The Team Masters Project (TMP) is the capstone activity for second-year students in the Master of Bioscience program at Keck Graduate Institute of Applied Life Sciences (KGI). Interdisciplinary teams of three to five students work with sponsoring companies to solve real problems. This project replaces the Masters thesis work required in traditional programs. The teams are advised by KGI faculty and an industry liaison. 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 bioscience industries. Representing about 35 percent of the academic work for second-year students, these contract research projects are designed to produce specific sets of deliverables for the sponsoring companies.

Two new features of the TMP program were introduced this academic year. For the first time, single-semester TMPs were offered: the projects sponsored by Invitrogen and Ortho Clinical Diagnostics were Spring-semester projects. The second new feature was that the TMP was offered as an elective for first-year MBS students in the Spring semester so some of the students listed in this program are first-year students.

The program also involves students and faculty co-advisors from Harvey Mudd College, the Peter F. Drucker and Masatoshi Ito Graduate School of Management, the Claremont Graduate University’s School of Information Systems and Technology and the School of Mathematical Sciences.

The TMP program is partially supported through a Partners in Innovation grant from the National Science Foundation.
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Assessment of Global Clinical Supply Chain Forecasting Methods

Team Members: Hezekiah Blake, Ambereen Burhanuddin, Tyler Kelly, Nida Moosa, Divya Shakti, and Nathan Lee

An optimal supply chain runs on the application of a total systems approach to manage the entire flow of information, materials, and services from raw material suppliers through factories and warehouses to the end customer. Pharmaceutical companies constantly face tension meeting customer needs via their inventory production forecast. Research has shown that many pharmaceutical companies overproduce therapeutics by approximately double the estimated market need to ensure that demand is met. However, the current market demand, competitive price and profit margin calls for more accurate clinical forecasting and creation of metrics to measure efficiency. In an effort to realize these goals, the KGI team assessed the efficacy of the current clinical forecasting methods employed by Amgen, benchmarked these processes against industry, delivered a three-year forecasting model and made recommendations about system optimization. The team also helped develop and validate business strategies to maximize efficiency, improve forecasting accuracy, and hone information flow through Amgen’s Global Clinical Supply Chain Management (GCSCM) department.

Evaluation of Novel Drug Packaging Solutions

Team Members: Adam Gross, Fiela Gutierrez, Oliver Hou, Justin Kim, Stanley Lee, Gina Ricci, Michael Wrenholt, Paul Yen

Amgen is interested in evaluating the use of novel pre-filled plastic syringes for commercial products and those in late stages of development. The major challenge in using currently available plastic
syringes for therapeutic protein storage is the inherent oxygen permeability of the syringe materials. During the last nine months, the KGI team has been working with Amgen to identify strategies to minimize oxygen permeation in plastic syringes. To validate these packaging solutions, KGI students have developed computer models to predict oxygen permeation levels inside the syringes, as well as a chemical method to measure oxygen levels through color changes. In addition, the team has conducted experiments to evaluate the integrity of the syringe closure and ease of use of these new syringes. KGI has complemented this technical evaluation by assisting Amgen in outlining a business justification for implementing plastic syringes. The justification includes a study of market trends and consumer preferences in the pre-filled syringe industry, as well as a cost analysis for integrating a plastic syringe line into Amgen’s existing production equipment.

**Symlin® Line-Extension Opportunity Assessment**

Team Members: Abhishek Agrawal, William Casey, Janelle Grimes, Curt Herberts, and Andrew Peters

Amylin Pharmaceuticals currently has two drugs approved by the FDA for the treatment of diabetes mellitus: Symlin® and Byetta®. The KGI team working with Amylin was involved in the development of a Symlin® line extension strategy based upon possible drug delivery options. This line extension would be a variation of the existing product, but offer additional benefit due to increased convenience of administration. The project required a technical assessment of available delivery options and an investigation of the clinical and regulatory requirements associated with each of these options. These technical and regulatory assessments formed the basis for prioritization of
viable business opportunities and value addition for Amylin, as well as other stakeholders, including patients, physicians and payers. The resulting options were ranked on the basis of a financial model, constructed by the team. A qualitative analysis, addressing technical, clinical & regulatory, and marketing considerations for each opportunity, was also provided. Taken together, the quantitative and qualitative analyses were used to create a commercialization strategy for future Symlin® line extension opportunities, that was presented to Amylin as the final deliverable for the TMP project.

Affinity Reagents

Team Members: Katie Burgess, Victor Chang, Kalpana Desai, Justin Hsiao, Sandeep Lad, Michael Tancer

Applied Biosystems offers a wide range of scientific products for basic research, pharmaceutical research, forensics, and food and allergy testing. Scientific advancements in the fields of phage display, a technique employing genetically modified viruses to screen for useful antibodies, and aptamers, RNA or DNA oligomers whose sequences have been selected to bind specifically to other molecules, have opened up the possibility that antibodies used in assays might ultimately be replaced by more selective binders that have higher affinity. Applied Biosystems is actively engaged in researching novel methods for the creation of antigen-specific binders and their incorporation into unique assay formats. In addition, Applied Biosystems is involved in developing a separate technology that amplifies a detection signal for a target or antigen of interest. Potentially, this technology could be used in concert with the antigen-specific binder technology.
The Team Masters Project, which consisted of students from KGI and the Drucker School of Management, worked with Applied Biosystems in assessing possible applications for these technologies. The team surveyed the competitive landscape and evaluated the scientific need for these novel technologies within broad and niche markets to explore commercialization strategies.

Commercialization Strategy of HbA1c Test for Diabetes Management

Team Members: Pradeep Babu, Yatin Gadgil, Anna George, Ralph Sachdev, and Jeff Xu

HbA1c is a variant of hemoglobin that contains bound glucose. Since the dissociation of glucose from hemoglobin is very slow, HbA1c is present in a red blood cell (RBC) throughout the cell’s lifetime of 90 to 120 days. The amount of HbA1c in an individual’s RBCs may be used as a measure of the average blood glucose level during a period of several weeks preceding the blood test. For diabetics, HbA1c levels provide a good assessment of whether their diabetes is under control.

The goal of this project was to develop a commercialization strategy for an innovative screening and monitoring test that measures HbA1c content per cell by discriminating among RBCs of different ages to assess mean glucose levels throughout the RBC life span. The team focused on market research and development, and market penetration and segmentation strategies including collection of primary and secondary data/information on HbA1c diagnostics and current pipeline of diabetes drugs/therapies to develop viable scenarios to facilitate the most effective means of commercializing the product.
Diagnostic Enzymes

Team Members: Steve Chiu, Polina Datsova, Eric Forman, Jonathan Jung

BioCatalytics produces a comprehensive array of enzymes useful in the synthesis of new drugs. These enzymes may also have applications as diagnostics in food and environmental safety testing, clinical diagnostics, and research. In 2004, BioCatalytics created a small group of diagnostic enzyme products for the purpose of evaluating the sales potential for these applications.

The KGI team conducted a market segmentation analysis to assess potential customer demands and current competitors in the diagnostic enzyme arena. The project also included assay development and construction of manufacturing protocols for a few identified products. The team analyzed regulatory and manufacturing issues associated with launching diagnostic enzyme products.

Development of Marker Systems for Selected Crop Species

Team Members: Melanie Clairy, Ryan Peeler, Thomas Quirk, Mariana Soffer, Swetha Makam, Liqiang Zhang

The development of molecular techniques for genetic analysis has led to an increase in knowledge of plant genetics. Molecular markers can be used to monitor DNA sequence variation in and among species and create new sources of genetic variation by reinserting enhanced genes into plants, thus introducing new or improved traits. Ceres is a plant biotechnology company that focuses largely on the production of improved plants and plant-based technologies. The identification of molecular markers linked to useful traits is based on genetic marker maps, linkage maps and pedigree charts.
A KGI team working with Ceres has evaluated the existing methods for processing, generating, and using molecular marker maps to develop a functional molecular marker software system. The team has validated the system by analyzing molecular marker data and by generating and using molecular marker maps. A second component of the project was to develop a database to hold competitive intelligence information. The team has designed such a database from scratch and gathered information from the plant biotechnology industry with which to populate it.

**Adaptive Viruses and Artificial Immune Systems**

**Team Members:** Nicolas Chaumont, Taimur Hassan, Dimitris Iliopoulos

The central theme of this project was the computational biology modeling of the interaction between novel computer viruses and artificial immune systems. The team was able to study a large class of novel distributed computer security systems based on the “honey-pot” and “honey-net” concepts, to respond to novel threats faster and more efficiently. The team drew analogies between biological immune systems and artificial immune systems that can be used as an alternative to current manual and semi-automatic computer defense strategies by establishing host-based intrusion detection and removal. The ultimate aim of the project was to produce a proposal for an artificial immune system based on findings from the modeling studies. Such a proposal was recently submitted to a private foundation.
**Chemical Dispensing Automation System**

Team Members: Xi Dieng, Karen Hsin, Susan Lin, Pengfei Luan, Faye Massen, Prachi Shah

Gilead Sciences is implementing a Chemical Dispensing Automation System (CDAS) to improve the accuracy and efficiency of the manual chemical dispensing process used currently. The system provides real-time monitoring of the dispensing of chemical raw materials through Gilead’s Enterprise Resource Planning (ERP) system, a business management system that includes tracking of inventory and manufacturing. The CDAS utilizes data collection software to interface wirelessly with JD Edwards ERP and is in compliance with FDA regulations and 21 CFR Part 11. The project has completed several phases starting with User Requirement Specifications and Functional Requirement Specifications, and progressing to Solution Requirement Specifications and Implementation and Training.

**Forecasting and Capacity Planning for Functional Genomics Services**

Team Members: Tim Friedman, Senthil Purushothaman, Gina Ricci, Liqiang Zhang

The process developed in this TMP supports forecasting and capacity planning for RNAi Services, Protein Production, cDNA Libraries, and Cloning Services. KGI students examined historical data using statistical tools to identify demand trends, resource consumption (both FTE and equipment), and scientific cycle times to develop models and tools enabling Invitrogen to coordinate fulfillment and process support staffing with anticipated demand. Key metrics utilized in this process include: Services Orders Not Yet Started, On-Time Delivery, Services Plan, Forecast and Actuals, and Services Scientific Cycle Times. The team worked with stakeholders at Invitrogen to ensure utility of this new process across several organizational groups.
An emerging trend in new diagnostic systems is the integration of clinical chemistry and immunodiagnostic assays into a single system with the capacity to run menus of 75-100 different assays. When calibrating such a system, the total number of calibrators required can be in excess of 200-300 fluids. This TMP has provided Ortho Clinical Diagnostics with information about the current best practices in the targeted market segment. Quantitative data was compiled and analyzed to provide a comparison/assessment of process steps, system complexity and overall user time, and requirements for market leading automated diagnostic test systems that target the hospital and reference lab market segment.
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would like to thank all our sponsors
for their generous support
of the Team Masters Project.

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