

KGI Descriptive Handout www.kgi.edu

Keck Graduate Institute is a pioneering, selective graduate school dedicated to the development of applications from the emerging discoveries in the biosciences, and to the rigorous education of leaders for the industry.

Founded in 1997, Keck Graduate Institute of Applied Life Sciences responds to calls in industry, higher education, and government for a rethinking of graduate education in the sciences. KGI is establishing a new standard of interdisciplinary technical, scientific and management preparation for individuals with strong science or engineering backgrounds and a desire to shape the future of the bioscience industries. With a focus on a two-year professional Master's degree, KGI students work intensively in teams, applying a broad set of disciplines to learn to solve practical, technical problems.

Our professional Master of Bioscience (MBS) program develops scientifically literate leaders for the biosciences industry. MBS degree recipients are skilled in the practical applications of the life sciences and qualified for a variety of leadership positions in industry. Combining rigorous scientific training, of the type usually associated with traditional PhD programs, with management, ethics, and policy studies similar to those found in MBA programs, the cross disciplinary approach of the MBS enables our students to hone their skills over a two-year period. The MBS stresses an understanding of the life science industry and culture, as well as of the technical, operational, and strategic issues critical to a company's success.

The MBS Curriculum

KGI's rigorous and interdisciplinary curriculum is structured with workshops, cases and projects, and includes an internship in industry. The teaching methodology is based on problem solving in a team environment. The KGI program is designed to develop leaders in the biosciences who have solid science and engineering skills as well as a strong grasp of management, policy, and ethical issues.

Core Courses

The first-year core curriculum is built around computational biology, biological systems, bioengineering, and management, ethics and policy, and bioscience economics and processes. Required of all students, these courses provide a solid platform of competency across numerous fields.

Industry Internship

A paid summer internship in a bioscience capacity actively engages students in the issues and current techniques associated with particular industry sectors and provides an understanding of the climate and culture of business.

Master's Project

Throughout the second year, the master's project provides a strong cross-disciplinary educational experience for students. In contrast to the initial project, the master's project requires original work in problem solving at the technical level, or at the level of newly integrated or adapting solutions to other problems. Guided by faculty, teams of three to five students tackle projects originating in industry. The master's project is the capstone experience of the KGI program and requires a serious technical and practical effort on the part of both student teams and faculty.

Keck Graduate Institute - Graduate Placements

Company **Position(s)**

ActivX Bioscience, Inc.

Research Associate

La Jolla, CA - ActivX Biosciences, Inc., a privately held biotechnology company, is a pioneer in the field of activity-based proteomics, the identification and analysis of active proteins. By focusing on protein activity, ActivX is addressing the biochemical mechanisms of disease more directly than standard genomics and proteomics techniques. ActivX is using its proprietary technology to solve the most important problems in drug discovery and development, including identification of novel drug targets, determination of target selectivity for drug candidates, and the assessment of efficacy and toxicity for candidate and established drugs.

Allergan, Inc.

Clinical Research Associate

Irvine, CA - Allergan is a technology-driven, global health care company providing eye care and specialty pharmaceutical products worldwide. Allergan develops and commercializes products in the eye care pharmaceutical, ophthalmic surgical device, over-the-counter contact lens care, movement disorder, and dermatological markets.

Amgen, Inc.

Project Management, Associate Engineer, Manager Medical Communications

Thousand Oaks, CA - Amgen is the world's largest independent biotechnology company. In-depth knowledge developed through the utilization of state-of-the-art cellular and molecular biology enables Amgen scientists to discover and develop both naturally occurring proteins and small molecules as potential human therapeutics. Focused on research and product development in areas such as oncology, nephrology, and rheumatology, such products may be used to treat cancer, disorders of the blood and bone marrow, infectious disease, obesity, and neurodegenerative diseases.

Amylin Pharmaceuticals, Inc.

Clinical Research Associate, Regulatory Affairs Associate, Technical Evaluation

San Diego, CA - Amylin is engaged in the discovery, development, and commercialization of drug candidates for the treatment of diabetes and other metabolic disorders. The company's lead drug candidate, SYMLIN, received FDA approval, subject to additional clinical work.

Chugai Pharma USA, LLC

Research Associate

San Diego, CA - Chugai Pharma USA, LLC. discovers and develops innovative therapeutic products that treat cardiovascular diseases and cancer. Cancer research activities are centered on developing drugs that alter the activity of growth control molecules (kinases) known to play key roles in tumor formation. In the area of cardiac diseases, they have identified a new, novel class of therapeutic agents (metabolic modifiers) for the treatment of stable angina and congestive heart failure.

CombinatoRx, Inc.

New Products

Boston, MA - CombinatoRx, a privately held pharmaceutical company, is creating new combination medicines that attack disease on multiple fronts. The company has an impressive clinical and preclinical pipeline of novel agents, including treatments in development for cancer and rheumatoid arthritis, and has ongoing research in respiratory, metabolic, and infectious diseases. CombinatoRx invented the world's first combination drug discovery platform to generate new medicines, based upon new insights into disease networks, in a broad range of therapeutic areas. Founded in 2000 by leading scientists from Harvard and MIT, the company has raised \$60M in venture capital and is executing on its business strategy to rapidly build and commercialize a portfolio of breakthrough products.

Eidogen

Strategic Planning

Pasadena, CA - Eidogen (formerly Bionomix) is a post-genomics company with an exclusive license to protein structure determination technology recently developed at the California Institute of Technology. It is dedicated to removing current and future bottlenecks in post-genome drug discovery and development.

Eli Lilly and Company

Business Development and Bioinformatics

Singapore - Lilly is a leading pharmaceutical corporation developing a growing portfolio of pharmaceutical products by applying the latest research from their worldwide laboratories, by collaborating with eminent scientific organizations, by making use of the most up-to-date technological tools and by providing exceptional service to their customers. Lilly has major research and development facilities in 9 countries and conducts clinical trials in more than 60 countries.

Genoptix, Inc.

Business Development

San Diego, CA - Genoptix is developing and will continue to acquire proprietary technology for cell separation and analysis utilizing biophotonics and biooptics. This advanced cellular isolation approach is highly complementary to later stage genomics and proteomics programs, enabling the next stage of development in the post-genomic era. Genoptix proprietary Optophoresis

technology is the only technology capable of simultaneously analyzing and isolating specific cells based on their differences at the atomic level.

HealthIQ

Market Research

Orange, CA - HealthIQ is a competitive intelligence firm, based in the City of Orange, specializing in the collection and analysis of strategic competitive information to support product development and product marketing decision making by major pharmaceutical manufacturers. HealthIQ is a subsidiary of PAREXEL International, one of the largest biopharmaceutical outsourcing organizations in the world, providing a broad range of knowledge-based contract research, medical marketing and consulting services through approximately 5,000 employees in 37 countries.

IMPATH, Inc.

Product Manager

Los Angeles, CA - IMPATH's mission is to develop and offer innovative products and services that lead to more accurate diagnoses and more effective treatments for cancer patients. With a database of nearly 960,000 patient profiles, IMPATH uses sophisticated technologies to provide patient-specific diagnostic, prognostic and treatment information to more than 8,300 physicians specializing in the treatment of cancer patients, in over 2,000 hospitals and over 570 oncology practices.

Iobion Informatics LLC

Western Technical Sales Representative

La Jolla, CA - Iobion Informatics is a bioinformatics software company offering turnkey software products, initially for the management and analysis of spotted microarray data. GeneTraffic Duo, the first of Iobion's software products, is used to manage and analyze spotted two-color microarray data.

Ionian Technologies, Inc.

Market Analyst, Business Development

Upland, CA - Ionian Technologies is a startup biotechnology company that develops and commercializes cutting edge measurement systems for high-throughput genetic and genomic applications such as Single Nucleotide Polymorphism (SNP) genotyping, quantitative gene expression measurements, and SNP allele frequency determinations.

Invitrogen Corp.

Product Manager

San Diego, CA - Invitrogen is an innovative partner in life science research and the commercial production of biomolecules. Through products and services, they strive to accelerate biological discovery and understanding so scientists can accomplish experiments faster, easier, and more reliably. Products encompass two key market segments in the life science industry, molecular biology and cell culture. Under the Gibco™ brand, Invitrogen is the leading supplier of cell culture products, services, and technologies for research and biopharmaceutical manufacturing applications.

Medpace, Inc.

Clinical Research Associate

Cincinnati, OH - Medpace is an independent full-service CRO (Contract Research Organization) providing comprehensive clinical research support to the pharmaceutical industry. At Medpace, the specialization in managing studies in the cardiovascular and metabolic fields provides an intimate familiarity with the clinical trial issues in these fields, bringing expertise and understanding to all aspects of the drug development process - from development plan design to New Drug Application (NDA) submissions and post-marketing studies.

Neurome, Inc.

Research Associate

La Jolla, CA - Neurome, Inc., develops standardized, quantitative databases that accurately depict and integrate gene expression patterns in the 3-dimensional context of the brain's structures, circuits and cells, and deploys these databases in primary research directed toward the discovery and development of gene targets for enhancement of brain function and treatment of brain-based disease.

NuLiv Science

Technical Services

City of Industry, CA - NuLiv is a leading science and research-based nutraceutical company specializing in the identification, development, and production of active, naturally occurring ingredients and novel formulated products.

QUIAGEN, Inc.

Internal Sales

Valencia, CA - QUIAGEN has been supplying researchers with high quality enabling technologies for over a decade. Their comprehensive portfolio of more than 320 proprietary, consumable products assist researchers with: nucleic acid separation, purification and handling; nucleic acid amplification; and sample prep. They also provide automated instrumentation, synthetic nucleic acid products and related services. QUIAGEN's products are used in more than 42 countries throughout the world in the academic research markets and leading pharmaceutical and biotechnology companies.

Roche Molecular Systems, Inc.

Product Management

Pleasanton, CA - Roche Molecular Systems develops and produces molecular-based diagnostic tests and automated testing platforms using the Nobel-prize winning polymerase chain reaction (PCR) technology. The Company has six unique areas of interest in the healthcare arena: Virology, Blood Screening, Microbiology, Genomics, Women's Health and Oncology. With its

uniquely broad nucleic acid technology (NAT) portfolio, Roche supplies a wide array of innovative testing products and services to researchers, physicians, patients, hospitals and laboratories worldwide.

St. Jude Medical

Technical Support Specialist

Woodland Hills, CA - St. Jude Medical, Inc. is a \$1.6 billion global cardiovascular device company with headquarters in St. Paul, Minnesota. The company sells products in more than 120 countries and has 15 operations and manufacturing facilities worldwide. The company's leading cardiac rhythm management products include pacemakers, implantable cardioverter defibrillators (ICDs), and electrophysiology catheters.

Stratagene

Technical Services

La Jolla, CA - Stratagene invents, develops, manufactures, sells and supports innovative technologies for life science researchers. Since 1984, they have been known for novel, reliable and time-saving products in fields spanning molecular biology, genomics, proteomics, drug discovery and toxicology.

UCLA Office of Intellectual Property

Market Analyst

Los Angeles, CA - The Office of Intellectual Property Administration (OIPA) is the technology transfer group within UCLA's Office of Research Administration (ORA). OIPA works with campus inventors to facilitate transfer of technologies created at UCLA into the commercial sector for public use. The scope of OIPA activities include: commercially evaluating new technologies; determining patentability and commercial value; prosecuting patents; marketing and licensing inventions; negotiating license agreements and Material Transfer Agreements; and receiving and distributing royalties and other income to the inventors, UCLA Campus, and its departments.

Zuyder Pharmaceuticals

Bioinformatics

Upland, CA - Zuyder Pharmaceuticals is a newly created spinout of Keck Graduate Institute (KGI), incorporated in 2002. Its mission is to accelerate the drug discovery process through computational target identification. Zuyder has developed a completely new bioinformatics technology solution that is capable of predicting protein-protein interactions and the binding partners of effectors and regulators that mediate human disease. Though Zuyder's technology can be used in many application areas, to date the company has focused on metabolic bone disease.

NOTE: David Finegold's presentation was not available in PowerPoint format. Per Dr. Finegold's suggestion, CPST gathered the following additional information from the Keck Graduate Institute's website, <http://www.kgi.edu>.

Overview of the Keck Graduate Institute:

Today the most exciting work in the life sciences, engineering, and management is happening in the biosciences industry. To translate new discoveries into applications that improve the human condition, industry demands a new kind of professional - scientifically proficient and managerially savvy. Keck Graduate Institute, in partnership with industry leaders, responds to this challenge with a pioneering graduate degree: the Master of Bioscience.

Designed to prepare the future generation of bioscience leaders, KGI breaks down and transforms traditional boundaries between the academic and corporate worlds. Our degree and research programs are singularly focused on the unique and specific demands of the biosciences industry, drawing widely on the guidance of a world-class advisory board that includes leaders in industry, science, and higher education.

Recognizing that the solution of practical, real-world challenges requires close teamwork, creative problem-solving skills, and cross-functional fluency, our curriculum is fundamentally interdisciplinary, incorporating an intensive technical component and a broad management and policy component, as well as innovative approaches to developing leadership skills. As a result, our students graduate with a practical understanding of the results-oriented, collaborative culture in which scientists.

Mission:

In early 2002 these statements of Keck Graduate Institute's unique mission, its innovative culture, and the core values that underpin both were developed collaboratively by essentially all faculty, staff, and students then at KGI. We seek to embody these objectives and principles in both KGI's strategy and its every-day operations. As we gain experience, the statements will evolve and be further refined.

Mission:

Keck Graduate Institute is dedicated to education and research aimed at translating into practice, for the benefit of society, the power and potential of the life sciences.

Culture:

KGI seeks to sustain an interdisciplinary and entrepreneurial culture, working in partnership with industry to develop leaders for the biosciences, while promoting academic freedom and the highest ethical standards.

Core Values:

- Entrepreneurial and Reflective
- Ethical and Responsible
- Collaborative and Independent
- Interdisciplinary and Applied

KGI Values: Detailed Description:

Entrepreneurial and Reflective

- encourages experimentation
- encourages new ventures, both internal and external, and treats them as learning opportunities
- tolerates risks and accepts that some experiments fail
- acknowledges that anxiety and ambiguity often attend risk taking
- treats each member of KGI as a partner who has a role in making it a success
- remains small, agile and unbureaucratic
- challenges higher education conventions
- takes the time and effort to learn lessons from the past and to plan for the future
- encourages change that arises from self-reflection
- works actively to foster personal, professional and intellectual growth for everyone in the KGI community.

Ethical and Responsible

- is dedicated to the highest ethical standards in all activities: learning, research, business, personal interactions, and external relations
- recognizes that potential conflicts of interest cannot always be avoided, but they can and must be openly acknowledged and carefully managed
- pursues open, honest, and frank interactions with each other and with our external partners
- is dedicated to "benefit society"
- works to raise awareness and develop innovative solutions to ethical issues facing the bioscience industry
- trusts each member of the KGI community to take responsibility for his/her own actions
- empowers all KGI members to "own" the process of their learning and professional growth and supports them in these efforts.

Collaborative and Independent

- promotes collaboration among the KGI staff, students and faculty
- actively partners with industry, non-profits, educational and government institutions
- preserves vigorously the highest standards of academic freedom
- cooperates with other Claremont colleges to leverage strengths of these diverse institutions and the consortium
- sees team-based activities as central to learning, research and administration
- acknowledges that true collaboration requires flexibility, information sharing, frequent communication, and mutual respect.

Interdisciplinary and Applied

- pursues integrated, cross-disciplinary research and teaching as central to KGI's mission
- avoids creation of separate academic departments that might foster isolation and discourage interdisciplinary work
- works closely with industry in all aspects of the KGI curriculum - technical, management and ethics - and through the summer internships and team masters' projects
- involves individuals from industry as full-time, adjunct and guest faculty members
- seeks input from industry members on the KGI Board of Trustees and Advisory Board to insure the ongoing relevance of KGI's curriculum and research directions.

In An Interactive Learning Environment

- Encourages all members of the KGI community to continue to develop their capabilities
- Fosters discussion and debate within the classroom
- Actively involves students in the design of course offerings and seeks their feedback to foster improvements
- Dedicates itself to action learning through projects
- Seeks a multi-talented and diverse student body whose members can learn from each other.

The MBS Program:

The KGI Master of Bioscience is a professional degree-and a direct response to leaders in industry, government, and higher education who asked for a new model of graduate science education. Because KGI created the MBS in partnership with industry, the requirements reflect workplace realities. Requiring two years of focused, full-time study, the program combines rigorous scientific training-the kind usually associated with traditional programs-with course work and experience in management, ethics, and policy studies similar to that found in MBA programs. Guided by knowledge of how the business of biosciences really works, our approach includes team projects and real-world case studies drawn from the biosciences industry. Students learn in a series of focused, intensive modules of about three weeks rather than over a semester, approaching problem-solving from multiple perspectives rather than from a narrow disciplinary focus.

As a result of KGI's focus on real-world problems and applications, our graduates are starting to make names for themselves in an industry that requires expansive thinking and an extensive vision. KGI graduates launch successful careers with entrepreneurial start-ups and corporate giants in areas from bioinformatics to clinical research to business development.

MBS Admissions:

The primary degree offered by KGI is the professional Master of Bioscience. The full-time program begins in August, lasts two academic years and includes a summer internship between the first and second years. Admission is for fall entrance only.

We currently enroll 30-40 new students per year. Eventually the size of each entering class will grow to 60 students, but we plan to reach that goal slowly to ensure that we maintain the unique character of the KGI experience.

Because we believe in the unique vitality provided by a heterogeneous student body, we seek students from a variety of backgrounds and at different stages in their careers. Students coming directly from undergraduate school see our program as an attractive alternative to training for research, academic, or medical careers through conventional doctoral programs. Others, with industrial, business, and policy experience in bioengineering, biotechnology, and related fields, are attracted to the expanding opportunities in life science-based organizations and seek additional graduate preparation to enhance their career options. We actively encourage applications from members of groups traditionally underrepresented in engineering and the natural sciences.

Student Background and Preparation

An admissions committee of faculty and senior administrators will thoroughly and conscientiously review each application. Applications will be considered in the context of the total applicant pool, as well as in relationship to our general admission standards. We do not use arbitrary grade point or test score cutoffs. Factors considered during review include colleges or universities attended; undergraduate (and graduate, when applicable) records, including curriculum and grades; standardized test scores; practical experience; career aspirations; leadership potential; a personal statement; and recommendations. All applicants must have received a bachelor's degree from an accredited university or college, or its international equivalent, prior to enrollment.

Of the factors considered during the selection process, academic preparation, practical experience, and career aspirations will be foremost. Although a major in the natural/life sciences, pre-med, mathematics, engineering, or computer science is likely to provide the most thorough academic preparation for our program, it is not a prerequisite for admission. However, the demanding and broad reach of technical training at KGI requires a comparable level of requisite knowledge and skills. Some deficiencies in preparation can be addressed during the first year of study. If additional preparation is required, it should be acquired before matriculation.

Ideal preparation would include coursework or its equivalent in some combination of the following areas:

- Biochemistry
- Organic chemistry (physical chemistry desirable)
- Molecular biology/basic genetics
- Mathematics (at least calculus and introductory probability and statistics; differential equations helpful)
- Physics (classical, calculus-based)
- Engineering (some systems-focused topics).
- Computer programming (PERL, JAVA, C++, MatLab, or UNIX/LINUX desirable)

We look favorably on work experience, especially in fields directly related to biotechnology, engineering, computing, pharmaceuticals, medical devices and instrumentation, and medical, environmental, and agricultural biotechnology. Employment in areas of policy planning, regulation, and businesses closely allied with the life sciences also provides relevant experience.

Promising applicants with appropriate professional experience but lacking adequate academic qualifications in mathematics and natural science may be offered conditional admission, contingent upon successful completion of additional academic work specified by the admissions committee.

Standardized Tests

We require the Graduate Record Examinations (GRE) General Test or the Medical College Admission Test (MCAT).

Applicants who receive their undergraduate degrees from a university where English is not the language of instruction, or have studied fewer than two years at a university where instruction is in English, must take the Test of English as a Foreign Language (TOEFL).

Our GRE and TOEFL institution code is 4166.

Other Supporting Material

Recommendations from three people who are familiar with your work, and likely to be able to judge your capacity for both academic and professional success, will be used in support of other admissions documentation. We prefer that two recommenders be professors with whom you have worked closely. The third can be an employment supervisor who is in a position to evaluate your work.

Accreditation:

Western Association of Schools and Colleges, through a term affiliation with Claremont Graduate University.

Keck Graduate Institute does not discriminate on the basis of race, color, creed, national origin, gender, sexual orientation, age, or disability in the administration of its educational policies, admission policies, fellowship and loan programs, or other programs.

MBS Curriculum:

The MBS curriculum mirrors the actual dynamics faced by managers of life sciences organizations.

First Year

Initial Projects – An initial two-week case-study project orients new students to the biosciences industry, familiarizes them with team-conducted work and project management, and encourages cross-disciplinary thinking and creativity.

Ramp-Up Courses – Because KGI students have diverse academic backgrounds, these courses, in computer science, mathematical methods, and biochemistry, are offered to provide a foundation of knowledge for the MBS.

Computer Science: As the pace of data collection in the biological sciences gathers speed, many researchers in industry and academia have become acutely aware of the need to apply the data handling capabilities of modern computing technology. The purpose of this course is to allow students to appreciate the problems and issues in computer programming using a hands-on approach. The skills and knowledge gained in this course will be invaluable in assisting students in many of the courses that will subsequently be taken at KGI and in their future employment.

The course covers a wide range of topics including learning a programming language in some detail. Data storage, retrieval and analysis will also be covered because of their increasing importance to modern biology. Other topics will include an introduction to scripting languages (Perl and Python), LaTeX/TeX (document handling), mathematical tools and rapid application development.

Mathematical Methods: This course provides the mathematical background required throughout the rest of KGI's MBS curriculum. Tutorials in probability and statistics, differential equations and linear algebra will be provided. Calculus is considered a prerequisite for this material, i.e., it is assumed that the students are comfortable with derivatives and integrals.

Topics to be discussed include:

- Probability and statistics
- Ordinary differential equations
- Linear algebra

Biochemistry: Research in the applied life sciences requires an understanding of biological processes at the molecular level. Students without previous training in biochemistry will obtain an understanding of fundamental principles otherwise covered in undergraduate chemistry and biochemistry coursework, thus providing the foundation for more advanced topics to be covered in the later modules and courses.

Students will acquire knowledge of the structures and reactivities of common classes of biomolecules, and methods for their synthesis, modification, isolation and characterization, with relevance to molecular biotechnology.

Topics will include:

- General chemistry
- Organic chemistry
- Amino acids, polypeptides
- Protein structure
- Thermodynamics
- General/enzyme kinetics
- Metabolic pathways
- Carbohydrates
- DNA & RNA
- Lipids
- Protein & DNA isolation
- Spectroscopic methods

Interdisciplinary Modules – Modules are theme-specific, integrate components from the core technical areas (biological systems, computational biology, and bioengineering), last about three weeks each, and meet three full days per week. They include lectures, seminars, guest presentations, field trips, labs, problem sets, team projects, research, and written and oral presentations.

Module 1.1- From Genes to Targets: Students will learn how the wealth of information in the human genome can be mined to identify new drug targets. To utilize data mining techniques requires that we first understand gene structure and learn how genetic materials are manipulated in the laboratory. Students will also examine how genetic information is organized within the genomes of organisms that represent the evolutionary spectrum of life on this planet. Advanced instrumentation and computer software have played a major role in uncovering these genomic secrets. Students use a selected set of software programs that have been instrumental in identifying genes within genomic sequences.

Module 1.2 - From Targets to Products: Students will learn how products (biologicals) are developed from protein targets identified by either mining the genome or by other techniques. The goal of this module is to introduce the students to computational methods for characterization of target proteins by identifying proteins with homologous sequences from sequence databases, different classes of protein-based products, various sources from which they may be obtained, and methods to purify and characterize them. Students will learn about industrial scale protein product manufacturing methods, which are usually divided into upstream and downstream processing of protein products. Students will be introduced to the essentials of regulatory requirements associated with protein/peptide-based biotechnological or pharmaceutical products. Students will also be introduced to bioprocess engineering with particular reference to fermentors and bioreactors used for protein production. They will learn about issues encountered by process engineers during design and implementation of methods for production of protein-based products using fermentors and bioreactors.

Module 1.3 - Introduction to High-throughput Technologies: Pharmaceutical and biotechnology research has undergone a transition from hypothesis-driven science to discovery-based science that is, to a large extent, based on technological advances in laboratory automation. The Human Genome Project to sequence the human genome, High-throughput Screening (HTS) of drug candidates, and current SNP consortium efforts are based on laboratory equipment that has been designed to automate biological tasks to generate large amounts of data that can be studied, and "mined" for potential breakthroughs.

With over 1.5 million mapped single nucleotide polymorphisms, the SNP Consortium has laid the basis for pharma and biotech industry to link known genetic variants with diseases and to develop diagnostic and therapeutic applications by correlating genetic SNPs with drug efficacy and toxicology. The enabling technologies include DNA sequencing and synthesis equipment, robotic process standardization, as well as advances in our ability to perform high-throughput biomolecular and cellular assays using flow cytometry and microarray systems. The goal of this module is for students to become familiar with lab automation equipment, methods, and processes as well as associated technologies that facilitate automation. Students use engineering design methodology and engineering science introduced in this module to develop a design for a PCR amplification system meeting desired user requirements. The lecture material and laboratory sessions are supplemented by class visits to Amgen's research and automation technology facilities and to the Association for Laboratory Automation's annual LabAutomation meeting.

Module 2.1 - Molecular Interactions, Recognition and Transport: In the applied life sciences, novel microfluidic and micromechanical technologies based on biomolecular interactions, recognition, and transport are finding widespread application. The goal of this module is for the students to learn the basic principles needed to understand and ultimately design biomolecular assays and devices, which includes a grasp of the fundamentals of molecular thermodynamics and a rudimentary understanding of solid and fluid mechanics.

Module 2.2 - Exploring the Proteome: Proteomics is the up-and-coming frontier that translates predictions from genomics into the reality of actual biochemistry of cells, and is emerging as a powerful discovery tool for the biotech and pharmaceutical industries. The goal of this module is to introduce the students to a variety of techniques currently being used in experimental and computational proteomics.

Module 2.3 - Enzymatic Control: The control of enzymatic reactions is an intrinsic capability of all living organisms. Understanding how enzymes work and how they are controlled is important for a wide variety of bioscience applications including drug discovery and bioprocess engineering. The goal of this module is for the students to learn basic concepts in enzymology, the modeling of enzymatic pathways and fundamentals of bioreactors.

Module 2.4 - Genetic Control: The regulation of gene function at transcriptional and post-transcriptional levels is the fundamental mechanism for controlling cellular behavior. Advances in biotechnology critically depend on detailed understanding of the mechanisms of gene regulation in normal and abnormal conditions. Recently, the availability of whole genome sequences, specialized expression libraries, high-density microarrays, various proteomics tools, and high-throughput functional analysis techniques have vastly accelerated the applications of gene control systems to biotechnology. This module will provide background on our current understanding of gene regulation, methods of analysis, and an exposure to microfabrication techniques that are essential for improvements in high-throughput analytical tools.

Module 2.5 - Cellular Analysis: The goal of this module is to develop an understanding of the compartmentalized organization of eukaryotic cells, protein folding and degradation processes, and the role of specific protein-protein interactions in cell function. The proteins and signaling events involved in mammalian cell adhesion and migration will also be studied. Both intracellular and extracellular protein

interactions will be considered with focus on the latter associated with biomaterials, protein adsorption, and experimental methods for characterizing cell-biomaterial systems. Finally, students will use various methods to characterize, count, and sort cells based on light-scattering and other physical properties.

Module 2.6 - Systems Engineering of Biotechnological Research Models: The goal of this module is to provide an opportunity for students to participate in a team-based effort that integrates design and technical skills developed during the year into an integrative, comprehensive effort. This work will be performed using a requirements-driven Systems Engineering approach for product development. The students will work as if they were employees of a corporation organized in a matrix structure: as a member of a project team and/or as a member of a functional group. Each student will contribute in a unique way to the project effort from the planning phase through the final design.

Business Management Courses – Closely connected to other areas of the curriculum, these courses cover pharmaceutical development, bioethics, finance, marketing, and management.

Pharmaceutical Development: The Health Care Industry is complex and diverse. What can happen in one marketplace may have a profound impact through the entire industry. To understand how the pharmaceutical industry interacts in the health care industry requires an understanding of the process of drug development through the pharmaceutical pipeline. The goal of this course is to define the pipeline from the concept of how to define a drug and how drug candidates fill unmet medical needs. What role does the pharmaceutical company play in this pipeline in contrast to the roles of biotechnology companies and the academic community? What are the different challenges in developing new molecular entities versus a biological product? What is the role of diagnostics in the development of a therapeutic agent? This course will provide the organizational structures as well as the industry vocabulary for understanding the challenges in bringing a drug to the clinic.

Bioethics and Business Ethics in the Applied Life Sciences: Issues of research integrity, the protection of human research subjects, and ethical marketing practices are increasingly central in science and business. This seminar will consider some of the ethical and social issues that currently confront the biotechnology and pharmaceutical industries. Using a set of case studies developed at the Stanford University Graduate School of Business and the Center for Biomedical Ethics at the School of Medicine, the course will consider a range of topics and issues for analysis and discussion and may include the following topics:

- University-industry research collaboration; conflicts of interest;
- Appropriate intellectual property practices regarding human genetic information;
- Corporate responsibilities for injuries to human subjects;
- Cultural relativism related to the conduct of research in developing countries;
- The limits of risk exposure for human subjects receiving placebo treatment;
- Gene test marketing to a vulnerable population;
- Achieving appropriate balance in direct-to-consumer drug advertising.

Finance: The Finance course will provide sufficient background to read, analyze, and draw conclusions from corporate financial statements and to gain some understanding of the corporate budgeting process. Additionally the course will present an introduction to capital budgeting procedures and corporate finance. No prior background in accounting or finance is assumed.

Designing High Performance Organizations: This course focuses on organization design and effectiveness. It will cover the different components of organization design and how they can be aligned effectively, from the individual work team to the macro-corporate structure. The class will draw heavily on

the most recent work of one of the world's premier research centers in the area of organization design and human resources, the Marshall School's Center for Effective Organizations. The course has an international focus, comparing U.S. organizations with their leading worldwide competitors. While the company examples come from a variety of sectors, we will compare each with examples from the bioscience industry.

The course's content is organized using the star model developed at the Marshall School's Center for Effective Organizations to illustrate the need for alignment among the five crucial elements of an organization:

- Strategy
- Structure
- Processes
- People
- Rewards

While each session will focus on one aspect of this star, there will be a continuous emphasis on the relationship among the different elements of the organization.

Marketing for Life Science Companies: The course will equip students with an understanding of the basic conceptual frameworks and analytical tools of marketing and provide an understanding of the key decisions in the development of marketing programs for technology firms in the life science domain. Students will understand the importance and strategic role of marketing during all stages in a life science organization. The course will also provide practice in applying the theoretical frameworks through the use of case studies and the invitation of biotech/marketing professionals.

Topics to be discussed include

- Introduction to High Tech/Life Sciences Marketing
- Marketing Research and its Applications
- Sales & Marketing
- Developing the Marketing Mix: Target Market Segmentation and Selection, Market Adoption and Product Positioning
- Product Life Cycle and New Product Development
- Marketing Communications, Promotional Strategies, Distribution and Channel Management
- Pricing Strategies
- Branding and International Marketing Strategy
- Global Marketing
- Ethics of Life Sciences, Future Challenges and Take Away lessons

Internships – Via a paid summer internship between the first and second years, students confront the issues and current techniques associated with particular industry sectors and gain insights into the climate and culture of business.

Second Year:

Career-Oriented Focus Areas – Students achieve depth in an area of interest by taking courses in career-oriented focus areas. Focus areas link KGI's curriculum more closely to potential biosciences careers.

Bioinformatics and Computational Biology: The bioinformatics and computational biology focus area is intended as preparation for students who wish to obtain positions in these fields. The required two-semester course Applied Stochastic Methods for Computational Biology and recommended electives are described below. Additional complementary electives include Drug and Vaccine Discovery, Advanced Pharmaceutical Development and business electives.

Business of Bioscience: The business of bioscience focus area will enable students to identify potential business opportunities in life science industries and to analyze the market, management, and technological and ethical issues for each. There will be strong emphasis on integrating business and technology, encouraging students to analyze commercial potential for science emerging from KGI and other leading research institutes. The focus area will cover material from strategy, marketing, entrepreneurship, organization development, operations, leadership and finance. The courses will be predominantly case study-based, with a strong action learning component. Students will be able to supplement these KGI offerings by taking courses at Drucker School of Management at Claremont Graduate University (<http://drucker.cgu.edu>).

Medical and Regulatory Affairs: Students will develop the skills and tools to understand the process of product development and the regulatory environments surrounding product development. The focus area gives an overview of how the FDA regulates the development of a novel product through pre-clinical pharmacology and clinical evaluation and addresses the challenges faced by a director of medical and regulatory affairs in bringing medical products to market.

Biopharmaceutical Discovery and Development: The Biopharmaceutical Discovery and Development focus area will train students in the theory and practical skills needed for both discovery and commercial development of small molecular weight drugs, protein therapeutics and vaccines. Courses included in this focus area, together with business electives, prepare students for careers in the R&D, strategic planning and business development sectors of the biopharmaceutical industry.

Engineering Tissues and Replacement Devices: The focus area in Engineering Tissues and Replacement Devices will enable students to identify and understand the issues surrounding engineered tissues and devices and to analyze current practices in replacing tissue or function. There will be a strong emphasis on applying fundamental knowledge to analyze and develop requirements and designs for new tissues and replacement devices. Business electives will cover regulatory issues.

Life Science Instrumentation, Assay Development and Diagnostics: This focus area will enable students to acquire the knowledge and skills necessary for the development of assays, instrumentation and data analysis tools required for clinical diagnostics, high throughput screening, genotyping, microarray technologies, proteomics, imaging and other applications.

Team Master's Project – The TMP involves students as consultants with real companies to solve real issues: problem-solving at the technical level. Guided by industry advisors and faculty, teams of three to five students tackle projects that produce results sponsoring firms can implement.

The Team Master's Project (TMP) is the capstone applied life sciences project for second-year MBS students. It replaces the traditional master's thesis of conventional MS programs.

Educational Purpose: The TMP emphasizes problem-solving, project (including budget) management, productive teamwork, and effective communications, skills that are critical to KGI graduates as they pursue careers in the bioscience industries. Representing about 35 percent of the academic work for second-year students, the project is an academic year-long effort aimed at providing useful results to sponsoring companies.

Corporate Sponsorship: The educational effectiveness of the TMP is enhanced substantially by corporate sponsorship of the project. The team views the corporate sponsor as its client. Importantly, the industrial problem to be tackled by the student team is one to which the client has need of a solution or answer; that is, projects have a real potential payoff for the client. Further, KGI particularly seeks projects that involve multiple disciplines, including, if possible, both science/technology and management/ethics issues, thus mirroring KGI's overall curriculum. Ideally, the project involves the application of science/technology rather than the pursuit of new discoveries, and is more complex and challenging than simply routine testing or computer programming.

Format and Schedule: The KGI student team typically consists of three or four second-year KGI students, advised by one KGI faculty member. One student is selected as the team leader; typically leadership of the team changes at mid-year. The faculty advisor is not a member of the team, but rather provides, to the team members. The team meets at least bi-weekly with the faculty advisor, and has contact with the company liaison as needed.

All participants in the Team Master's Project meet bi-weekly to exchange oral progress reports; typically, each team will report twice in each semester. Each team provides its sponsoring company with an interim report at the end of the first semester. A public presentation of all TMP projects occurs at the end of the semester. Teams are also available to make personal presentations of their work at the sponsoring companies' sites.