MASTER OF BIOTECHNOLOGY
A PROFESSIONAL SCIENCE MASTER’S
THE SEMESTER-IN-RESIDENCE CAPSTONE PROJECT

California State University
SAN MARCOS

Extended Learning
**Program Overview**

The Semester-In-Residence (SIR) program is a unique part of the California State University San Marcos’ Professional Science Master’s in Biotechnology. The program provides students with the opportunity to work in a biotechnology or related life sciences business to address a real-world issue, project or problem by integrating new skills and information gained from their coursework.

The project functions as a capstone experience in lieu of a Master’s thesis, and runs for approximately 15 weeks requiring 300 hours of work. It is similar to a structured internship with a very specific, comprehensive schedule of deliverables established by the student, in consultation with the CSUSM Biotechnology Advisory Committee and the community partner.

SIR projects demonstrate the students’ ability to integrate technical science principles learned in class with fundamental business practices including project management, team building and communications skills.

Students write proposals with detailed deliverables, work plans, budgets and a performance assessment. Once approved, projects are initiated and regular progress reports are provided to the Advisory Committee. At the conclusion of the project a final report is submitted and the work is presented and orally defended. Projects may be undertaken individually or as members of a team of 2 to 3 students.

Students working in the life sciences industry may opt to conduct a project at their site of employment or with an outside organization. As a stretch goal, the project is meant to contribute to the student’s professional development. Hence, the endeavor must be above and beyond the student’s normal responsibilities within their organization.

This brochure provides abbreviated case studies of four SIR projects completed by students that demonstrate the breadth and depth of these endeavors, the combination of technical science and business applications in each study, and the impact CSUSM Biotechnology students have addressing problems important to the life sciences industry. These case studies have been modified due to space limitations and to make them more understandable to non-technical audiences.

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**Developing Trial-Size Products to Offer More Effective Solutions for Experimental Design**

**MATT MICELI FOR BD** **APRIL 2015**

**ISSUE:**
BD (Becton, Dickinson and Company) is an internationally recognized leader in developing and creating innovative research tools for the biotechnology and academic research fields. The Biosciences business of BD manufactures flow cytometers and reagents and provides a number of services to accompany its products. Over the last 30 years, flow cytometry has grown to become a leading technology in the field of biomedical research. The set of reagents used in a flow cytometry experiment is called a panel. Researchers often need several iterations of reagent testing before arriving at the optimal panel design for their experiment. Currently, many reagents come in large quantities, at times making this panel-design process costly and wasteful. As flow cytometry experiments used to research disease become increasingly complex, researchers need tools and products dedicated to making experimental design as efficient and cost-effective as possible.

**PROJECT:**
The goal of this project was to recommend a strategy for BD to offer more convenient options for customers to test panels before committing to large orders. The three specific aims of this project were to: 1) construct and administer a survey for BD’s flow cytometry customers to gain information about panel design needs, 2) perform an analysis of the multicolor flow cytometry market to better understand the strengths and shortcomings of BD’s current offerings, and 3) recommend an optimal trial-size product for BD and determine the financial implications of offering this product. To accomplish this task, the student designed and administered a survey to flow cytometry users across the United States to determine their current workflow and unmet needs. Concurrently, a market analysis was performed, comparing BD offerings to those of other flow cytometry reagent providers. Finally, an internal assessment was performed to understand the operational and financial implications for carrying out the recommended plan. Based on these activities, an initial recommendation for a trial-size strategy was formed.

**RESULTS:**
The market analysis revealed that BD has an opportunity to enhance their offering of trial-size reagents, as well as boost sales performance of its existing trial-size products through increased awareness. The survey results showed that there was a significant segment of customers who desired trial-size products, and that trial sizes are in high demand for specific categories of reagents. Finally, the operational analysis revealed that BD can move forward with a targeted strategy of new trial-size releases and increased awareness for these products online and with sales representatives. These recommended actions will help researchers design new experiments more efficiently and increase brand loyalty and revenue growth for BD.

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“Our students are making a real impact in our industry because the Semester-In-Residence (SIR) program allows them to work in world-class organizations and laboratories addressing real-world applications that cannot be duplicated in the classroom. The SIR component makes our biotechnology program one of the most impactful in the country.”

DR. BETSY READ, PROFESSOR OF BIOLOGICAL SCIENCES AND FOUNDER/DIRECTOR OF CSUSM’S BIOTECHNOLOGY PROGRAM, CALIFORNIA STATE UNIVERSITY SAN MARCOS

“What we value most about the Semester-In-Residence program is its very defined nature before the student steps foot in our facility. Unlike an internship where you are trying to place a student in an area of interest, this program has very specific goals and objectives set and agreed upon on day one, and this is invaluable to both the student and the host firm.”

LAURA HENDERSON, DIRECTOR OF HR, CLINIQA CORPORATION
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Marketing Plan for the Commercialization of Biopellet Fertilizer

EKTA PRIYAM FOR ENCINA WASTEWATER AUTHORITY APRIL 2012

ISSUE:
The Encina Wastewater Authority (EWA) operates, maintains, and administers the Encina Water Pollution Control Facility in Carlsbad, California. EWA is a joint powers agency that treats solid waste sewage water from member agencies and converts it to non-potable water for use in municipal-run parks and regional golf courses. This process reduces the need for potable water sources to irrigate large landscaped recreational spaces and recycles waste water into a useful commodity. The process creates biosolid waste products that EWA was formally making into pellets which were then either disposed of at out-of-state landfills or burnt as fuel for cement manufacturing industry. EWA retained a consulting firm to determine if other best-use options to this costly disposal process were available. The firm looked at a number of options and determined that the waste product could be turned into a commercial-grade fertilizer. But the recommendation did not include a comprehensive market analysis about the feasibility of selling and marketing the fertilizer or the development of a marketing plan.

PROJECT:
CSUSM PSM Biotech student proposed a project to examine the feasibility and market potential of selling these biosolid pellets and thereby recovering costs for EWA rather than incurring costs borne by the expensive disposal process. Five potential market segments were examined for this plan including nurseries/specialty agriculture farms, soil blenders, golf courses/turf management companies, fertilizer distributors, and local communities. The marketing plan consisted of an executive summary, market overview, competitive overview, product overview, a SWOT analysis (Strengths, Weaknesses, Opportunities and Threats), creation of marketing goals and objectives, and a marketing strategy examining positioning, product, pricing, distribution, and promotion. From this, strategies for an action plan, implementation plan and evaluation process were developed for EWA.

RESULTS:
Through the student’s work and marketing plan, EWA moved forward to commercialize the sale of the biosolid pellets. The plan named the product Pure Green and recommended it for sale to all five identified markets segments in 50 pound bags. This marketing plan for the Pure Green fertilizer will generate a net long-term revenue for EWA while eliminating the disposal fees, offsetting the hauling costs and recovering the production costs of the pellets.

“...The PSM Biotechnology program at CSUSM has had a significant positive impact on my career. The combination of traditional business courses with science courses taught by local industry leaders provided a unique and powerful experience that allowed me to make meaningful contributions to my company right away. My Semester-In-Residence project, sponsored by both CSUSM faculty and company leadership, led to a strategic recommendation for my company that was approved and successfully implemented.”
MATT MICELI, MASTER OF BIOTECHNOLOGY GRADUATE, BD LIFE SCIENCES

FOR MORE INFORMATION: CSUSM.EDU/EL/PSMBIOTECH

A Target Enrichment and Fast PCR Method for Rapid Detection of Infectious Pathogens

JOSEPH MUSMACKER FOR IBIS BIOSCIENCES, AN ABBOTT COMPANY MARCH 2013

ISSUE:
Ibis Biosciences (Ibis), an Abbott Company, offers an innovative approach to the detection and characterization of a broad array of pathogens for the management of infectious diseases. One of the diseases that Ibis addresses is sepsis. This is a systemic infection that is associated with a high patient mortality rate as a result of an infection caused by a pathogen. Patient survival relies heavily on rapid identification of the causative pathogen(s) to facilitate a specific and effective treatment therapy. While the gold standard for pathogen identification continues to be blood culturing, which is a time-intensive process requiring upwards of several days for accurate identification of the microorganism, molecular diagnostic tests might reduce the “time-to-answer” (TTA) needed for quicker pathogen identification.

PROJECT:
The primary objective of this SIR project was to evaluate whether a molecular diagnostic testing process might be faster than blood culturing to identify the infectious sepsis pathogens. The study focused on using a custom thermocycler and polymerase chain reaction (PCR) conditions that would yield a reduction in amplification time needed for rapid pathogen identification. The study tested combining use of Ibis’ custom-built thermocycler along with a commercially available polymerase capable of rapid DNA polymerization to examine if this process, did indeed, afford an ultra-fast PCR amplification needed for faster pathogen identification.

RESULTS:
This study resulted in a dramatic 86% reduction in PCR amplification time compared to the identification process normally used through blood culturing. As such, developing a commercial-grade ultra-fast PCR thermocycling system for amplifying DNA isolated directly from whole blood samples, in conjunction with Ibis’ proprietary BAC assay primers and PLEX-ID platform, has the potential for significantly reducing time of early of infectious pathogens such as those causing sepsis. Early detection of the causative microorganism responsible for sepsis is critical for improved patient prognosis and recovery. This project demonstrated an ability to reduce the time-to-answer by two hours representing a potential 14% decrease in patient morbidity. The ability to rapidly amplify nucleic acid opens many doors that can lead to a variety of faster point-of-care diagnostics. Molecular diagnostic tests, like those perfected by Ibis, have emerged as viable options that take advantage of the polymerase chain reaction (PCR) to amplify the DNA of the infectious microorganisms and reduce the testing times to identify the causative pathogen(s).

“One of the key benefits we get from the Semester-In-Residence program is being able to take a high-level project we want to develop but don’t have the time or resources to implement, and hand it off to a Biotech Master’s student. The depth and quality of work they provide is invaluable to us and the experience the student gets is invaluable to their education.”
SHERMAN CHANG, PH.D., VICE PRESIDENT OF RESEARCH AND DEVELOPMENT, AUTOCOMICS, INC.

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“Achieving this feat required collaboration with our marketing expert, industry leaders, and EWA’s in-house operations. The coordination of these efforts was challenging, yet ultimately successful.”
MATT MICELI, MASTER OF BIOTECHNOLOGY GRADUATE, BD LIFE SCIENCES

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Chicken Fibroblast Cell Fusion with Avian Germline Stem Cell

MADHAWI ALOHALI FOR SAN DIEGO ZOO INSTITUTE FOR CONSERVATION RESEARCH
MAY 2015

ISSUE:
San Diego Zoo Global (Zoo) is a conservation organization dedicated to the science of saving endangered species worldwide. Their conservation work takes place locally at three campuses and reaches to more than 140 conservation field projects in 80 countries. To date, the Zoo has reintroduced 33 species back into the wild including: mountain yellow-legged frogs, five species of reptiles, 17 species of birds, and 10 species of mammals. In many cases, these efforts have meant the difference between extinction and survival. As such, preserving the genetic material of exotic species is essential to maintaining genetic diversity and ensuring the survival of captive populations. Avian-assisted reproductive technologies (ARTs) are more limited than for mammals, due, in part, to the differences in their reproductive systems. To overcome this obstacle in avian conservation, many techniques are being developed and tested.

PROJECT:
Avian ART is restricted to sperm collection, sperm cryo-preservation, artificial insemination, and artificial incubation. In contrast, mammalian ARTs include more advanced techniques such as in vitro fertilization, embryo transfer, and cloning. An alternative to cloning is somatic nuclear transfer (SNT) and/or xenotransfer of germline stem cells to host embryos. Mammalian SNT is successful in mammals, but cannot be applied to avian species. As an alternative, in this SIR project chicken fibroblast (FB) nuclei are inserted into inactivated avian germline stem cells (GSC) using a cell fusion technique. This technique has the potential to recover the genetic information from live, non-reproductive, captive individuals for transfer to the reproductive systems of a host. Likewise, this technique may be used to collect the germplasm of wild birds without removal from the wild, ensuring improved genetic diversity of the captive population without impacting the wild population. Eventually, these cell constructs will be cultured and injected into the blood stream of host embryos to test for migration and colonization of host-embryo gonads. This procedure could potentially introduce new genetic material from exotic avian species into the captive gene pool. Chicken embryos were chosen as a model for this study due to their availability and robustness. In addition, the incubation period for a chicken egg is shorter compared to other species. This study’s findings raise the possibility of using advanced ART techniques with endangered species for conservation purposes.

RESULTS:
The student found a significant difference is achieved when comparing targeted to standard cell fusion protocols. A future application could be to use this ART in combination with xenotransfer to clone and incorporate valuable genetic information into captive propagation. This study demonstrated that FBs and UV-inactivated GSCs can survive fusion and short-term culture. The next step will be to demonstrate that fused cells can be used for xenotransfer to chicken hosts.

“Science is the creation of new knowledge. Technology is the application of it.”
DR. AL KERN, RETIRED DIRECTOR OF BIOTECHNOLOGY PROGRAMS / RETIRED INTERIM DEAN OF EXTENDED LEARNING, CSUSM

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Biotechnology Master’s Semester-In-Residence Community Partners*

Abbott Vascular • Active Motif • Alere Inc. • Althea Technologies • Ambryx Inc. • Ardea Biosciences • Autogenomics • BioLegend • BD Biosciences • Carlsbad Aquafarm • Cliniqa Corporation • Cliniqa Corporation • Encina Waste Water Authority • Genentech, Inc • Genmark Diagnostics, Inc. • Genoptix • Howard Hughes Medical Institute • Ibis Biosciences, an Abbott Company • Illumina Inc. • Imgenex Corporation • Life Technologies • MaVax Therapeutics • Myron L Company • Millipore • Neuropore • Quidel Corporation • Point Loma Wastewater Treatment Plant • Promethean Biofuels Cooperative Corp. • San Diego Zoo Global Institute for Conservation Research • San Diego Sheriffs Department, Crime Lab • Sapphire Energy • Seacoast Science, Inc. • Sirigen/BDB. • Syntron Bioresearch, Inc • T2 Energy • Thermo Fisher Scientific Inc. • The Scripps Research Institute • Time Logic • Valicor Renewables

* This is a partial listing of Community Partners. For a complete listing, See csusm.edu/el/psmbiotech/sir

“The Professional Science Master’s degree is the fastest growing graduate degree program in the country, in part, because it combines the science component of the degree with MBA-level business and industry relevant courses. That’s what employers want! We know this by the high rate of placement of our graduates.”

Mike Schroder, Dean of Extended Learning, California State University San Marcos

If your organization is interested in having a CSUSM Professional Science Master’s (PSM) student in Biotechnology conduct a Semester-In-Residence project in your organization, or you want more information on the Master’s programs, please contact Dr. Betsy Read at 760-750-4129 or visit csusm.edu/el/psmbiotech.

CSUSM also offers a Professional Science Master’s in Cybersecurity and a corresponding Semester-In-Residence project. Because of the increasing cyber threats that businesses and organizations face each day, and the vulnerabilities that Biotech firms have with the protection of their research and development work and intellectual property rights, your business may be interested in CSUSM’s Cybersecurity PSM or associated SIR. For more information on these programs, please contact Teresa Macklin at 760-750-4787 or visit csusm.edu/el/cyber.