBisome®

Students: Navya Anne, Lara Bajakian, Justin Mathew, Christian Torres, Luke Wejrowski

Corporate Liaisons: Richard Aman, Craig Johnson

Faculty Advisor: Ken Gruys

Gilead Sciences is an American biopharmaceutical company founded in 1987. Today, Gilead has offices in 35 countries, approximately 11,000 employees and $24B in revenue. Gilead’s commitment to advancing the treatment of viral and inflammatory diseases and cancer has led to the development of dozens of life-saving therapeutics.

The active ingredient of AmBisome®, Amphotericin B, was first licensed in 1959 and has been in use for over 60 years as antifungal medication for serious fungal infections. Approved in 1997, AmBisome® is a liposome encapsulation manufactured at Gilead in La Verne, CA. One step in the manufacturing process entails lyophilization of liquid product, and our team is developing methods to monitor equipment performance during this critical step using data visualization and analysis. Specifically, we are evaluating selected tags for their association to successful product batches.

A tag refers to an equipment measuring unit such as pressure or temperature.

We use software such as Batchview and Microsoft Excel to analyze tag data from historical production runs and identify trends that indicate ideal or non-ideal equipment parameters. Our deliverable will entail a reporting tool to alert Gilead personnel when production line equipment parameters begin trending outside specific limits with the goal that the deviation can be remedied before the production batch is negatively impacted. Additionally, our tool will provide a means to visualize and analyze tag data after the lyophilization step is complete.
Survey of Electronic Batch Record Options for Clinical GMP

Students: Liliia Bibikova, Caleb Hale, Jennifer Joseph, Terry Mawuko Etse Kugbe, Elena Nuñez

Corporate Liaisons: Kathleen Lingo, Tina Torabi, Lane Yunghans

Faculty Advisor: Michael Koeris

Gilead Sciences is a biopharmaceutical company that discovers, develops, and delivers medicines for life-threatening diseases mainly in immunology, cardiovascular, metabolic, and oncology therapeutic areas. Through bold and transformative science, the company is driving innovation that has the potential to become the next generation of life-changing medicines. This dedication to addressing the complexity of an ever-evolving drug landscape is evident in its Vision, Mission, and Core Values.

Gilead Oceanside is currently seeking to explore the use of Electronic Batch Records (EBRs) in a clinical GMP setting that enables increase flexibility, speed and compliance in a multi-product manufacturing environment.

By sponsoring this TMP, Gilead Oceanside hopes to leverage the expertise and research acumen of the KGI team to help identify an EBR software candidate that will provide the necessary platform to mimic its existing paper batch records, provide flexibility of use for all batch record stakeholders, and in real-time, generate an electronic report of batch records. By doing so, management seeks to accelerate the time required to review batches, identify non-conformities, and speed up approval time in a clinical setting while strictly adhering to safety and compliance regulations.

In order to address this challenge, the project scope of the KGI team encompasses delivery of the following:

- Recommendation of vendor/software
- Surveys of internal stakeholders, vendors, and industry peers
- Comparison of paper vs EBR vs hybrid Prioritization of user requirement specifications
- Recommendation with evaluation framework (what criteria to use to evaluate software choices)
- Project Report & Presentation
Determining Entry Points to Integrate Hologic BCI Test into the NCCN-Designated Cancer Centers

Students: Jovanny Guzman, Viana Le, Siyuan Liu, Yvonne Macias, Melat Zewdie

Corporate Liaisons: Lisa Whitmeyer, Lindsey Tornabeli

Faculty Advisor: Shannon Braun

Hologic Inc., founded in 1985, is a medical technology company focused on leading innovation in women’s health ranging from diagnostics, surgery, to medical imaging. Biotheranostics was acquired by Hologic in 2021 bringing Hologic two proprietary products to expand their diagnostic division. With Biotheranostics’ BCI test, Hologic seeks to be a large player in the oncology field.

Our TMP team is helping Hologic achieve its goal through a “top-down” approach within the breast oncology market. By integrating the BCI test in the National Comprehensive Center Network (NCCN) centers, the BCI test will be used by prestigious institutions and thus, will be more highly visible in the breast oncology market. The Hologic Key Accounts TMP project produced dossiers on each of the 31 NCCN cancer centers with information on the center’s leadership structure, performance metrics, values, active NCI clinical trials and population health initiatives.

To accomplish the project goal, we performed secondary research and utilized various search tools to collect information. By the end of the project timeline, we will have provided 31 dossiers and generated key insights to identify opportunities and ways to determine target entry points. Based on the top-down method, the Hologic TMP team hopes to help Hologic to identify a $34 M+ revenue opportunity on BCI.
1) Creation of a Predictive Shipping Analytics Tool
2) CGT Autologous Competitive Intelligence

Students: Dylan Davis, Tyler Nellos, Alice Wen, Melissa Guardado, Ngoc Thuy Vy Nguyen

Corporate Liaisons: Bala Sreenivasan, Jerry Docchio, Keith Lawlor, David Komjati (Project 1); Bala Sreenivasan, Michael Krepps, Matthew Strohl (Project 2)

Faculty Advisor: Jay Chok

Merck & Co. is a leading, multinational pharmaceutical company with headquarters in Kenilworth, NJ. Their focus is on oncology, vaccines, infectious diseases, and cardio-metabolic disorders for human therapeutics. Merck has been a market leader for over 130 years. Their supply chain is vast and sophisticated given its extensive, global reach.

In this TMP, Merck divided the project into two segments within the Global Supply Chain: 1) The Creation of a Predictive Shipping Analytics Tool and 2) Generating a Competitive Intelligence for Autologous Products. We have divided this summary into two segments as well.

Project 1

The KGI team worked with the Global Supply Chain Management (GSCM) organization, to create a globalized, single source of predictive shipment planning data. This initiative was sponsored by the Digital Logistics & Analytics functional area, within the Global Distribution & Logistics Center of Excellence, with a goal of enhancing the predictive, decision making capability of the various, “Global” and “Regional” Planning Teams regarding shipping choices.

To accomplish these objectives, the KGI team explored the various data warehousing tools available at Merck, plus the utilization of external partner services, and selected a “Self Service Insight (SSI) platform”, which allows for data warehousing, manipulation, and visualization to develop and create the predictive tool. After the KGI team extensively explored the data and identified primary keys to link the various data sets together, the team completed a proof of concept (POC) that will be used for investigating larger shipment data sets to complete the predictive analytics capabilities.

This project improved logistics analytics capabilities, including: transportation capacity planning, shipment efficiency, budget planning, savings, and sustainability. This project also provided the KGI team with a holistic understanding of the complexities of the drug shipment planning and delivery process. This POC serves as a building block for Merck
to derive supply chain insights that build upon its goal of supporting cost-effective and timely shipment planning, while mitigating and managing future ad hoc disruptions.

Project 2

The KGI team is gathering competitive intelligence on the key biopharma companies in the CGT space, particularly the companies that launched the 5 currently marketed autologous products. We were tasked with building case studies to assess key learnings on the supply chain strategies from each of the 5 marketed autologous product’s manufacturing capacities, supply chain distributions, and technology capabilities. In addition, the case study includes an overall market trend, CDMO manufacturing facilitates trends, financial investments made, and recommendations/next steps. The information gathered will help aid the development of a commercial and supply chain strategy for Merck.

To accomplish these objectives, the KGI team is conducting an in-depth analysis for each of the products, as well as using primary research gathered from last semester’s conference and secondary research to derive our trends and recommendations.
Serum-Free Media Development and Cell Line Suspension Adaptation for the Cultivated Meat Industry

Students: . . . . . . . . Christian Mark Antonio, Kevin Arcos, Cole Azevedo, Austin Chandra, Joaquin Del Mundo, Elizandro Medina-Escalante, Isabel Condori Roman

Corporate Liaisons: . . . Laura Daley

Faculty Advisor: . . . Michael Koeris

Orbillion Bio, Inc. is a premier biotechnology company in the cultivated meat industry specializing in high throughput technologies and cell culturing techniques aimed to further consumer options for premier meat products. The company is regarded for its focus on cultivating heritage meats to improve consumer accessibility while reducing the carbon footprint and escaping the cruelties of current meat production.

The team was tasked with improving the efficiency and scalability of cell lines for cultivated meat to achieve high production standards. To accomplish this task, the project deliverables were divided into three areas. The first area focuses on the development of chemically defined media for tissue culture expansion. The team tested a variety of different media components that allowed for the creation of a defined media formulation for economically viable, commercial production. The second area centered around the development of a defined media to maximize proliferation in 3D culture systems. The third area focused on developing an approach to expand cells in a bioreactor-like setting with defined media formulations obtained from the first area, along with additives to promote cell expansion. The combined efforts of the team in achieving these goals were integral in supporting Orbillion Bio. with improving the scalability and efficiency of cell lines for cultivated meat.
Developing Global Clinical Development Plans and Medical Strategies

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Corporate Liaisons: Bonnie Vlahos, Paul Sanders, Amy Cha, Juliana Canosa

Faculty Advisor: Alan Rothfeld

Pfizer is one of the world’s premier biopharmaceutical companies. Grounded in a powerful purpose—breakthroughs that change patients’ lives—Pfizer works to translate advanced science and technologies into therapies that matter for patients in need. Pfizer conducts worldwide research and development in different disease areas and tasked the TMP team with two projects within medical dermatology. The TMP team developed comprehensive analyses for a topical therapy in development and a currently approved therapy. The analyses intended to investigate the therapeutic value of the drugs and their potential for meeting unmet needs within specific dermatoses.

Deliverable 1 focused on creating global clinical development plans for a new topical therapy in early development for the treatment of two inflammatory skin conditions which currently have no FDA approved medication therapies. The plans address the unmet treatment needs of the diseases, data on competitor drugs, target product profiles and phase 3 clinical trial designs. The value of developing these programs is to obtain regulatory approval to address the significant unmet need of therapies within these specific dermatoses.

Deliverable 2 focused on developing resources and medical strategies and tactics for educating and creating a path of awareness for atopic dermatitis (AD), specifically on proactive treatment. The team created a KOL map, FAQ and Scientific Narrative. Additionally, the team is working on designing an internal and external Training and Education Plan, Evidence Generation Plan for Post-hoc Analysis Plan, Evidence Dissemination Plan and Health Care provider, caregivers and patients Communication Plan.
Process Development of Non-Platform Molecules using Mechanistic Modeling

Students: Innara Basria, Jared Cristobal, Minh Hoang, Jose Mendez, Bea Portez, Alexander Tuason

Corporate Liaisons: Arch Creasy, Jeff Salm, Daniel Celic

Faculty Advisors: Saurav Datta

Pfizer, Inc. is a multinational pharmaceutical and biotechnology company first founded in 1849. Efforts by Pfizer are focused on core therapeutic areas including, chronic inflammatory and autoimmune diseases, vaccines, oncology, cardiovascular and metabolic disease and rare diseases. To support their drug pipeline over the years, Pfizer, Inc. has developed all the capabilities needed to bring their drugs to patients, from drug discovery to commercial manufacturing.

Monoclonal antibodies (mAbs) make up a large portion of Pfizer’s biologics portfolio. To enable accelerated development of mAbs, Pfizer uses a well-established platform purification process. However, due to the emergence of non-platform antibodies, there is a need for a 3rd non-platform chromatography step in order to remove product related impurities (High Molecular Weight Species, misfolded mAb, fragments), that are associated with these new class of molecules. This third chromatography step is usually Cation Exchange Chromatography (CEX) or Hydrophobic Interactions Chromatography (HIC). Pfizer is interested in shortening the optimization process of this polishing step by utilizing mechanistic modeling to predict chromatographic separation performance and productivity, based on limited experimentation.

The goal of this TMP is to obtain chromatographic and fractional analytic data for the molecules provided by Pfizer to predict the optimal operating conditions of CEX and HIC resins utilizing Cytiva’s GoSilico™ Chromatography Modeling Software. To obtain the necessary data, multiple chromatography runs must be performed via ÄKTA™ Pure with both resins and elution fractions being analyzed from each run via high-performance liquid chromatography (HPLC) size exclusion chromatography (SEC) and HIC. Running these models will allow Pfizer to quickly characterize complex chromatographic separations and develop robust downstream unit operations for clinical and commercial manufacturing.
Expansion of Medical Device Electronics Manufacturing Services

Students: Daron Afaryan, Makenna Fall, Alec Frias, Morgan Malloch, Giovannie Shoushi

Corporate Liaisons: Tom Klopack, Michael Lopez, Rosie Medina, Dick Otte

Faculty Advisor: Angelika Niemz

Promex Industries, Inc. is a fully integrated cGMP manufacturer of FDA compliant Class II/III medical devices and biotechnology assemblies. Founded in 1975, Promex's services offer a low-risk pathway ranging from small-scale prototype development to full-scale production while maintaining the necessary requirements for FDA compliance and full manufacturing process validation, in a cost-effective manner.

The Promex team was tasked with identifying ways to engage with potential medical device clients, conducting competitive intelligence on similar electronics contract manufacturers, and enhancing Promex's digital marketing strategies. To accomplish these objectives, the KGI Promex TMP team created a database of potential medical device client companies using scoring metrics to measure and rank Promex alignment. From this database, the team identified potential contact points and conducted interviews to develop strategies that could aid Promex in increasing its clientele. To determine opportunities for Promex to further expand its marketing approach, the team compiled a list of Promex's competitors and documented relevant and effective digital marketing and customer acquisition techniques. This project is intended to help Promex expand its medical device electronics manufacturing services.
Investigation of Human Mesenchymal Stem Cells through Growth Kinetics and Product Characterization

Students: Carlos Cabrera, Pablo Garcia, Theresa Nguyen, Lea O’Brien, Purnima Singh, Jasper Worlikar

Corporate Liaisons: Jigesha Dholakia, Lydia Lim, Andrew Norton, Dipali Patel, Shalini Raj Unnikandam Veetil, Kiran Umesh, Timothy Wong

Faculty Advisor: Saurav Datta, Hu Zhang

The SanBio Group is a global leader in the regenerative cell medicine business spanning research, development, manufacture, and sales of regenerative cell medicines. Founded in 2001, SanBio has consistently worked to advance the development of regenerative medicines with the mission to create a new category of medicine, and to deliver breakthrough therapies to patients in need around the world. SanBio’s proprietary regenerative cell medicine product, SB623, is currently being investigated for the treatment of several conditions including chronic neurological motor deficit resulting from traumatic brain injury (TBI), ischemic stroke, and hemorrhagic stroke. SB623 is in Phase 3 clinical trials in Japan and is being considered for trials in the US, EU, and China, for treatment of TBI.

The SanBio TMP team was asked to work with the process development and analytical development departments at SanBio to complete two projects within the 2021-2022 school year. In the Fall, students executed multiple experiments to optimize SanBio’s manufacturing process and to further cultivate their stem cell growth kinetics. Main points of interest include cell growth, morphology, and metabolite levels which were monitored daily throughout the experimental timeline. In the Spring, students ran experiments involving exosome analysis and cytokine quantification to better characterize SB623’s mechanism of action. Completion of these projects have provided SanBio further insight into reproducibility of their manufacturing process as well as a deeper understanding of their leading product.
Supply Chain Analysis for MTO vs. MTS

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Corporate Liaison: Tony Cano

Faculty Advisors: Yun Liu

Sangamo Therapeutics, founded in 1995, is a genomic medicine company aiming to transform patients' lives. Sangamo is one of the few companies that focuses on applying groundbreaking science into the field of genomics to eliminate frequent, life-long treatment for patients and their families affected by rare and severe diseases with high unmet needs.

Sangamo currently has a gene and cell therapy close to global commercialization and needs to establish an efficient supply chain. Based on market forecasts, Sangamo aims to determine which supply chain plan between Made to Order (MTO) and Made to Stock (MTS) is best for the benefit of their company and for the end-users.

The Sangamo TMP team was tasked with conducting a supply chain analysis which defines the activities of both the MTO and MTS models and assesses their operational and financial implications. Through primary stakeholder interviews, secondary research, value stream mapping, and financial modeling, the team developed models incorporating aspects of packaging, labeling, storage, inventory, and global distribution based on commercial forecasts. Furthermore, a dashboard tool was created to enable a sensitivity analysis for various market sizes. Completion of this project has provided Sangamo with a recommendation of a supply chain model for global commercialization of their gene and cell therapy and a versatile tool that can be used across programs.
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With an entrepreneurial approach and industry connections, KGI provides pathways for students to become leaders within healthcare and the applied life sciences. KGI consists of three schools: Henry E. Riggs School of Applied Life Sciences, School of Medicine, and School of Pharmacy and Health Sciences.

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