Team Master’s Project

PUBLIC PRESENTATIONS
FRIDAY, APRIL 30, 2021
VIA ZOOM

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 30, 2021

**8:15–8:30 a.m.** Welcome by Sheldon Schuster, KGI President, Shannon Braun, Senior Director of Corporate Partnerships, Ken Gruys, TMP Program Director

**8:40 a.m.–12:00 p.m.** Team Presentations – Zoom Group “A” & Zoom Group “B”

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10 minute presentation, nine minutes of Q&A, and a one-minute transition to the next team
Innovators Start Here
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Assessing the Net Promoter Score (NPS) for 3M Biopharmaceutical Purifications

Students . . . . . . . . . . . . . . . . . . Karina Arriaga, Kaylee Cruz, Emma Finn, Gabriela Gavilanes, Grace McDonald, Julie Tobar-Sosa, Luis Torres

Corporate Liaisons . . . . . . Himanshu Nivsarkar, LP Raman

Faculty Advisor . . . . . . . . . . . Jay Chok

Founded in 1902, 3M is an American multinational corporation and is among the leading manufacturers of products for many of the markets it serves today. 3M is diversified with a global presence in the following businesses: Safety and Industrial; Transportation and Electronics; Health Care; and Consumer. The project scope for this Team Master’s Project involves 3M’s Biopharmaceutical Purification business, which is housed within the Separation and Purification Sciences Division. Through their Biopharmaceutical Purification subdivision, 3M has become a market leader in supplying the most effective depth filter technology within diverse product portfolios.

The KGI TMP team engaged in an exploratory study to further understand what biopharmaceutical customers think about 3M’s depth filter business. This was conducted via a customer satisfaction survey utilizing a Net Promoter Score (NPS) framework. The NPS survey categorized customers as either promoters, detractors, or passives based on their NPS response. Detractors (score 0-6) are unhappy customers who can damage 3M’s brand and impede growth through negative word-of-mouth. Passives (score 7-8) are satisfied but unenthusiastic customers who are vulnerable to competitive offerings. Promoters (score 9-10) are loyal enthusiasts who will keep buying and referring others, fueling business growth.

The survey provided insight on customer views and allowed the team to analyze quantitative and qualitative trends related to factors affecting perceptions of 3M’s products and technical abilities. The team provided recommendations to 3M to help improve customer loyalty and overall customer experience, as well as what could be done to convert detractors and passives to promoters.
Enable a Resilient Supply Chain—Incorporate and Minimize Risk for Strategic Decisions

Students . . . . . . . . . . . . . . . . Jeeda Al-Taki, Placide Gatabazi, Stephanie Lee, Siyuan (Kitty) Liu, Carolina Moraes de Souza, Steven Pervez, Aditya Thiyagarajan

Corporate Liaisons . . . . . . . Pratik Ahuja, Becky Calvin, Asit Goyal

Faculty Advisor . . . . . . . . . . Joel West

Amgen discovers, develops, manufactures, and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was among the first companies to realize the promise of novel science by delivering safe, effective medicines starting from the laboratory to manufacturing plant, and ultimately, to the patient. Amgen has a presence in approximately 100 countries and regions worldwide, and its medicines have reached millions of patients in the fight against serious illnesses. They focus on six therapeutic areas: cardiovascular disease, oncology, bone health, neuroscience, nephrology, and inflammation.

In order to serve every patient, every time, it is critical to maintain a well-defined supply chain strategy that balances speed, cost, and risk. Amgen continues to advance its risk mitigation strategy and is interested in developing a framework for its pipeline programs, which includes creating a comprehensive risk mitigation algorithm, decision criteria, and finally, playbooks for its clinical programs. This algorithm will allow Amgen to better understand and minimize risk for strategic decisions, enabling a resilient supply chain. The Amgen TMP team assessed strategies utilized by in-class competitors and other methods described in secondary research. By analyzing interview commonalities and researching risk modeling techniques, the team developed an adaptive algorithm consisting of prime factors relating to clinical risk, including “affected patient population”, “manufacturing cost”, and “inventory supply”. The holistic algorithm will serve Amgen’s business needs by allowing appropriate supply chain decisions to be made, furthering the robustness and resilience of its clinical supply chain.
Amgen is one of the largest independent biotechnology companies in the world. This project aims to produce commercial insights across oncological indications in the hematological and solid tumor space to inform Amgen’s strategy and commercial development. Value will be provided to Amgen by first producing a comprehensive and accessible clinical trial database capturing various technologies currently in the pipeline for development in oncology therapeutics. The database will then be used to produce competitive insights including forecasted evolution of the oncology landscape, major players and key assets, and approval timelines.

The main outcome for the fall semester was producing a comprehensive excel database encompassing pertinent data obtained from multiple public resources (e.g. clinicaltrials.gov). After thorough discussions and working sessions with the Amgen liaisons, the TMP team designed a clinical trials database to capture the emerging trends in oncology and a thorough understanding of each relevant clinical trial occurring throughout the world. Ultimately, the Amgen team built a database capturing information for over 460+ clinical trials to guide the development of strategic insights.

During the spring semester, the team leveraged the compiled database and additional resources to conduct competitive intelligence on the evolving oncology landscape. Particular attention was given to notable partnerships, size of companies, pipelines, recent developments, and alternative technological approaches. With this information, the team has developed strategic insights in the oncology space for our Amgen liaisons and Amgen’s stakeholders.
Development of High Throughput Non-Shadowing UVGI Disinfection Device for N95 Masks in a Medical Setting

Students. . . . . . . . . . . . . . . . . . Angelo Beltran, Kelsey Elliott, Samantha Figueroa, Sifuni Mwangomola, Candida Toribio, Kevin Williams

Corporate Liaisons . . . . . . . Sean Gallagher, Darius Kelly

Faculty Advisor . . . . . . . . . . . . . Anna Hickerson

Analytik Jena (AJ) is currently one of the global leaders in manufacturing life science products including supplying bioimaging systems for academics, pharmaceutical and biotechnology applications. They specialize in fluorescence and luminescence-based imaging applications especially in proteomics, genomics, and plant imaging.

In January 2020, a global health emergency was declared due to the identification of a new virus, which was later officially termed as “COVID-19.” The spread of the virus throughout various countries worldwide led to one imposing problem, a drastic shortage of PPE in the medical field.

To tackle this problem, our TMP team partnered with AJ to develop a high throughput, non-shadowing UVGI disinfection device for N95 masks in a medical setting. To accomplish this task, the team performed literary research regarding the effects of UVC light on N95 masks, analyzed AJ’s current UVGI disinfection device, the “CrossLinker CL-3000,” and examined the direct competitor products that are available in the market. Experiments were performed to verify literature findings, and a survey was conducted to fully understand the user requirements.

The team developed a device design through computer programs such as CADs and Ray Tracing for system validation, prior to manufacturing. Defining the FDA approval path, and IP and manufacturing strategies will be completed to ensure that the device prototype does not infringe on other patents, will be approved by the FDA, and can be manufactured by AJ. As a final deliverable, the team will test a manufactured device prototype to validate that it works as designed.
Ascendis Pharma (Ascendis) is quickly becoming a leader in new cutting-edge therapies using its innovative TransCon technology platform. The use of TransCon technology enables Ascendis to create therapeutics that combine prodrug and sustain-released capabilities. Ascendis is currently developing product candidates in two therapeutic areas, endocrinology rare diseases and oncology.

The COVID-19 global pandemic has driven the digitization of the life science industry, forcing companies to transition from traditional clinical trial modalities towards decentralized modalities. Additionally, the increase in data generated through digital technologies has not only presented challenges in data management quality, but also opportunities to implement technologies like data lakes. A final focus of Ascendis for direct-to-patient clinical trials has been home health nursing, as it is an essential component of decentralized clinical trial design.

KGI Team Master Project students were tasked in the first semester with examining the industry landscape of decentralization enabling technologies and evaluating their compatibility with Ascendis’ current clinical trial infrastructure. This was to provide a vendor recommendation in the sectors of decentralization, data management, and risk-based monitoring. In the second semester, the team's efforts shifted towards evaluating data lake and data warehouse implementation and determining the necessity of either with corresponding best-in-class vendor recommendation. The team is also working to develop and refine a request for proposal (RFP) process for home health nursing services to help Ascendis identify a capable vendor. Lastly, the team is helping develop a high-level process map with integrated standard operating procedures of Ascendis’ study start-up process.
Atara Biotherapeutics is a leading allogeneic T-cell immunotherapy company developing off the shelf treatments for patients with serious diseases. Since its founding in 2012, Atara has cultivated a robust pipeline with therapies for cancer, autoimmune, and viral diseases.

As a part of the FDA's Pre-Approval Inspection (PAI), Atara is required to have an inventory control program in place to facilitate the transition from clinical to commercialization of their foundational product Tab-cel® (Tabelecleucel). To assist with this transition, the Atara TMP team was tasked with developing and implementing a novel process to manage equipment and spare part inventory critical for manufacturing operations.

The Atara TMP team generated a list of critical spare parts with specifications, developed a process for classifying equipment and part criticality, established an inventory control program, and formulated a stock location plan. Completion of this project enables Atara to streamline their inventory management initiatives, thus supporting current and future cell therapy operations at multiple facilities. Additionally, the Atara TMP team has supported adoption and integration of these processes into the existing system at Atara.
The Single Use Technology (SUT) Material Database project and the Supply Chain Data Alignment project are both aimed to track and monitor a raw material supply chain.

A SUT portfolio can include many materials, procurements, and technical data points that require efficient, real-time monitoring and management. An excel database tool was created to manage these data. To create this tool, the database requirements were determined by consulting subject matter experts (SMEs), an excel database was built with refined attribute columns and categorical rows, and data population was completed. The creation of this centralized data source allows for 1) easier management of SUT data and 2) quicker, more intelligent business decision making within the SUT portfolio.

The supply chain data used to purchase raw materials and the data within the raw material specifications must align to comply with federal regulations ICH Q9 & Q10. The innovative tools and optimized strategy developed by the team reduces the risk of non-compliance.
Boehringer Ingelheim (BI) is a privately-owned, research-driven pharmaceutical company, with the aim of improving health and quality of life of humans and animals by developing innovative treatments for diseases with no or few satisfactory existing treatments. Characterizing bioreactors and performing mixing studies are critical processes for drug manufacturing because they can help predict and/or ensure cell productivity, protein quality, upstream timeline, and potential economic costs. Utilizing Computational Fluid Dynamics (CFD) allows for visualization of single-phase flow in stirred tanks that may not be possible via empirical experiments, thus providing in-depth details about the fluid flow with less experimental resources.

During the 2020-2021 school year, KGI collaborated with BI in a Team Master’s Project (TMP) to characterize and optimize four different sizes of bioreactors using Computational Fluid Dynamic (CFD) simulations. The team built bioreactor models and ran simulations to confirm or determine the power numbers, vector profiles, and mixing times. In addition, the team compiled a handbook that incorporated the work done this year with that of the previous four years of CFD work on BI reactors and mixing tanks. All together, this provided BI with a comprehensive characterization of their bioreactors and mixing tanks, allowing for more efficient use of resources.
Creation of Data Visualizations and Reporting for Process Optimization

Students . . . . . . . . . . . . . . . . Cole Azevedo, Terezie Cernosek, Vincent Ma, Benjamin Nittayo, Cindy Saliba, Molly Spaniac, Massimiliano Zocchi

Corporate Liaisons . . . . . . . Pamela Barton, Scott Biedron, Morgan Gillies, Emily Schirmer, Victor Vinci

Faculty Advisor . . . . . . . . . . Sue Behrens

Catalent Pharma Solutions is one of the world’s largest contract development and manufacturing organization (CDMO) companies, providing integrated technological solutions for the industry. This allows for 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 intellectual property pipeline.

Prior to this project, the Madison, Wisconsin site had individual departments manually collecting trending data, resulting in process trending and analysis inefficiencies. The KGI Team is working on developing and/or selecting a centralized process information management system that will trend upstream and downstream manufacturing processes on a periodic basis. This data will be used to create reports and visualizations that will allow the Catalent technical team to more efficiently identify potential process risks and optimization opportunities during daily review. This process information management system will also be used by the Catalent technical team to confirm process performance qualification (PPQ) readiness by evaluating product quality attribute data, process parameter data, step yields, processing times, and bioburden and endotoxin data.

This centralized process information management system will also be a powerful tool for showcasing and informing clients of the process data throughout a product’s manufacturing lifecycle. The dashboards containing the reports and data visualizations will be designed with ease of customization in mind to meet specific client needs, ultimately helping further enhance Catalent’s already strong client relationships.
Capacity Modeling Tool for Process Development Scheduling & Cross-functional Workflows

**Students**  Gabriela Gavilanes, Vishakha Jain, Marie Kern, Martin Maccarone, Jose Mendez, Maya Ogawa-Okada, Christian Torres, Jonathan Ventura

**Corporate Liaison**  Brian Zedalis

**Faculty Advisor**  Michael Koeris

Gilead has established high-throughput capabilities within each functional area to meet development timelines of the organization. As Gilead’s pipeline continues to grow, development teams should consider lab capacity and available resources, to ensure overall efficiency in their required deliverables. Lab equipment availability and asset utilization within each functional area is of focus in order to enable, in parallel, prioritized forecasting, planning, and execution of numerous project intakes.

The KGI team will help Gilead Oceanside create an integrated approach for expected project intake (scenario planning) that clearly maps out and links experimental work blocks in an end-to-end fashion across Cell Culture, Purification, and Analytical. A roadmap utilizing process flow diagrams that outlines capacity and resource requirements to enable timely development, will be developed through a detailed report and business tool. This tool will help facilitate the forecasting, planning, and execution of activities required within development workflows, based on lab capacity modeling and available resources. Potential bottlenecks and pinch points within labs will be identified, and recommendations made for optimized lab layouts or expansion to support continued growth.
Improving Service Offerings and Outreach Through Modern Workplace Platforms

Students . . . . . . . . . . . . . . . . Ayman Abdelaaty, Uchechukwu Anyaduba; Xavier Aparicio, Gisel Lopez, Kelly Lyons, Joseph Pecoraro

Corporate Liaison . . . . . . . . Thomas Upton

Faculty Advisor . . . . . . . . . . . Krishna Kumar

Founded in 1987, Gilead Sciences is an American pharmaceutical company based out of Foster City, California with an emphasis on medical innovation for life-threatening diseases. As one of the largest national pharmaceutical companies, Gilead specifically focuses on antiviral products and is well known for its role in developing Remdesivir for the treatment of COVID-19.

Among their various functional departments, Technical Services strives to provide analytical, formulation, process development and manufacturing support to greater Gilead. However, much of Technical Services’ capabilities have been underutilized by external Gilead functional groups. To improve outreach, increase awareness, and maximize utilization of their services and capabilities, Technical Services would like to implement recent workplace efficiency applications to communicate value and offerings outside of their normal reach, as well as improve communication and information sharing within the Technical Services department’s various project teams.

The Gilead TMP team was tasked with developing, functionalizing, and rolling out various digital platforms to improve communication across both the internal Technical Services department and Gilead externally. To complete this objective, the Gilead TMP team created platforms on various Microsoft applications including SharePoint and Teams to assist in modernizing the Technical Services’ communication tools. Additionally, an engagement strategy leveraging Gilead’s networks was developed to connect with the greater Gilead communities and increase awareness of Technical Services offerings. Completion of this project will enable complete utilization of Technical Services’ capabilities by external Gilead functional groups and improve data-sharing within the Technical Services team.
Development of a Statistical Analysis Platform for Biologic Control Strategy

Students            Marie Kern, Justin Ratzan-Wank, Sham Shah, Ruikang Tao, Erik Wehse, Yutong Zhong

Corporate Liaison  YenRu Pan

Faculty Advisor     Jim Osborne

Gilead Sciences is a pharmaceutical company founded in 1987 with headquarters in Foster City, California. Gilead’s Oceanside site primarily supports the development and manufacturing of therapeutic biologics. This established company thrives on creating improved outcomes through cutting edge innovation, always keeping the patient as its main focus. Their mission, to discover and deliver innovative therapies for people with life-threatening diseases, was proudly embraced by its KGI TMP team.

Gilead Oceanside plans to build a statistical platform that links their data storage system to statistical tools to support the setting up of specifications for drug products, determining shelf life, and establishing a workflow from data sources to data analysis tools. To address this business need, the KGI team conducted literature searches to understand industry practices and regulatory expectations for refining control strategy and performed a feasibility assessment for a model data analysis workflow. In the end, the team provided a comprehensive package describing best practices that Gilead can leverage for future initiatives in building a streamlined data management system. This was a one semester project in Fall, 2020.
Evaluating Drivers and Associated Key Performance Indicators for Customer Retention and Consolidation in the Molecular Diagnostics Industry

Students . . . . . . . . . . . . . . . . . . Omar Asad, Elizabeth Iantosca, Katherine Erickson, Aaron Jensen, Shahil Patel, Pianpian Robin Peng, Chaoran Yang

Corporate Liaisons . . . . . . . Derek Babin, Allan Harris

Faculty Advisor . . . . . . . . . . . . . . . . . . . Yun Liu

Hologic Inc. is a global company focused on healthcare and diagnostics, with core competencies in Women’s Health, including but not limited to, breast and skeletal health as well as gynecological surgical solutions. Hologic also provides diagnostic testing beyond Women’s Health, namely its recent efforts to address the lab-based challenges brought on by the COVID-19 pandemic. Molecular Diagnostics account for 40% of Hologic’s overall business and within this segment, Hologic has identified three primary areas of interest: Women’s Health, Acute Care and Virology.

As the U.S. molecular diagnostics market continues to change and the needs of customers develop, Hologic strives to put customer satisfaction at the forefront. Due to increasing competition, the threat of platform consolidation, and the difficulties faced by all companies during the COVID-19 pandemic, the urgency to better understand these changes has only increased.

The Hologic TMP team was tasked with contributing to the continuous improvement of Hologic’s Molecular Diagnostic portfolio. The team’s main goal is to provide recommendations to support the strategic direction of Hologic’s commercial function. To accomplish this, the Hologic TMP conducted market segmentation, competitive analysis, and customer perception assessments. The TMP team successfully deployed a survey and conducted extensive data analysis to assess customer satisfaction and better understand the drivers of customer retention and referral. The outcome of this project will provide Hologic with key information and targeted recommendations to inform their strategy and investment within its Molecular Diagnostics portfolio.
Promoting Transparency and Streamlining Product Inspection Process Time through Dashboard Implementation

Students: Alexandra Anaele, Justin Ratzan-Wank, Sham Shah, Ruikang Tao, Erik Wehse, Yutong Zhong

Corporate Liaisons: Crystal Achenbach, Dragos Agafitei, Trinidad Mireles

Faculty Advisor: Jim Osborne

Founded in 1949, Medtronic is the largest medical device company in the world. Involved in 150 countries with over 100 products in 15 unique fields, the company is always seeking to innovate in a rapidly changing market and develop new technologies in order to deliver the best possible healthcare products.

Medtronic’s Neurovascular Incoming Quality Control department (IQC), which is responsible for inspecting and releasing raw materials and parts used to manufacture products, worked closely with KGI’s TMP team to 1) create a digital dashboard displaying metrics that will promote transparency and assist in the reduction of raw material inspection time. The team analyzed the current inspection process, researched common inventory software, and designed the dashboard based off of user needs. And 2) increase capacity of the IQC department through prioritization of inspection demand and streamlined inspection criteria of products. Ultimately, the team will provide a comprehensive package describing best practices that Medtronic can leverage for future initiatives in building a streamlined data management system for their IQC.
Improving Patient Compliance with Topical Therapies, Creating an Innovative Phase 3 Clinical Study Design including Decentralized Solutions, and Conducting Secondary Clinical Research in Preparation and Support of a New Development Program

Students . . . . . . . . . . . . . . . . . Maria Angulo, Simran Bhogal, Julia Catolico, Zion Faye, Khuong “Kent” Le, Jake Patterson-Kohout, Marie Starksen

Corporate Liaisons . . . . . . . . . . . . . . . . . Bonnie Lynn Vlahos, John Werth, Daniela Graham, Amy Cha, Helen Tran

Faculty Advisor . . . . . . . . . . . . . . . . . Alan Rothfeld

Pfizer is a multinational, fully integrated biopharmaceutical company dedicated to improving the lives of people facing the burdens of illness. Their motto “Breakthroughs that Change Patients’ Lives,” articulates how the company devotes its research and development efforts to pharmaceuticals that address unmet needs among the patient population, ultimately to improve their quality of life. Their goal to, “translate advanced science and technologies into therapies that matter for patients in need”, was a fixture of this Team Master’s project.

This project included development and research activities on a life cycle product, expanding the use of an approved Pfizer topical therapy. The team evaluated challenges and potential solutions of administering target application rates of topical therapies.

Working as an extended team of the product’s Global Medicine Team, our TMP was responsible for completing three separate projects. The first project entailed finding tools and developing training to aid in improving patient compliance when administering a topical therapy. The second project included secondary clinical research to identify key leaders plus medical and patient societies, and to compile and organize disease-specific information on new disease indications for Pfizer’s medical liaisons. The third project aimed at designing a Phase 3 clinical trial incorporating decentralized solutions that meet regulatory standards and requirements.
Development of a Healthcare App to Enable Best-in-Class Treatment Experience for Gene Therapy Patients

Students . . . . . . . . . . . . . . . . . Kevin Arcos, Alison Lee, Mercy Lee, Lorenzo Santamaria, Diti Shah, Rima Patel, Owen Wang

Corporate Liaisons . . . . . . . . Allicyn Aubut, Luca Maggioni, Emily Regan

Faculty Advisor . . . . . . . . . . . Ken Gruys

Sarepta Therapeutics Inc. is a global biotechnology company on an urgent mission: to engineer precision genetic medicine for rare diseases that devastate lives and cut futures short. Based in Cambridge, MA, Sarepta is ushering in a new era of drug development with the goal of to drive efficiencies, including shortening the time from lab to patient. Sarepta has over 40 therapies in various stages of development that utilize various modalities including gene therapy to treat diseases such as Duchenne Muscular Dystrophy, six Limb-Girdle muscular dystrophies, and other CNS-related disorders. Sarepta is in a race to transform genetic knowledge into genetic medicine as every day is an opportunity to save lives from rare diseases.

This year’s TMP expands on the previously work completed by last year’s KGI team in support of Sarepta’s gene therapy team. Specifically, the objective of this year’s project was to define innovative technologies that would create a cohesive, easily accessible, and fluid patient experience before, during and after their treatment. This would enable Sarepta Therapeutics to provide a best-in-class patient treatment experience.

This year’s KGI team started with, and then significantly expanded the initial mobile app framework created last year. The project included generating a business plan for app development, identifying and rationalizing app functionalities, target app users, app data collection and analysis features, compliance considerations, and app development and deployment timelines. The team deliverables include suggestions for vendor partners, a budget analysis, and app prototypes that highlight key features and functionality. The team’s direction is based on insight gained from interviews with healthcare providers, caregivers, patients, and vendors.
The Soil Carbon Company focuses on developing tools that help farmers restore carbon to their soil. They believe that global warming could be significantly ameliorated through improved agricultural crop management utilizing fungi to sequester carbon and fortify soil. The company’s mission is to simultaneously address both agricultural productivity and atmospheric carbon dioxide reduction through the development of products that will capture carbon from the atmosphere and return it to the soil.

SoilCarbon has identified a number of microbial organisms with the potential to increase carbon sequestration in soil. To leverage their investment in these microbes, SoilCarbon aims to explore and identify key components of the microbial genomes.

The SoilC TMP team was tasked with assembling genomic sequences of unknown and potentially novel microbial genomes and investigate biochemical pathway-related genes involved in carbon assimilation. To accomplish this objective, the TMP team conducted a series of short read genome sequence assemblies for 20 eukaryotic genomes, discovered genome-wide open reading frames and conducted phylogenetic analysis to establish the novelty of the findings. Predicted proteins were further analyzed for the conservation of defined structural domains and motifs and potential novel enzymes were modeled. The data collected and analyzed on these microbes are confidential to Soil Carbon Co. In light of this, we have provided a report that details our analytical methodology, including various machine learning algorithms, and the analytical pipeline.
Computational Fluid Dynamic (CFD) Modeling of Cell-Free Synthesis Applications

Students  . . . . . . . . . . . . . . . . Jared Cristobal, Niki Fujimoto, Minh Hoang, Jialiang Huang, Tamara Mustafa, Marvin Orellana, Camille Ybanez, and Misbah Zafar

Corporate Liaisons  . . . . . . . Lisa Sawicki, Robert Hoffman, Bob Kiss

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Sutro Biopharma, Inc. is a clinical stage biotech company founded in 2003. The company’s main focus is clinical stage drug discovery, development, and manufacturing of oncology therapeutics using its proprietary cell-free protein synthesis platform. Sutro’s manufacturing center in San Carlos, CA, and is the only cGMP cell-free synthesis manufacturing facility in the world. The company’s platform is not just limited to developing its own oncology pipeline. Sutro has collaborated with select pharmaceutical and biotech companies to discover and develop next generation therapeutics designed to target cancer cells.

Unlike the conventional methods of using a cell line for protein expression, Sutro’s cell-free platform utilizes extracts of cellular components to produce proteins. As a pioneer in this technology, Sutro would like to learn more about the efficiency of their process. In any mixing procedure, effective mixing is essential to obtain a homogeneous solution with high product quality. By means of a computer-based program, computational fluid dynamics (CFD) allows for in-depth characterization and easy visualization of mixing systems with minimal investment in engineering resources.

The goal of this TMP was to utilize CFD to simulate and quantitatively predict fluid flow in select unit operations in Sutro’s platform. We were tasked to characterize mixing in four cell-free synthesis bioreactors and identify relevant parameters to support scale up. In addition, residence time was determined by tracking particles through a static mixer at different flow rates. Overall, these models will help support better process understanding of the systems used in Sutro’s different unit operations.
Assessment of Media, Feed, and Resin on Cell Growth and Protein Purification

Students  . . . . . . . . . . . . . . . . .  Kaushik Amancherla, Seth Barrington, Andres Felipe Romero Camelo Jessica Felix, Kathrine Parga, Bea Portez, Magaly Aguirre Sanchez, Angelica Sabandal, Vanely Ponce, Amparo Valdovinos

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Thermo Fisher Scientific Inc. is one of the world leaders in developing resources for the scientific community with their unique cell lines, media, laboratory instruments, and more.

The goal of this laboratory-based project was to evaluate both non-commercially available and commercially available media and feed using a CHO cell line. To complete this experiment, the CHO cell line was directly adapted to the provided media and a working cell bank was created. Two 14-day fed batch studies in shake flasks were completed. The cells were monitored and data was collected including metabolite, viability, and titer information in order to determine the best performing combination of media and feed. Cell culture conditions and cell growth profiles were monitored using in-house KGI equipment. Following the completion of shake flask studies, the optimal conditions were assessed in 3L bioreactors. In addition, evaluation of novel purification resins provided by Thermo Fisher were evaluated to generate a sample for product quality assessment. Using culture materials from the media and feed evaluation studies, binding capacity and storage conditions were assessed for each resin using in-house KGI equipment. The completion of this project has provided Thermo Fisher with an unbiased assessment of each provided media, feed, and resin.
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