

**MANAGING INDUSTRY INTERNSHIPS**  
**FOR FACULTY IN**  
**COMMUNITY COLLEGE BIOTECHNICIAN EDUCATION PROGRAMS**

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With

2003 Epilogue  
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**A Bio-Link Monograph**  
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## ADDENDUM

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This monograph is one of a series being prepared by the Southwest Regional Center of Bio-Link for national dissemination. The series focuses on the documentation of innovative, successfully implemented, instructor development programs performed as special projects by the Southwest Regional Center. These projects are intended to demonstrate effective transferable models designed to improve the preparation of instructors to staff biotechnician education and training programs at the nation's community and technical colleges.

The first monograph in the series documented an innovative instructor training program that utilized community college classrooms as living laboratories to prepare biotechnology industry personnel to serve as effective visiting, adjunct, and/or full time instructors in biotechnician education programs.

This monograph is the second in the series and documents a successfully implemented multi-disciplinary / multi-college industry internship program conducted at a bio-pharmaceutical manufacturing company for faculty currently developing and/or operating biotechnician education programs.

For additional information about these projects and related training opportunities, contact Bio-Link's National Center at City College of San Francisco, [www.bio-link.org](http://www.bio-link.org) or Southwest Regional Co-Director Herald Kane at San Diego City College: [hkane@sdccd.cc.ca.us](mailto:hkane@sdccd.cc.ca.us); or connect with us through our link to the California Community Colleges Economic & Workforce Development Program's Biotechnology Initiative Program at [www.cccewd.net](http://www.cccewd.net), or more directly via Initiative Director Mary Pat Huxley at [mpuxley@vcccd.net](mailto:mpuxley@vcccd.net).

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### **PROJECT FUNDING: (NSF Award #9850325 & #0118933) & (CCCEWD Award 01-304-001)**

The purpose of the project documented by this monograph has been to develop and field test a transferable model for developing and managing industry internships for faculty in community college biotechnician education programs. The project has been funded through a sub-grant to San Diego City College (SDCC) from City College of San Francisco (CCSF), which serves as the primary grantee and administrator for the National Science Foundation's (NSF) National Advanced Technological Education (ATE) Center for Biotechnology (Bio-Link). Dr. Elaine A. Johnson is Director of Bio-Link's National Center headquartered at CCSF. San Diego City College utilizes its sub-grant funds to operate the Southwest Regional Center of Bio-Link, which serves five southwestern states. The project described in this monograph has been a special project of the Southwest Regional Center. The California Community Colleges Economic and Workforce Development Program, through its Biotechnologies Initiative, provided funding for the follow-up study that resulted in the 2003 Epilogue which is appended to this document.

### **DOCUMENT CREDITS:**

Technical writer Jann Einfeld prepared this report with the editorial guidance of Dr. Joan A. Stepsis, Dean of Applied Competitive Technologies at San Diego City College (SDCC) and Director of the Southwest Regional Center of Bio-Link. Content for the report was provided by project coordinators, Mr. Richard G. Buecheler, Manager of ED>Net's Southern California Biotechnologies Center (SCBC) at SDCC and Dr. Herald Kane, Professor of Chemistry at SDCC and Co-Director of Bio-Link's Southwest Regional Center. Dr. Kane is credited for the contribution that his keen academic perspectives made to the preparation of this monograph.

The resulting monograph is based on detailed interviews with the project coordinators, with Mary Schwalen, Manufacturing Training Manager at IDEC Pharmaceuticals, and with the participating faculty interns: Dr. Ram Gurumurthy, Assistant Professor of Chemistry at SDCC; Dr. Roya Lahijani, Assistant Professor of Biology at Palomar College; Ric Matthews, former Biology instructor at Miramar College and new Dean of Mathematics and Science at MiraCosta College; and industrial technology instructors, Jeremiah Lynch, Professor of Environmental Control Systems, and Douglas R. Welch, Professor of Manufacturing Technology at SDCC. The report draws extensively from the daily journals maintained by participating faculty during their internship at IDEC.

### **ACKNOWLEDGEMENTS:**

Project participants wish to acknowledge their gratitude to Dr. Joan Stepsis, for her dedication to the larger program goal and her role in securing funding for the project; to Dr Elaine Johnson for her acknowledgement of the value of the internship program to the professional development of faculty in biotechnician education, and the timely financial support provided by Bio-Link; and to IDEC management, particularly to David Broad, Vice President of Manufacturing, for IDEC's contribution of staff time and resources to host the program, and for the company's commitment to forging a strong partnership with community colleges in San Diego to develop a highly-skilled local biotechnician workforce. A special thanks is due to Mary Schwalen, whose passion for the project expressed itself in her determination to overcome considerable obstacles that arose during the final planning stages of the project; to Rich Buecheler, whose calm guiding hand inspired trust in all parties at all times; and finally to IDEC employees who unflinchingly shared their time, expertise, and enthusiasm for their work with the community college instructors.

## **ABSTRACT**

### **Developing and Managing Industry Internships for Faculty in Community College Biotechnician Education Programs**

Bio-Link is the National Advanced Technological Education Center for Biotechnology funded by the National Science Foundation (ATE/NSF). Bio-Link's mission is to strengthen and expand biotechnology technician education at community and technical colleges throughout the nation. In order to achieve its mission, Bio-Link funds the development, implementation and dissemination of models and methodologies designed to increase the number and diversity of well-trained biotechnicians in the workforce. Critical to this effort is the systematic preparation of qualified instructors to staff these biotechnician programs. In response to this goal, this monograph has been prepared to facilitate the dissemination of a tested and proven model for developing and managing industry internships in biotechnology companies that can be utilized by other colleges and companies throughout the nation to guide the systematic preparation of instructors and programs to meet the needs of the evolving and expanding biotechnology industry.

The monograph offers community college faculty and administrators with interest in developing biotechnician education programs the justification, guidelines, and a proven methodology for planning and implementing faculty internships in industry as an important step in building instructional programs to meet the expanding workforce needs of the industry.

The monograph reports on the specific experience of Bio-Link's Southwest Regional Center at San Diego City College in conducting a summer internship program for five faculty from San Diego County community colleges at IDEC Pharmaceuticals from July 10 to August 15, 2002. It presents the outcomes of this internship experience, and the lessons learned as to the prerequisites for project success.

The monograph begins with background information on the recent move of the biotechnology industry in southern California into large-scale manufacturing with the construction of a major manufacturing complex by IDEC Pharmaceuticals in the City of Oceanside in North San Diego County. The report then explains how the internship idea was first conceived, the program goals, costs, and distinguishing features such as the multi-college and multi-disciplinary composition of the selected faculty participants. Next the monograph provides a guide on how to negotiate project issues and obstacles, from how to select a suitable partner for the internship program, to how to respond to the biotechnology company's need for product confidentiality. The subsequent section provides a step-by-step guide for colleges and biotechnology manufacturing companies on how to plan, implement, and evaluate an internship program, describing the roles and responsibilities of the project leaders in the colleges and in industry. An analysis of the project outcomes, benefits, and evaluation strategies follows. The monograph summarizes the main factors that correlated with project success and concludes with an epilogue that identifies the longer-term project benefits as of December 2003. The appendix gives sample documents to aid in replication of the internship program in other locations.

# Managing Industry Internships for Faculty in Community College Biotechnician Education Programs

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# CHAPTER ONE: Intro to the Industry / Faculty Internship Model

## 1. Bio-Link

Bio-Link is a National Advanced Technological Education Center for Biotechnology funded by the National Science Foundation (ATE/NSF). Bio-Link's mission is to strengthen and expand biotechnology technician education at community and technical colleges throughout the nation in order to:

- Increase the number and diversity of well-trained technicians in the workforce;
- Meet the needs of industry for appropriately-trained technicians; and
- Institutionalize community college educational practices that make high-quality biotechnology education available to all students.

In order to achieve its mission, Bio-Link funds the development and implementation of activities intended to:

- 1) Develop, implement, and then disseminate, industry responsive technician education and training programs designed to increase the number of skilled workers available to the biotechnology industry as regionally appropriate.
- 2) **Design, field test, and disseminate models and appropriate methodologies for the systematic preparation of qualified instructors in numbers adequate to staff the programs referenced in goal number one (1) above.**
- 3) Provide a sophisticated, time-sensitive, user-friendly, web-based, national communications link and clearinghouse for information and curricular materials pertinent to biotechnician education & training. ([www.bio-link.org](http://www.bio-link.org) )
- 4) Design a responsive and manageable referral system, which facilitates the matching/utilization of the specialized expertise of the various Bio-Link partners and associates to provide person-to-person consultation, coaching, and direct technical assistance to start-up programs within and among regions.
- 5) Appropriately coordinate the Community College focused efforts of Bio-Link with the related programs of educational providers at the middle school, high school, four-year college, and university levels through joint activities, networking, and articulation agreements.

This monograph is a product of Bio-Link that focuses on goal two (2) above. It is designed to disseminate a model which can be used by community colleges and biotechnology industry personnel throughout the nation to operate and manage faculty internship programs in biotechnology companies to meet the currently expanding need of the industry for appropriately-trained technicians.

## 2. Specific Purpose of this Monograph

This monograph has been produced by Bio-Link's Southwest Regional Center at San Diego City College (SDCC) in southern California for the purpose of disseminating to community college and industry personnel a successful model for planning and implementing faculty internship programs in biotechnology manufacturing companies.

Community college faculty and administrators can find herein the justification, guidelines, and a proven methodology for planning and implementing faculty internship programs in biotechnology manufacturing, as an important step in building instructional programs to meet the expanding workforce needs of the industry nation-wide.

The monograph reports on the specific experience of Bio-Link's Southwest Regional Center at SDCC in conducting a summer internship program for five faculty members from San Diego County community colleges at IDEC Pharmaceuticals from July 10 to August 15, 2002. It presents the outcomes of this internship experience, and the lessons learned as to the prerequisites for project success.

## 3. A Roadmap for the Reader

The monograph is organized as follows:

- **Chapter Two** describes the growth of the biotechnology industry in the San Diego region and the recent move into large-scale manufacturing with the construction of a major manufacturing complex by IDEC Pharmaceuticals in the City of Oceanside in North San Diego County. Motivated by its need for skilled technicians for this expansion, IDEC is working with local community colleges and the Southwest Regional Center of Bio-Link to develop programs in biotechnology manufacturing. The chapter then describes how the internship idea was first conceived, a successful precedent in northern California, the program goals and special features, including the internship teams' multi-college and multi-disciplinary nature, and a summary of project costs and cost sharing.
- **Chapter Three** outlines a number of issues and obstacles that arose as the internship idea was being developed both at the college level and at IDEC. The chapter provides a guide on how to negotiate such issues as selection of a suitable partner for the internship program, and how to respect the company's need for confidentiality relating to its pharmaceutical products.
- **Chapter Four** provides a step-by-step guide for colleges and biotechnology manufacturing companies on how to plan, implement, and evaluate a college faculty internship program. The chapter outlines the roles and responsibilities of the project leaders, and gives details of the agendas of major meetings, ongoing

monitoring strategies to address problems that can arise during implementation, and the role and purpose of the final presentation meeting. The chapter concludes with chapter markers established to measure medium and long-term program goals.

- **Chapter Five** describes the project outcomes and gives detailed quotations from daily journals kept by the interns about their experiences at IDEC. The chapter describes some immediate applications by the instructors of what they learned during the internship program and some additional unanticipated project benefits.
- **Chapter Six** summarizes the major factors which correlated with project success, including personal characteristics of project leaders, a conducive company culture, and a strong spirit of partnership between industry and education representatives.
- An **Epilogue**, based on a follow-up study and added to this monograph eighteen months after the internships were completed, summarizes the longer term effects of the project on the development and implementation of biotechnology technician education courses and programs within the region; on regional coordination and individual college specialization; and on biotechnician education and training at state and national levels.
- **Appendix:** The appendix provides sample documents and pertinent reference materials including sample correspondence, the program schedule, report forms, and information on the company and on the Bio-Link organization.

#1: Profile of IDEC Pharmaceuticals & Statement of Company Core Values
#2: Summary of Biotech Company's Internal Procedures
#3: Sample Confidentiality Agreement between Biotech Company and Interns
#4: Sample Letter from Biotech Company to College Deans Offering the Internship
#5: Sample One-Week Internship Program Schedule
#6: Extract Displaying Format of Instructors' Journals
#7: Contact Information for Bio-Link National & Regional Centers

# **CHAPTER TWO: Background, Beginnings, and Goals of the Project**

## **1. Background and Context**

### **Needs of the Biotechnology Industry Cluster in San Diego County**

Over the last fifteen years more than three hundred biotechnology and related medical device companies have been established in San Diego, California, giving the county the third largest concentration of bioscience companies in the U.S. After more than a decade and a half of development, the industry is rapidly evolving from R&D into the production of its newly developed and FDA approved biotechnology products. According to BIOCUM, the region's primary industry trade association, there are currently 225 products in phase three clinical trials in San Diego County.

In 2001 IDEC Pharmaceuticals had the second of its revolutionary anti-cancer therapies for non-Hodgkin's Lymphoma approved by the FDA and released into the marketplace. With these successes IDEC announced plans to build two production plants in the City of Oceanside in North San Diego County. One plant will develop products for clinical trials, and a second much larger plant will manufacture the company's already FDA approved products. With a capital investment of over \$600 million, IDEC is pioneering biotechnology manufacturing in southern California. Ground breaking for the 450,000 square foot manufacturing facility in Oceanside occurred on May 30, 2002. When their facility is fully commissioned in 2006, IDEC will need between 500 and 700 highly-trained staff for their manufacturing operations. The scale of this demand represents a substantial shift in the educational needs of the biotechnology industry in southern California, from its former emphasis on preparing R & D laboratory technicians to training technicians skilled in small batch bioprocessing and large-scale bioproduction. (For more information on IDEC see [www.idecpharm.com](http://www.idecpharm.com).)

### **Response of the Region's Community Colleges**

Given these industry trends, the Southern California Biotechnologies Center at San Diego City College (SDCC), which as part of the State of California's Economic Development Network (ED>Net), is responsible for coordinating the regional community college system in the planning and implementation of high quality biotechnician education and training programs, has worked with IDEC in a series of partnered activities. SDCC also hosts the Southwest Regional Center of Bio-Link, a project of the National Science Foundation to develop linkages and facilitate improvement among the nation's community college biotechnician education programs.

In January of 2002, the SCBC invited faculty from all of the community colleges in the San Diego region to a meeting with IDEC personnel to assess existing capacities and identify gaps in the regional delivery system for biotechnician training. Richard Buecheler, SCBC Manager and former President of Hanford Pharmaceuticals in Syracuse, New York, and Mary Schwalen, Manufacturing Training Manager at IDEC, met with the participating college personnel to discuss how the colleges might individually and collectively address the gap in bioproduction education programs that existed in North San Diego County where IDEC's new production facilities were being

built. The only college that had developed and institutionalized such bio-manufacturing programs to date was San Diego City College (SDCC) located in metro San Diego, far from IDEC's north county site. In addition, it soon became clear to all present that few of the community college faculty members had a clear understanding of the technical skill requirements of large-scale bio-pharmaceutical manufacturing operations, or knew how these competencies differed from the skill sets currently being taught to students preparing for employment in biotechnology research and development operations.

## **2. Evolution of the Industry/ Faculty Internship Concept**

In response to this lack of knowledge about bio-manufacturing processes and necessary skill sets, Richard Buecheler, Mary Schwalen, and Joan Stepsis, Dean of Applied Competitive Technologies at San Diego City College, discussed the idea of establishing industry internships for local faculty. A precedent involving a faculty member from Solano College in Northern California who had interned at Genentech Corporation for six weeks, and then subsequently developed an industry responsive bio-manufacturing program at that college, suggested that an internship program conducted inside a bio-pharmaceutical production facility could serve as a major impetus to the development of such programs locally. Out of this discussion came a commitment to further explore the possibility of an internship program at IDEC, and to make every effort to fast-track planning to allow program implementation during the following summer when faculty would most likely be available to participate.

## **3. Program Goals and Objectives for College and Industry Partners**

What emerged from these planning meetings between SDCC and IDEC personnel was a comprehensive set of program goals which served both college and industry partners. The colleges would benefit from the development of new, relevant courses and programs in biotechnology manufacturing; the industry partner would gain access to a new, larger pool of local workforce candidates trained according to the industry's own specifications. The specific objectives were to:

- Give instructors an understanding of the skills required in biotechnology manufacturing and how these differed from research and development skills;
- Develop relationships between college instructors and IDEC staff, to encourage IDEC input on curriculum development and have IDEC staff as guest speakers and visiting instructors in college classes;
- Promote coordination and cooperation among the colleges' programs which relate to the biotechnology field;
- Give instructors an appreciation of how each of their disciplines interrelated with other academic disciplines in the biotechnology manufacturing setting;
- Disseminate the lessons learned to help other colleges and districts develop internships in the industry sector; and
- Promote enthusiasm among students for careers in the biotechnology industry and disseminate information about IDEC employment opportunities.

Achieving these objectives would contribute to the larger program goal of developing

relevant courses and programs in biotechnology manufacturing to meet the needs of the expanding industry.

#### **4. Distinguishing Features**

The internship program had several distinguishing features. The first concerned the expanded scope to include five instructors from three regional community colleges which either had ongoing programs or were planning to train students in the biotechnology field. The objective was not only to expose as wide a cross section of the college community to biotechnology manufacturing as possible, but to educate and promote coordination and cooperation among community colleges, as they developed their programs to serve the needs of the industry.

The second feature of the internship program design was its integrative or multi-disciplinary approach. Traditionally, biotechnology education in community colleges has been biology-based. Yet while biology is the key to biological products per se, other disciplines are integral to the manufacturing process; for example, many of the processes are grounded in the traditional chemistry curriculum. In addition, in the bioproduction setting other disciplines such as manufacturing technology, cleanroom technologies and facilities control, and instrumentation calibration, play critical roles. If the diverse faculty members, often isolated in their respective disciplines, interned together, they could see within the manufacturing process the linkages and interdependence among their specialties.

The third notable feature was that the internship program was to serve as a model or blueprint for industry/ education internships nation-wide. Other community colleges and biotechnology companies throughout the U.S. could build on the experience of the project. This project experience would be disseminated throughout the country to serve the needs and competitiveness of the US biotechnology industry. Finally, the internship program was industry-driven. A true partnership with common goals is evolving between community colleges and the biotechnology industry in San Diego. This strong partnership and the commitment of both parties were key to overcoming a number of obstacles as they arose.

#### **5. Project Costs and Financing**

The objectives of the internship program were consistent with those of Bio-Link. As the Southwest Regional Center for Bio-Link, SDCC applied for funding to pilot the internship program from the Bio-Link National Center at City College of San Francisco. Bio-Link agreed to provide stipends for the participating faculty interns, and to fund program coordination and administration including the expense of preparing and disseminating this monograph. Bio-Link's contribution was matched by IDEC Pharmaceuticals, which provided facilities, equipment, and personnel time to conduct the internship and hosted the final project event for company and community college representatives.

## **CHAPTER THREE: Project Issues, Obstacles and Solutions**

### **1. Issues Encountered by College Project Leader**

The project coordinators encountered a number of issues and obstacles in project planning and implementation that required creative solutions. From the college viewpoint, issues included:

#### **• Selection of colleges and candidates**

The physical proximity of two North San Diego County community colleges to the new IDEC bio-manufacturing plants made these colleges logical candidates for the program. The already established expertise of San Diego City College in small batch bioproduction, automated process control, and cleanroom technologies, coupled with the college's regional coordination role as both the Southwest Regional Center for Bio-Link and the Southern California Biotechnologies Center for ED>Net, made this college an obvious third choice. College administrators were asked to nominate interns to be part of the interdisciplinary team. Their nominees were:

1. Ram Gurumurthy, Ph.D., Assistant Professor of Chemistry at SD City College
2. Roya Lahijani, Ph.D., Assistant Professor of Biology at Palomar College
3. Ric Matthews, former biology instructor at Miramar College and new Dean of Mathematics and Science at MiraCosta College
4. Jerry Lynch, Professor of Environmental Control Systems at SD City College
5. Doug Welch, Professor of Manufacturing Technology at San Diego City College

#### **• Selection of biotechnology company or companies**

IDEC was instrumental in developing the internship program from the start, making company selection a non-issue for this project. For colleges that are seeking a company to partner with, selection criteria would include: the endorsement of senior management, the availability of an enthusiastic and competent project leader in the company, and a suitable corporate culture which would tolerate risk taking and could adapt to the intrusion of outsiders into its daily operations.

#### **• Coordination of instructors' schedules and industry activities**

The timing of the internships was dictated by the availability of the instructors, summer being the optimum time for the group as a whole. IDEC had a strong preference for having the interns come as a group, rather than individually. The three instructors in chemistry and biology were scheduled to spend five weeks at IDEC, for twenty hours per week and attending sessions on Mondays, Wednesdays and Fridays; while the two industrial technology instructors would focus on technology concerns in an eight day program. The two groups would overlap for key sessions. (See program description in Chapter Four, section 2.)

## **2. Obstacles that Arose for the Industry Project Leader**

As IDEC moved to accommodate the new activities set out by the internship plan, several obstacles arose due to the company's established policies and procedures:

- **Confidentiality**

Protecting IDEC's confidentiality requirements was addressed by having its legal department develop special confidentiality agreements which were signed by each instructor. (See Appendix: Document #3.) In addition, managers monitored the access by interns to specific areas and operations.

- **Access to Restricted Areas**

Instructors were given limited access to plant facilities. For example, they were free to walk to the lunchroom, restroom and copy machines, but not to production units unless accompanied by staff.

- **Payment and Compensation**

In the internship offer sent by IDEC to the college instructor's dean (See Appendix: Document # 4), it was clearly stated that instructors were not employees of IDEC and therefore would not be eligible for any compensation or benefits from the company.

- **Safety**

When visiting the plant construction site, personal safety was assured by providing hard hats, an escort, and a safety orientation program. For safety in production areas, the interns received the same safety training given to new IDEC employees.

- **Coordination with ongoing production work**

Ongoing production work took priority over the instructors' visits to specific areas of the plant. This meant that the program was constantly subject to change, as processes which were to be viewed at an appointed time, were delayed, or at the appointed time, production processes closed to observation were being carried out. Constant monitoring by the industry coordinator, liaison with managers, and frequent adjustments to the internship schedule were required. Patience and flexibility by all parties were obviously essential. On one occasion, interns' questions led to an interruption in an operator's concentration while working on a complicated task. Feedback from the affected production unit quickly led to implementation of a remedial plan.

- **'Just in Time' Planning**

IDEC's company culture fit particularly well with the need for flexibility and adaptation to program changes, sometimes on a daily basis. Internship programs in bio-manufacturing companies should anticipate and be sympathetic to impromptu schedule changes given the nature of production work.

- **Staff Time**

The project absorbed more staff time than anticipated due to the need for constant liaison with a number of IDEC production staff about schedule changes. IDEC's project coordinator recommended that a staff person be specially designated to oversee the internship program in the future and that planning should start in fall for the next cycle.

## **CHAPTER FOUR: Guide to Setting Up an Internship Program**

This chapter provides a step-by-step guide to the planning, implementing and evaluating of faculty/industry internship programs and sets out the role and responsibilities of education and industry representatives. Document #2 in the appendix provides a detailed list of the industry procedures for the project.

### **1. Roles & Responsibilities in Planning Industry Internship Programs**

- a) Join and/or work with organizations with industry-wide memberships and perspectives, to stay in touch with current biotechnology industry operations, standards and workforce needs. In the San Diego area this was facilitated through the BIOCUM, the regional industry trade association, and by the Bio-Link network (see Appendix: Document # 7).
- b) Identify a coordinator for the program who can take the lead in giving program direction. In this case the Manager of the Southern California Biotechnologies Center (SCBC) at San Diego City College where the Southwest Regional Center of the Bio-Link network is also based, played the coordinating role among the community colleges, and chaired meetings with college faculty to find gaps in the relevance or content of community college curriculum.
- c) Start the planning process for summer internships in September of the preceding year.
- d) Identify a biotechnology company with a need for educational services or workforce training. Since the San Diego internship project met the needs of a major regional enterprise, company selection was not an issue here. But in general, finding a company that is a good match is critical. Selection criteria include support by senior management for the project, availability of a suitable project leader, and a conducive company culture.
- e) Select and coordinate community colleges, and faculty interns. In this case the SCBC Manager contacted the deans of the selected colleges to seek their support and request nomination of an appropriate internship candidate.
- f) Seek support from management of the biotechnology company. An internal e-mail was sent from the industry program coordinator describing the internship idea, listing the project goals and benefits to the company, and seeking upper management's approval.
- g) Clarify objectives, scope, and timing with instructors and the biotechnology company. With in-principle commitment on both sides, conduct a meeting between education and industry representatives to clarify project design, goals, timing etc.

- h) Arrange project financing. With a clear project outline, parties can approach funding sources. In this case Bio-Link financed the project.
- i) Plan project daily/weekly schedule for interns with industry representatives. With agreement as to the scope and objectives of the program, detailed scheduling and planning is done within the biotechnology company. Relevant section heads are contacted and appointments set up for the internship period.
- j) Formalize arrangements and agreements between community colleges and the biotechnology company. A letter is sent from the biotechnology company to deans of the relevant college departments offering the internship opportunity, setting out the goals and clarifying important issues like confidentiality, payment and workers' compensation (see Appendix: Document #4 for a sample letter). Confidentiality agreements are drawn up by the legal division of the company.

## **2. Implementation, Project Description, and Ongoing Monitoring**

The purpose of the orientation meeting is to go over the schedule, ensure that agreements are signed, clarify mutual responsibilities and address a number of practical issues. In the orientation meeting of the interns at IDEC on July 15, it was agreed that the three instructors in biology and chemistry would intern for five weeks, for twenty-hours each week on Mondays, Wednesdays, and Fridays. The two technology instructors, who required a shorter internship which focused on the technology used by IDEC in their new manufacturing facility, would intern for eight days. The two groups would overlap for key sessions including the IDEC New Hire Orientation Program and the visit to the construction site in Oceanside.

Other topics covered at the orientation meeting included the signing by all instructors of confidentiality agreements, overview of the rules for being escorted, note taking and photocopying based on confidentiality agreements, parking, lunchrooms etc. An outline of the program schedule was discussed with the understanding that it would be dynamic and closely coordinated with ongoing production schedules. (See Appendix: Document # 5 for a sample of the program schedule).

### **Responsibilities of Interns: Keeping the focus: Instructors' journals**

Keeping instructors focused on why they were there, and providing adequate documentation to aid in evaluation and accountability were important considerations in the project design. Each instructor was required to keep a journal to describe his/her experiences (See Appendix: Document #6 for sample excerpts) and was asked to address three questions daily:

- What have I learned today that is new to me?
- What have I seen that is familiar?
- How will I use this information at my own college, either in curriculum development, or in the students' direct experience in lectures, laboratory experiments or otherwise?

In addition, interns were asked to summarize what they had learned from the internship experience at IDEC, and how this would be incorporated in their teaching, at a final presentation meeting at the end of their internship experience.

### **Program Description**

The specifics of the interns' daily schedules flow from the project goals and objectives. In this case, IDEC sought to expose instructors to every step in the production of monoclonal antibodies, from cell banking through to safety elements. The program sought to give interns an understanding of:

- working under FDA regulations and cGMP (current good manufacturing practices)
- working in a cleanroom environment and gowning procedures
- validation processes
- equipment maintenance and calibration
- functions of quality control group
- functions of quality assurance group
- buffer and media preparation
- mammalian cell culture
- protein purification, concentration, and formulation
- job descriptions, interview processes, the performance review process, and the skill sets needed by IDEC

The following sample schedule gives an idea of a typical day for the interns at IDEC:

<b>Time</b>	<b>Activity</b>
9:00 - 10:30	Overview of cGMP -Good Manufacturing and Documentation Practices
10:45 - 12:00	Job descriptions, performance review, career path, training overview
12:00 - 1:00	Lunch
1:00 - 3:00	Gowning Training
3:00 - 5:00	Cell Culture and purification processes overview

The two industrial technology instructors focused on the new automation, environmental and process control technologies at NIMO (New IDEC Manufacturing Operation) and NICO (New IDEC Clinical Operation), and IDEC staff put them in touch with equipment vendors who might donate equipment to the college programs.

All of the interns were invited to attend IDEC's new hire training program for manufacturing employees. This exposed the instructors to the history of the company, its code of conduct, and core values. The importance of developing "soft skills" for effective team interaction, meeting and e-mail etiquette, and taking responsibility to ensure quality, was emphasized.

### **Ongoing monitoring**

Ongoing monitoring during the course of the internship was important for troubleshooting purposes, and to enable intervention by project coordinators if issues arose.

The college program coordinator met weekly with the interns to evaluate the progress of the project, including their personal journals, and to work with any concerns or requests that they might have. On the IDEC side, the industry coordinator maintained daily contact with the interns overseeing the program that was constantly adjusted to the needs of the production areas. The industry coordinator also sent e-mails to director-level staff to request feedback on the internship program and its impact on specific workstations. With this degree of careful attention, issues were readily addressed, and settled, as they arose.

### **3. Final Presentation Meeting, Evaluation and Follow-Up**

A final presentation meeting served several important purposes. First, it disciplined the faculty interns to concisely communicate what they learned and how they would apply these lessons in their role as college instructors. Second, it provided the forum to bring senior level administrators from participating colleges, to encourage institutional support for implementing the instructors' recommendations that would flow from the project. Funding agency representatives and IDEC management were also invited to review the project and participate in planning future steps. And last, media coverage was encouraged, to advertise the college-industry internship programs, community college courses in biotechnology, and careers in this new field.

#### **Evaluation and Follow-Up Meeting**

A final meeting of the project coordinators and interns, held after the presentations and chaired by the college coordinator was an important final step in evaluating the project and determining follow-up action. Several points were discussed:

- Were the project goals met and how will the project outcomes be quantified?
- How will this experience change college curricula?
- What is the ability and the timeframe for the colleges to implement these changes?
- Would IDEC consider repeating the program in future years?
- What should be done differently in future internship programs?
- What is the follow-up action?

### **4. Measuring Medium and Long Term Goals**

The importance of setting up clear markers to measure the medium and longer-term impact of the project was highlighted in these discussions. The college and industry partners agreed to meet each six months to evaluate specifically:

- the number and type of curriculum changes made in existing instructional programs
- the progress on developing new curriculum and facilities for programs in biotechnology manufacturing
- the number of community college students referred to, interviewed by and hired by IDEC
- the effectiveness of the collaboration among colleges in developing their distinct areas of expertise in biotech manufacturing programs

# **CHAPTER FIVE: Program Outcomes and Benefits**

## **1. Program Outcomes**

All participants agreed that the program outcomes exceeded expectations. Every specified short-term goal was achieved, and additional ones recognized during the project were reached as well.

### **Appreciation for how biotechnology product manufacturing differs from R &D:**

From the internship at IDEC, the instructors developed an appreciation for how large-scale manufacturing of biotechnology products differs from the R & D phase of operations. Biology instructor Roya Lahijani's years of experience working as a research scientist in pharmaceutical companies prior to accepting her current position in academia, meant she was well qualified to see the differences. "When you're doing R & D on the bench top, as hard as it is, with the 80% failure rate, you can't even imagine how much more difficult this would be on a large scale under scrutiny of the FDA, and knowing you are going to be injecting this into people...it just magnifies on a logarithmic scale and that was impressive to see," said this biology professor.

Former Biology instructor Ric Matthews drew upon his years in research laboratories and noted the stringency of FDA requirements for project documentation which differed from R & D. "What impressed me most was seeing the FDA rules and regulations for precision and documentation...in research the documentation is different...in this case it is a team approach."

The interns developed a respect for the scale, complexity, and intricacy of the production process and came to see how this would impact the development of appropriate courses and programs. Technology instructor Doug Welch was impressed by the level of detail required to manage a project of this size. "What a project! Intellectually I knew the basic idea of project management but to see a project of this magnitude in action was an eye-opener. The Gantt chart for the project covers both walls of a long corridor, and it is written in small type. The massive amount of detailed drawings is impressive and it is only the start."

Roya Lahijani was similarly struck by the scale of the operations. Observing the fermenters at IDEC's Oceanside facilities, the biology instructor admitted she felt like "an ant standing in front of Mount Everest." And while she has had ample experience with media and buffer preparation in R & D settings, she was very impressed by the manufacturing operations. "Until you see the manufacturing operations," she said, "you can't understand what it takes to make these large-scale media and buffers under clinical conditions and FDA guidelines. It's just phenomenal!"

“The level, complexity and depth of the SOPs surprised me”, noted Doug Welch. “I will have to include variability and percentage of uncertainty in the class. The accuracy level at IDEC is much higher than other industries, and this is information that I need if I am to be successful with this next class in terms of biotech.”

The instructors also came to understand the challenges of the physical environment, of working under cGMP guidelines in clean room conditions. A true appreciation of the manufacturing environment could only be gleaned by being there and experiencing the full gowning procedures. “I was aware of GMP conditions,” said Roya Lahijani, “but I had never worked under such conditions, where it was very stringent. The first time I had to suit up [in aseptic gowns] the thought going through my mind was ‘this is an experience I need to relate to my students’...I had never done it, so I didn’t have a full appreciation of it. Until you do, you never know.”

Doug Welch also developed a new appreciation for cGMP and found the internship experience gave him the confidence to incorporate current industry practice in his college courses. “GMP has been a mystery to me and this session cleared up many of my questions,” said the instructor. “I honestly believe that now I can teach the subject...With the wealth of information we obtained, I can now finish my course outline on documentation.”

### **Understanding the skill requirements for biotechnicians in manufacturing:**

The interns found the face-to-face contact with IDEC managers invaluable for developing an understanding of the precise skills needed in bio-manufacturing, which can increase their credibility among their peers in the community college curriculum review process. “If we can see exactly what it is they need, if we can talk to the people and have them tell us exactly what they are looking for,” explained Dr Lahijani, “then we can write a curriculum specifically for their needs rather than write something generic...then [in faculty curriculum review committees] you can quote them...and that carries credibility.”

IDEC managers were able to explain exactly how and where current programs fell short of their requirements. “All the managers told me what qualities were lacking [in their new employees], what qualities they are looking for...and we will develop courses with that in mind. What are the students missing? What is it that they didn’t get in their formal education so that we can emphasize that and prepare them for the job they’re going to have at the end of line”, said Lahijani.

The technology instructors gained very specific information on what should and should not be taught in their courses to equip students for jobs in biotechnology manufacturing. “Based upon the methods that must be used to monitor and calibrate field devices, I can see that the technicians should have ample computing skills since this will be their primary troubleshooting and calibration tool,” noted Welch.

### **Developing mentoring relationships with IDEC staff:**

Developing strong relationships with IDEC staff was a major project goal and all the interns came away from the internship with several professional contacts in IDEC whom they could call upon for advice with facilities and curriculum development, and ask to come as guest speakers/visiting instructors to community college classrooms. “The IDEC experience has provided significant benefits in the form of collaborative contacts with IDEC staff,” said Jerry Lynch. “This will help immensely in the development of our curriculum and labs.”

Doug Welch explained that industry contacts are critical in the technical education field where technology is constantly changing. “If you’re not cognizant of those changes you get behind,” said the instructor. “You have to stay current in your field. We formed relationships with people who maintain the plant, who do the calibration ...to make sure what we’re teaching is relevant and is what students need to know.”

The value of this internship experience to the community college instructors will persist well beyond their summer visit. “Everyone was interested in being involved with this beyond the scope of the internship,” said Ric Matthews who is drawing heavily from his experiences with IDEC in drafting the proposed new course curriculum for biotechnology manufacturing technicians at MiraCosta College. “If I had a question with plant layout a month later, I feel they’d be receptive to hearing from me.”

All the interns agreed that these relationships with industry personnel were highly beneficial and benefited students in a variety of ways. For example, instructors could establish credibility for their programs and institutions, and recommend their students to industry contacts for jobs. “We’re there to form relationships, to let the company see us (i.e. evaluate the trainers)...I [also] now have people over there, so I can say [about my student], ‘Jo Blow here is the best I’ve seen,’” said Welch.

### **Developing relationships with each other, among academic disciplines, and among regional community colleges:**

Instructors developed a new appreciation of the relationship between their disciplines and saw how physics, biology, and chemistry combined in the biotech manufacturing setting. “We all were real interested in learning from each other,” said Ric Matthews. “We were as good listeners as we were talkers.”

During many discussions the interns came to appreciate the role of basic science education in the bio-manufacturing setting and how they might carry this knowledge into the classroom. Ram Gurumurthy noted: “Asking students why cell culture fluid is maintained under regular conditions in a bioreactor- from a biology perspective, the answer is we want the cells to grow, from a chemistry viewpoint, we are dealing with protein molecules, with protein stability; until now I have never had a good example to use when I teach them chemistry principles like reverse osmosis.” (Ram Gurumurthy)

The interns also became familiar with courses and specializations of their respective colleges and discussed how their programs might be coordinated to suit the needs of the industry. “I really enjoyed the interaction among the participants...I could discuss the role of the colleges [in biotechnology education] with Ric Matthews,” said Roya Lahijani. Ric Matthews concurred. “[The internship] opened tremendous doors to dialogue between representatives of various colleges, it’s a step in the right direction, and the forum for communication, the dialogue has made a bridge.”

In addition, the technical instructors were enthusiastic to interact with the academic instructors. “We instructors need overlap in our knowledge,” said Doug Welch. “I benefit by learning about the procedures to design the product and the academic instructors learn about the procedures to manufacture the product.” They also came to appreciate how critical both equipment maintenance and calibration are to the whole operation. “The equipment/maintenance overview indicated the critical nature of instrumentation and calibration to the entire process,” noted Jerry Lynch. “There is an interesting relationship of the actual equipment and instruments in the process, being part of the process with respect to the FDA license to manufacture a particular pharmaceutical.”

### **Developing ways to incorporate lessons learned into ongoing and future curriculum development efforts:**

The interns were asked to focus on specific ways to incorporate what they learned into current and future college courses. Each instructor emerged with creative ways they would implement this in the classroom. Jerry Lynch saw what was missing in the present course content and how to respond to the bio-manufacturing industry’s needs:

“It is clear from our experience at IDEC that there are a significant number of omissions and changes to curricula and lab operations that need to be accomplished, for example:

- a) inclusion of maintenance and working constraints of the aseptic clean room environments
- b) concepts of cGMPs (current good manufacturing practices), SOPs (standard operating procedures), government oversight regulations and quality assurance
- c) automated control using various protocols and bus structures such as “Field Bus”
- d) maintenance calibration and statistical control methods for instrumentation...”

Ram Gurumurthy discovered there were useful ways to incorporate what he learned during his five-week internship into his ongoing courses at the college. “The concepts of incorporation of radioactive isotopes and how antibodies bind to the surface of specific cells is interesting. I would like to use these ideas when I teach topics such as radioactivity, enzyme action, and drug synthesis,” said the professor. He also found ways to modify ongoing courses to make them more relevant to the needs of the biotech industry. “We need to stress more proper ways of recording measurements , we can fine tune our wording, and proper ways to make corrections, and pay more

attention to the importance of rounding-off rules...we have to teach good techniques for use of instruments...the precision and detection limits of the instrument itself is crucial here to meet FDA regulations.”

From an administrative viewpoint, Ric Matthews, in his role in developing new programs in bioproduction at MiraCosta College in Oceanside, found what he learned during the internship was indispensable: “The experience was invaluable...to understand the job skills they need to have, then to come back and translate these into curriculum and look at that curriculum and say what we need in terms of space and equipment to support that curriculum, it was invaluable...it would have been hard to do that without having access to bio-manufacturing companies to see what the reality is versus what the perception is, based on literature or conversation.”

### **Spin-off effects for other community college programs:**

The college instructors found that they emerged from the internship experience with new knowledge and tools that could be applied in other college courses and programs. “Interestingly many of the concepts and specific approaches we covered at IDEC used in this industry will transfer to other areas of our curricula and lead to more competent and more professional graduates in other industries,” said Jerry Lynch. “As an example in my own program in the field of general environmental control systems, the statements of good practices for particular tasks has never been developed and documentation has never been formulated very well. We hope to use many of the approaches used in this industry to rectify this.”

Instructors also saw the desirability of incorporating IDEC’s core values and competencies in community college students. “IDEC’s core values fascinated me,” said Ram Gurumurthy. “What they expect of employees we would like to instill in our students also...integrity, perseverance, peer relationships, learning on the fly...we can incorporate and monitor this in our lab curriculum without any difficulty.”

## **2. Immediate Application by Instructors**

Since the IDEC internship, instructors have reported immediate application of what they learned. They came away with a lot more from the IDEC experience than an understanding of the technical requirements of the manufacturing workforce. The interns were particularly struck by IDEC’s core values and the emphasis on soft skills, and have already applied some of these concepts in their course instruction (See Appendix: Document #1.):

- At San Diego City College Doug Welch has incorporated IDEC procedures for executing operations through SOPs (standard operating procedures) in several courses, including Blueprint Reading, Electronics and Electricity, and Manufacturing Processes.

- “[While at IDEC] I got a whole new appreciation of the value of the SOP and how they might be implemented in the classroom, how they might become the nucleus of a course of instruction that would have both structure, and at the same time require a thorough understanding of the theory behind the particular task involved.” This not only familiarizes students with following SOPs, a requirement in many industry jobs they would be seeking, but also encourages core values like initiative, responsibility, adaptability, accountability and creativity.
- Welch said: “What impressed me most about IDEC was their code of conduct, core competencies. IDEC values teamwork, being able to learn and adapt to strange situations, being able to think on your feet and get things done. I really want that kind of environment for my students. One of my core concepts is to use your head before you use your hands. IDEC encourages employees to contribute ideas and come up with innovative solutions to problems. I want that kind of environment for my students.”
- Roya Lahijani at Palomar College has also used the experience at IDEC in the demonstration of the importance of “soft skills” to her students. Her students have been more attentive when she related real life experience in a biotechnology company in San Diego. “I think when you tell students, ‘this is something I saw, this is something I participated in’, the students have a lot more respect for it, they take it a lot more seriously,” said Lahijani, who has described some of the expectations of IDEC in soft skills like presentation, neatness and legibility in completing documentation to her students. “I told them ‘This summer I had an internship at a pharmaceutical company here in town and this is what they told us they are looking for in their future employees and these are the important things’”, said Lahijani “It grabs them, it grabs their attention because its a specific example and not just a generalization.”

### **3. Additional Benefits of the Project**

Besides the immediate and inventive applications of the internship experience detailed above, the program has projected additional benefits on several levels. IDEC anticipates a significant reduction in costs simply by being able to hire well-trained people locally. With the anticipated increase in preparedness among college-trained candidates, the currently imposing learning curve for new recruits to the company will be markedly diminished. Taken as a whole, the project is seen as an important piece of an evolving cooperative effort between community colleges and the biotechnology industry to build a highly-skilled biotechnology manufacturing workforce, in the interests of good jobs for college graduates, the continued vibrancy of this new industry locally, regionally and nationally, and ultimately in stimulating US global competitiveness in this cutting-edge field.

# **CHAPTER SIX: Blueprint for Success**

## **1. Mutual Benefits and Institutional Commitment**

The project leaders identified a number of lessons learned that were critical to the success of the internship programs and underlined the importance of:

### **Clear mutual benefits**

In order to justify the substantive input involved, each of the parties must see clear returns on their investment. Given the dearth of qualified technicians nation-wide, IDEC was highly motivated to build a pool of local candidates to staff their expansion into manufacturing. At the same time, college administrators and faculty were keen to achieve academic excellence in the form of relevant training to meet the needs of the marketplace.

### **Institutional Commitment**

High level endorsement in both industry and college sectors was a critical factor in surmounting obstacles to project implementation. In industry enthusiasm for the project was not limited to IDEC management, but included a large cross-section of employees. Many staff members asked to meet with the visitors and there was great excitement when former students re-encountered their college instructors and took the opportunity to demonstrate their skills on the job. At the colleges, support from the deans was essential in the selection of faculty and in securing financial backing for the project.

## **2. Project Coordinators, Interns, the Company and the Administration**

### **Passion of the Project Coordinators**

Both the college and industry coordinators felt passionate about the project and believed they would make it happen. Their creativity, dedication, and willingness to go the extra mile laid the groundwork for success.

### **Credibility of the Project Coordinators**

It was clear that negotiations with industry were streamlined by the fact that the college coordinator had significant prior experience in the bio-pharmaceutical manufacturing industry. He was thus able to empathize with industry representatives, and to provide reassurance that their concerns would be understood, respected and transmitted accurately.

### **Personal Qualities of the Interns**

All interns were highly motivated. They were devoted to providing relevant up-to-date instruction to their students and were prepared to sacrifice their summer free time in this pursuit. Cooperation among instructors was a significant factor in project success. Interns spent a great deal of time together in fairly close quarters, often with unplanned lulls in the schedule. This required flexibility and adaptability to constant changes in

plans. The individual instructors brought an open spirit of inquiry and willingness to learn from each other. Credit for the synergy that developed in the group goes to the enthusiasm, dedication and personal integrity of its members.

### **Company Culture**

Company culture was a significant factor in project effectiveness. Fostered as IDEC's core values, "perseverance", "risk-taking", "learning on the fly" and "just-in-time planning" were experienced directly as vital elements in project progress.

### **Initiative and Responsiveness by Administration and Funding Source**

The internship idea was first discussed in March/April of 2002 for a June/July start date. This meant a quick response by project administrators, the initiative of college administration, in particular Dean Joan Stepsis who secured project financing, and the responsiveness of Bio-Link in recognizing the value of the project and expediting project approval.

## **3. A Spirit of Partnership**

Strong links with industry are essential to developing an internship program. These links can be built on an individual basis or through organizations like BIOCUM or Bio-Link. (See Appendix: Document # 7.) The project went well because of excellent working relationships between industry and college representatives. There was and is a strong sense of partnership with a shared common goal. Richard Buecheler sums it up well: "The project was a rare combination of [industry and education] being responsive and intending to serve each other, while keeping the larger picture in mind."

This monograph is one of a series being prepared by the Southwest Regional Center of Bio-Link for national dissemination. The series focuses on the documentation of innovative, successfully implemented, instructor development programs performed as special projects by the Southwest Regional Center. These projects are intended to demonstrate effective transferable models designed to improve the preparation of instructors to staff biotechnician education and training programs at the nation's community and technical colleges.

The first monograph in the series documented an innovative instructor training program that utilized community college classrooms as living laboratories to prepare biotechnology industry personnel to serve as effective visiting, adjunct, and/or full time instructors in biotechnician education programs.

This monograph is the second in the series and documents a successfully implemented multi-disciplinary / multi-college industry internship program conducted at a bio-pharmaceutical manufacturing company for faculty currently developing and/or operating biotechnician education programs.

For additional information about these projects and related training opportunities, contact Bio-Link's Southwest Regional Center @ 619-388-3081, or e-mail Richard Buecheler: [rbuecheler@cact-sd.org](mailto:rbuecheler@cact-sd.org) Herald Kane: [hkane@sdccd.net](mailto:hkane@sdccd.net) or Joan Stepsis: [jstepsis@cact-sd.org](mailto:jstepsis@cact-sd.org) or connect with us through our link on the Bio-Link website at [www.bio-link.org](http://www.bio-link.org) .

# MANAGING INDUSTRY INTERNSHIPS FOR FACULTY IN COMMUNITY COLLEGE BIOTECHNICIAN EDUCATION PROGRAMS

## 2003 EPILOGUE

### Introduction

In the summer of 2002, five community college faculty members from three community colleges in San Diego County participated in a five-week internship at IDEC Pharmaceuticals, Inc. IDEC, a major biotechnology company in southern California, is pioneering the way into biotechnology manufacturing in the region with the construction of two manufacturing plants in the City of Oceanside in Northern San Diego County. The five-week internship program was designed to familiarize community college faculty previously focused on training biotechnicians for research and development positions in the industry, with the training needs of employees involved in the manufacture of biotechnology industry products. IDEC management projects that the company will need between 500 and 700 skilled workers for their manufacturing operations in 2004-2005.

At the completion of the internship program, a report entitled *Managing Industry Internships for Faculty in Community College Biotechnician Education Programs* was produced by the Southwest Regional Center of Bio-Link at San Diego City College (SDCC). This document provided a blueprint on how to manage community college faculty internship programs in the biotechnology industry and outlined the immediate project outcomes and benefits. This epilogue to that report is based on detailed follow-up interviews with project participants and reports the longer term regional impact of the project as of December 2003.

In spite of budget reductions and resulting program terminations/consolidations in community college biotechnician education programs in the region in 2002-2003, the internship project had a substantial positive impact on biotechnology course and program development, on regional coordination and specialization among the region's community colleges, and on coordination between the colleges and the biotechnology industry. It also had significant outcomes of a broader application to community college program relevance and the efficient delivery of education for biotechnician training at state and national levels thereby contributing to increasing U.S. global competitiveness in the biotechnology field.

## **1. Course and Program Development and Implementation**

### **Biotechnology Manufacturing Certificate Program at MiraCosta College**

On the basis of the experience gained during the IDEC internship, Ric Matthews, Dean of Mathematics and Science at MiraCosta College, designed and obtained approval for a new certificate program for Biotechnology Manufacturing Operators in 2003. The college's curriculum committee approved two new courses developed in consultation with IDEC employees: Business and Regulatory Practices in Biotechnology (BTEC 120) and Bioprocessing (BTEC 220). This program, due to begin in Fall 2004, is the first of its kind in the region and resulted from Matthews experience during the summer internship at IDEC. Matthews said, "I don't think any of this [Biotech manufacturing program and industry/community support for the training facility] would have happened if we hadn't had IDEC open up [its] doors through the internship."

### **Biotechnology Feeder Course at Palomar College**

During her interviews with IDEC management and staff, intern Roya Lahijani, Assistant Professor of Biology at Palomar College, discovered that the performance of new employees at IDEC was impeded by their lack of knowledge of the fundamental principles of biology, chemistry, mathematics, and microbiology as they relate to the biotechnology industry. With this in mind, Lahijani designed a biotechnology preparatory course to provide this basic knowledge and to act as a feeder program for students entering the certificate program at MiraCosta College. Lahijani obtained approval for her Biotechnology Preparatory Course (Biology 160) from the college's curriculum committee and subsequently enrolled twenty-six students in the course for the Fall semester of 2003. In preparing the course outline, she worked closely with fellow intern Ric Matthews at MiraCosta College and with IDEC employees to ensure that the course would be relevant to both the MiraCosta program and to needs of industry. IDEC employees then participated as guest lecturers in the Fall semester course. Lahijani confirmed the importance of the internship to the whole process. "Based on the information I gathered during the internship I developed a course called Biotechnology Preparatory Course. What I have incorporated in this course is based on those interviews [at IDEC]."

### **Biotechnology-related Curriculum Materials Added to Industrial Water Quality Program at Palomar College**

In the context of the close working relationship developed between IDEC and Palomar College employees during the internship, the curriculum committee at Palomar College approved another new biotechnology-related course in industrial water quality in 2003. The course, suitable for biotechnology product manufacturing as well as other manufacturing industries, grew from the rapport established during the summer internship program. Mary Schwalen, IDEC training manager confirmed the linkage with the internship: "As an offshoot of the internship, [we worked with] Palomar College to develop a new Industrial Water Quality program, modifying the ongoing water quality program for companies in the pharmaceutical and food industries."

### **Career Focus and Industry Links Introduced into Traditional Academic Chemistry Courses at San Diego City College**

During his internship, chemistry professor Ram Gurusurthy developed a new appreciation of the role of chemical processes in the manufacture of biotechnology products and saw the need to alert students to the employment opportunities in the industry. Stimulated by his exposure, his department is seeking further financial support to develop more partnering opportunities with biotechnology companies. Following his internship experience, Gurusurthy arranged industry tours for his students and drew on his new contacts with industry to successfully place one of his students in an internship with a biotechnology company in San Diego. This internship opportunity led to a job offer from the company for the chemistry graduate and opened up the perspective of the chemistry department as to its potential role in promoting job placements for its students. Herald Kane, Chair of the Chemistry Department at City College, commented on the broadening of the perspective of his department as a result of the exposure to industry during the IDEC internship: "We experienced a sense of being locked into the strictly academic side of preparing students [thinking] they would all go on to a four year [college] experience [and major] in organic chemistry. [We now understand] that jobs are an alternative and that [failure to perceive this] had been a deficiency in the preparation of our students."

### **A New Course in Advanced Environmental Control Systems with a Focus on Bio-production Facilities Was Developed at San Diego City College**

In addition to modifying existing courses in environmental systems control immediately after the internship, intern and SDCC instructor Jerry Lynch designed a new course--Advanced Control Systems for Environmental & Process Control for technicians in manufacturing--that drew upon what he had learned at IDEC. Professor Lynch is further calling on his contacts with IDEC staff made during the internship to prepare a video to promote careers in environmental systems control and cleanroom technologies.

### **New and Modified Curriculum Components in Industrial Automation and Equipment Maintenance for the Bio-Pharmaceutical Industry Were Piloted at San Diego City College**

Based on his internship experience, Doug Welch, Professor of Manufacturing Technology at SDCC, modified existing course materials and produced new course outlines for biotechnology-related courses in industrial automation and equipment maintenance for incorporation into the existing manufacturing technology program at City College. These developments included new and or modified course outlines in engineering documentation and communication; technical metrology (science of measurement); calibration and maintenance of biotechnology manufacturing equipment and systems; and biotechnology manufacturing processes associated with growing cells, purification, quality assurance, and product packaging.

## **2. Regional Coordination and Community College Specialization**

### **Partnership Between Community Colleges and Industry**

The internship provided the opportunity to deepen the partnership between the community colleges and industry that had been developed in the region by project staff at San Diego City College including Richard Buecheler, Manager, Southern California Biotechnologies Center (SCBC), Herald Kane, Co-Director of Bio-Link's Southwest Regional Center, and Joan Stepsis, Dean, Applied Competitive Technologies, and Director of the SCBC and Bio-Link's Southwest Regional Center. While the interns learned about the training needs of employees in biotechnology product manufacturing, IDEC staff developed a vested interest in working with community college professionals to help design effective college courses and programs to meet industry needs. IDEC employees now routinely contact their training manager before discarding unused or obsolete equipment and materials to see if these might be of interest to regional community colleges; IDEC employees attend career days hosted by the colleges, participate as guest lecturers in college courses, and provide ongoing advice on curriculum development and state-of-the-art technology. Furthermore, through contacts made during the five-week program, Dean Ric Matthews has drawn on the expertise of IDEC contractors from the Oceanside construction sites, who have contributed design services and equipment for the training facility at MiraCosta College for the manufacturing operators certificate program.

### **Coordination & Cooperation Among Community Colleges in Biotechnician Education**

Built into the internship program designed by Buecheler, Kane, and Stepsis was the goal of strengthening coordination and avoiding unnecessary duplication of effort between and among community colleges involved in biotechnician education and training in the region. The project proved highly effective in breaking down barriers to a cooperative effort among the community colleges: "For the first time, [we had] a collaboration, rather than a competitive or adversarial relationship to demonstrate to our administration," said Lahijani, echoing the sentiments of all the interns. In March 2003, and given declining budgets throughout the community college system in California, Buecheler hosted a mini-conference at SDCC for faculty from regional community colleges involved in biotechnician education. This meeting was designed to assist each of the colleges to choose areas of specialization that in the face of declining funding would never-the-less ensure a coordinated and comprehensive response to the needs of the biotechnology industry on a regional basis. Based on this effort and its outcome, a single brochure on biotechnology training opportunities at the various community colleges throughout the region was produced by Ric Matthews of MiraCosta College utilizing a mini-grant obtained from a regional community college coordinating agency.

Herald Kane, Co-director of the Bio-Link Southwest regional center at SDCC, commented on the significance of this improved coordination for the cost effectiveness of community college education: "Because of our IDEC involvement we saw the first shadow or premonition of something much bigger, a potential opening into regional cooperation in which it is not incumbent on any one college to put in lots of money to

create a [comprehensive] program.... [The internship] provided an opening or threshold experience into regional cooperation in which different colleges might provide [specialized components] of the total educational experience of students thereby allowing students to be “regionally trained.””

### **3. State and National Impact**

#### **Statewide & National Dissemination of a Blueprint for Faculty Internships in the Biotechnology Industry**

With the production and the dissemination of this report through the National Science Foundation’s Bio-Link ATE Center and through the California Community Colleges Economic and Workforce Development network, educators and industry personnel throughout California and across the nation now have access to a proven methodology on how to effectively manage faculty internships in the biotechnology industry based on the lessons learned in the Southwest Region.

#### **National Dissemination of a New Teaching Methodology for Industrial Education**

Following his exposure to the Standard Operating Procedures (SOPs) used by IDEC for all their manufacturing processes, SDCC’s Professor Welch envisioned that SOPs could be an effective instructional method for industrial education courses: They could teach the subject, teach students how to follow the procedures they would encounter in jobs in manufacturing, develop documentation skills, and foster qualities such as initiative, self-discipline, and creative problem-solving. In his courses during the Fall and Spring semesters of 2002-2003, Welch used and refined the SOP teaching methodology. He then further tested his technique on the participants in another NSF funded ATE project, the Rapid Prototyping Workshop for industrial technology instructors held at SDCC in the summer of 2002 (DUE-0302314). More than thirty community college instructors from across the nation responded favorably to the concept during the workshop and have subsequently reported their positive experiences in using this SOP approach in their classrooms.

IDEC training manager Mary Schwalen commented on industry’s likely reaction to using this approach to train students: “SOPs are applicable to many industries,” she said, “it would be an exceptional thing for someone to have [documentation of this type of experience] in [his/her] portfolio for a job interview.” Welch’s initiative sprang from his internship experience at IDEC: “There would have been no thought in my mind to use SOPs as a teaching method if it hadn’t been for that internship,” he said. Details of the SOP approach and Welch’s experiences in field-testing it are available through another monograph being distributed through Bio-Link and through the California Community Colleges Economic and Workforce Development program. (See below for reference information and contacts.)

## Summary

Despite the adverse financial environment for community college education in 2002-2003, the internship program had a substantial impact on developing effective biotechnician education programs in the San Diego area region: A new biotechnician education certificate program was developed and approved; a feeder course for this program was developed, approved, and conducted; curricula for courses in facilities and equipment maintenance necessary to support the industry were created, recorded, and made available for national distribution; a new industrial education teaching methodology with application to a growing number of manufacturing industries in the United States was developed, tested, and disseminated; community college cooperation promoted in the internship program design became the basis for efficient and coordinated biotechnician program planning in the region; and the partnership between biotechnician educators and biotechnology industry personnel strengthened and deepened.

The impact of the project was reflected in Schwalen's final comments on the internship program's success in the context of IDEC's recent merger with BIOGEN, a biotechnology company based on the nation's east coast: "Because we're merging with BIOGEN, which has a well established community college curriculum and biotech program of instruction, we're capable of showing now that we [on the west coast] are doing something comparable in Southern California. It puts us on an equal footing with BIOGEN in relation to preparation of the workforce."

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This internship report and epilogue is part of a series prepared by the Southwest Regional Center of Bio-Link at San Diego City College to promote biotechnician education both regionally and nationally. The other two monographs entitled *Training Industry Personnel as Instructors for Community College Biotechnician Programs: The Industry Instructor Practicum Model*, and *Educating Industrial Maintenance Technicians for the Bio-Pharmaceutical Industry* are also available as electronic copies through Bio-Link's National Center at City College of San Francisco at [www.bio-link.org](http://www.bio-link.org) and through the California Community Colleges Economic & Workforce Development Program's Biotechnology Initiative Program at [www.cccewd.net](http://www.cccewd.net), or more directly via Initiative Director Mary Pat Huxley at [mphuxley@vcccd.net](mailto:mphuxley@vcccd.net).

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## **APPENDIX TO THE MONOGRAPH: Documents 1- 7**

### **Developing and Managing Industry Internships for Faculty in Community College Biotechnician Education Programs:**

#### **Sample Documents**

**Document #1: IDEC Pharmaceuticals & Statement of Company Core Values: page 28**

**Document #2: Summary of Biotech Company's Internal Procedures: page 29**

**Document #3: Sample Confidentiality Agreement between Biotech Company and Faculty Intern: page 30**

**Document #4: Sample Letter from Biotech Company to College Deans Offering the Internship: page 31**

**Document #5: Sample Internship Program Schedule: page 32**

**Document #6: Extract Displaying Format of Instructor Journals: page 33**

**Document #7: Contact Details for Bio-Link Regional Centers: page 34**

# Document #1: IDEC Pharmaceuticals & Statement of Company Core Values

## IDEC Pharmaceuticals

IDEC Pharmaceuticals, located in San Diego California, is a Bio-Pharmaceutical company that is making the transition from research and development to manufacturing. The company has received FDA approval for two monoclonal antibody based medications for the treatment of non-Hodgkins lymphoma. IDEC is currently constructing manufacturing facilities in northern San Diego County for the production of these anti-cancer products.

IDEC credits much of its success to strict adherence to specific corporate core values and competencies.

## Statement of Company Core Values and Competencies



*IDEC Core Competencies are behaviors that demonstrate our Core Values. A person who demonstrates these behaviors is living our company values. A person who lives our values . . .*

### **Has integrity and is trusted**

Is widely trusted; is seen as a direct, truthful individual; can present the unvarnished truth in an appropriate and helpful manner; keeps confidences; admits mistakes; doesn't misrepresent him/herself for personal gain.

### **Perseveres**

Pursues everything with energy, drive, and a need to finish; seldom gives up before finishing, especially in the face of resistance or setbacks.

### **Uses Creativity**

Comes up with a lot of new and unique ideas; easily makes the connection among previously unrelated notions; tends to be seen as original and adds value to brainstorming.

### **Develops effective peer relationships**

Quickly finds common ground and solves problems for the good of all; represents his/her own interests and yet is fair to other groups; solves problems with peers with a minimum of noise; is seen as a team player and is cooperative; easily gains trust and support of peers; encourages collaboration; and is candid with peers.

### **Learns on the fly**

Learns quickly when facing new problems; is a relentless and versatile learner; is open to change; analyzes both successes and failures for clues to improvement; experiments and will try anything to find solutions; enjoys the challenge of unfamiliar tasks; quickly grasps the essence and the underlying structure of most topics.

## **core competencies**

*A manager living our values. . .*

### **Shows managerial courage**

Doesn't hold back anything that needs to be said; provides current, direct, complete, and "actionable" positive and corrective feedback to others; lets people know where they stand; takes negative action when necessary.

### **Motivates others**

Creates a climate in which people want to do their best; motivates individuals and team or project members; assesses each person's hot button and uses it to get the best out of him/her; pushes tasks and decisions down; empowers others; invites input from each person and shares ownership and visibility; makes each individual feel his/her work is important; is someone people like working for and with.

### **Manages innovations**

Is good at bringing the creative ideas of others to market; has good judgement about which creative ideas and suggestions will work; promotes the creative process of others; facilitates effective brainstorming; projects how potential ideas may play out in the marketplace.

### **Builds effective teams**

Blends people into teams when needed; creates strong morale and spirit in his/her team; shares wins and successes; fosters open dialogue; lets people finish and be responsible for their work; defines success in terms of the whole team; creates a feeling of belonging in the team.

### **Applies strategic agility**

Sees ahead clearly; anticipates future consequences and trends accurately; has broad knowledge and perspective; is future oriented; articulately paints credible pictures and visions of possibilities and likelihood; creates competitive and breakthrough strategies/plans.

### **CORE VALUES**

*Creation of New Standards of Care  
Trust, Honesty, Integrity, Quality  
Team as Source of Strength  
Zeal and Commitment  
Growth, Transformation and Renewal*

## Document #2: Summary of Biotech Company's Internal Procedures

1. Discuss ways to develop appropriate curriculum for biotechnology manufacturing programs, teaching expertise and credibility of instructors with community college representatives. Discuss the likely benefits of an internship program for college instructors in industry, to familiarize them with the manufacturing environment and the work performance requirements.
2. Discuss the program concept with CEO/Manufacturing VP/ IDEC managers requesting their reaction to the idea of hosting an internship program.
3. Based on a positive response by management, prepare a project plan document, setting out a vision for the project, and describing the rationale, project scope and benefits. Include a draft visitation plan.
4. Circulate the planning document within the company requesting feedback. Especially seek feedback on which areas of the company and which processes interns should observe.
5. Meet with college administration about company concerns re confidentiality, interruption of work schedules, funding etc
6. Arrange with Human Resources and Legal Departments the appropriate agreements related to company confidentiality, and personal liability and compensation (see Appendix C and D).
7. Circulate a draft implementation plan to directors seeking their views on the proposed schedule and requesting any further ideas re areas of the company interns should visit.
8. Based on this feedback, draft daily/weekly schedule for interns.
9. Email all company staff confirming who the instructors are, and when they will be at the company, reiterating the goals, objectives and likely benefits of the internship to the company.
10. Send invitations to identified departments asking when it would suit them to have interns.
11. Set up first meeting with interns to work out program schedule and discuss practical matters like access, sign confidentiality agreements etc.
12. Confirm schedule with different area managers.
13. Report on the progress of the internship program to senior management at weekly meetings.
14. Monitor daily appointments to assess whether production areas can accommodate visitors as planned.
15. Email directors, managers, and supervisors asking for their evaluation as to how the program is going and if they have any concerns.
16. Monitor and readjust schedule on a daily basis, based on changes in production schedule, any concerns of managers, and special requests by interns.
17. Continually adjust the schedule in accordance with the company production schedule.
18. Towards the end of the program, invite guests, book room, make arrangements for the final presentation meeting.
19. Hold the final presentation meeting followed by a final wrap-up meeting with interns and college representatives.

Report to senior management on the final evaluation and outcome of the project, an estimate of project costs to the company, and follow-up actions including how achievement of medium and long term goals will be measured.



## Document #4: Sample Letter from Biotech Company to College Deans Offering the Internship

<Name and Title>  
<College Name>  
<College Address>

July 5, 2002

Dear <Name>,

IDEC Pharmaceuticals is pleased to offer a Visiting Instructor opportunity to <Instructor(s) Name(s)>, as part of our new IDEC Industry Visitor Experience Program in partnership with the Southwest Regional Bio-Link Center located at San Diego City College.

The purpose of the industry Visitor Experience Program is to support industry education of instructors in San Diego. The project has been funded through a sub-grant to San Diego City College (SDCC) from City College of San Francisco (CCSF), which serves as the primary grantee and administrator for the National Science Foundation's (NSF) National Advanced Technological Education (ATE) Center for Biotechnology (Bio-Link). San Diego City College utilizes its sub-grant funds to operate the Southwest Regional Center of Bio-Link, which serves five southwestern states. Due to IDEC's growing needs in the expansion of large-scale manufacturing in Oceanside, California, a new set of job opportunities and educational requirements is evolving. In order for the San Diego County Colleges to meet IDEC's needs and the demands from other growing biotech companies, IDEC is pleased to participate in this program.

The industry opportunity will begin on July 10, 2002 and will end with a presentation sometime mid-August. <Company Representative> will be the primary program contact for IDEC Pharmaceuticals. Industry visitors are not considered employees of IDEC Pharmaceuticals and therefore will receive no compensation or benefits from IDEC Pharmaceuticals. Please contact Dr. Joan Stepsis, Director of the Southwest Regional Bio-Link Center or Richard Buecheler, Manger of ED>Net's Southern California Biotechnologies Center at San Diego City College, for details on intern compensation and program costs at 619-388-3081.

As part of the Industry Visitor Experience Program, instructors are expected to be on site at IDEC for a minimum of 40 hours the week of July 15 through 19, 2002. Instructors will be required to sign a Confidentiality Agreement and complete a case study documenting what they have learned from the experience and how they have used or plan to use it. The case studies will be provided to IDEC Pharmaceuticals for review and approval prior to publication to ensure confidentiality of proprietary information is maintained.

We look forward to working with <Instructor(s) Name(s)> as part of the Industry Visitor Experience program. If you, have any questions please feel free to call me or \_\_\_\_\_.

Sincerely,

\_\_\_\_\_  
(Director Human Resources)

**Document #5: Sample Internship Program Schedule**

**Schedule for Visiting College Instructors at IDEC Pharmaceuticals**

<b>Day</b>	<b>Time</b>	<b>All Instructors</b>	<b>Presenter/Location</b>
Fri., _____	9:00 AM	MTS Validation Overview	<presenter name>, MTS New Hire Program
	10:15 AM	Equipment Maintenance Overview	<presenter name>, Maintenance New Hire Program
	11:15 AM	Plant Maintenance Tour	<presenter name>, Maintenance New Hire Program
	12:15 PM	Lunch	Cafeteria
Mon., _____	9:00 AM	Kickoff Meeting	<presenter name>, & Training, Dept. Room # _____
	10:00 AM 10:30 AM	Facility Tour Parking permits and badges	<presenter name>, Security Office
	11:00 AM	Manufacturing Process Overview	<presenter name>, Room # _____
	12:00 – 1:00	Lunch – On Your Own Facility Tour	Cafeteria
	1:00 – 1:30	Overview of Curriculum Resources	<presenter name>, Room # _____
	1:30 PM	New Employee Safety Orientation Short Tour of _____	<presenter name>, Room # _____
	3:00 PM	COMPANY – Past, Present and Future	<presenter name>, and Training Dept. Room # _____
	4:15 PM	Overview of “Soft” Skill Requirements for Technical Positions	<presenter name>, Room # _____

## Document #6: Extract Displaying Format of Instructor Journals

*Wed. July 17*

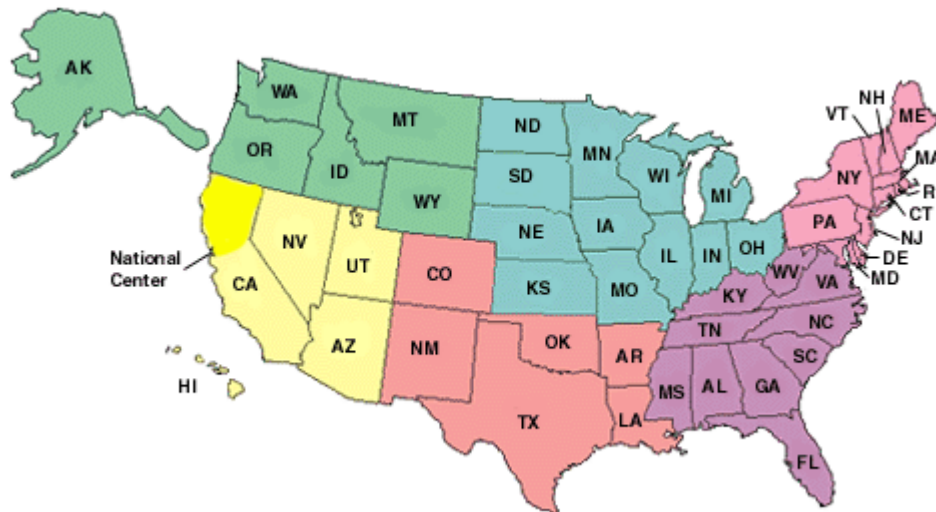
<Company Representative> from the Compliance department talked about FDA regulations, Good Manufacturing, and Documentation Practices. This was a very interactive session. We all asked quite a few questions and <Company Representative> answered each very carefully and when appropriate used specific examples of recent cases. A very informative talk.

<Company Representative> explained the new hire process at IDEC starting with Job description, the interview process, the new hire training program and the process of performance review.

We spend the afternoon in Cell Culture in MSM. We went through the gowning procedure to enter the facility. It was very impressive to see the cell culture operations. We were able to see CIP and SIP operations. All the operations are computer driven. Obviously, operating the bioreactors is meant for those who are mechanically oriented. Physical strength is also important. All the operators followed SOPs while performing their tasks and they made entries into logbooks as they went along. The floors were cleaned when we were there and they said that the floors were cleaned at least twice a day. The cell culture group was provided with a color-coded schedule that clearly defined the tasks that needed to get done on each day and how it was coordinated with the activities of other groups, namely: cell banking and purification.

- **What have I learned today this is new to me?** Although I am very familiar with FDA regulations and cGMP guidelines, <Company Representative> examples were very informative. Gowning up to enter MSM. The actual experience of being in a cell culture suite of a biomanufacturing company and witnessing the action.
- **What have I seen that is familiar?** I was familiar with Good Manufacturing and Documentation Practices. I was familiar with gowning procedure but had never gone through it myself. I was familiar with cell culture practices at the small scale.
- **How will I use this information in curriculum in terms of lecture, laboratory experiment, or otherwise in the students' classroom experience?** To make sure students understand the importance of compliance with cGMP requirements and to demonstrate to students what the industry does to comply. To emphasize the importance of following SOP and to provide them with practice. To teach students about cell culture and all that is needed to keep cells happy and dividing. Bioreactors and how they are operated. CIP and SIP processes. Why is gowning necessary?

## Document #7: Contact Details for Bio-Link Regional Centers



<p><b>National Bio-Link Center</b>  <u>Dr. Elaine A. Johnson</u>                      City College of San Francisco                      50 Phelan Avenue, Box S-12                      San Francisco, CA 94112                      (415) 487-2472                      ejohnson@biolink.ucsf.edu</p>	<p><b>South Central Region Bio-Link Center</b>  <u>Dr. Linnea Fletcher</u>                      Austin Community College                      1212 Rio Grande                      Austin, Texas 78701                      (512) 223-3282                      linneaf@austin.cc.tx.us</p>
<p><b>Northern California Region Bio-Link Center</b>  <u>Dr. Mike Solow</u>                      City College of San Francisco                      50 Phelan Avenue, Box S-54                      San Francisco, CA 94112                      (415) 239-3500                      msolow@ccsf.org</p>	<p><b>North Central Region Bio-Link Center</b>  <u>Dr. Joy McMillan</u>                      Madison Area Technical College                      3550 Anderson Street                      Madison WI 53704-2599                      (608) 246-6001                      jmcmillan@madison.tec.wi.us</p>
<p><b>Northwest Region Bio-Link Center</b>  <u>Dr. Caralee Cheney</u>                      Shoreline Community College                      16101 Greenwood Ave N                      Shoreline WA 98133                      (206) 546-4543                      ccheney@ctc.edu</p>	<p><b>Northeast Region Bio-Link Center</b>  <u>Dr. Sonia Wallman</u>                      NH Community Technical College                      320 Corporate Drive                      Portsmouth NH 03801                      (603) 334-6306 x23                      swallman@tec.nh.us</p>
<p><b>Southwest Region Bio-Link Center</b>  <u>Dr. Joan Stepsis</u>                      San Diego City College                      1313 Park Blvd.                      San Diego, CA 92101-4787                      (619) 388-3081/388-3588                      jstepsis@cact-sd.org</p>	<p><b>Southeast Region Bio-Link Center</b>  <u>Bill Woodruff</u>                      Alamance Community College                      PO Box 8000                      Graham, NC 27253                      (336) 506-4224                      bill.woodruff@alamance.cc.nc.us</p>