The Role of the Regional Biotechnology Center: The Development of an Emerging Convergent Technology as Curriculum

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A quick study of the biotechnology grants infrastructure for the United States suggests that there are significant challenges in new technology introduction. Deployment involves new education of faculty, integration into existing text based laboratories and maintenance of the new technology program. Biotechnology upgrades are particularly challenging because the technology to be introduced may simultaneously involve new convergent knowledge of several disciplines, including biotechnology, nanotechnology, computer science and cognitive science. This chapter reviews the development of a biotechnology program from its origins as single technology modules to a statewide organization.

The responsibilities of biotechnology center directors includes encouraging individual colleges to maintain and expand their curriculum for training students for employment in companies and transfer to the university. Additionally, a valuable service to existing biotechnology employees and executives is provided by a center offering skills upgrades and specialized training upon request. Center directors also devote a great deal of time to networking with economic development professionals and the venture capital community where appropriate, as these resources provide key indicators of the ongoing emergence of new technology companies, and spin-offs of existing biotechnology companies. In California,

there are currently six centers for biotechnology and a statewide director. More centers are planned. The entire effort was the brainchild of two key faculty-administrators at Ventura College (Dr. Robert Renger and William Thiemann, Dean and Chair respectively at Ventura College) and developed to become part of the California Community Colleges Workforce and Economic Development Program.[1] In addition, a statewide grant writing team organized by Robert Renger pulled together national resources to launch the Bio-Link Center in San Francisco.[2]

Those of us who have been concerned with the practicalities of biotechnology program educational development for entry-level employees in start-up companies know the challenges of acquiring and introducing new curricula. Often an opportunity starts with a new networking event and a new conversation. Quickly communicating the essence of biotechnology has been vital. An interdisciplinary definition of biotechnology that satisfied both educators and venture capitalists to the following: *You make loads of money in biotechnology by brewing genetically engineered wine in swimming pool sized stainless steel vats while wearing a space suit.* This single sentence translates the mundane fundamentals in biotech commonly known as adequate cash flow, high technology and skilled technical labor into an easy to remember one-liner. Inventing the language and allegory for bringing together different disciplines for biotechnology educational program development involves a rather basic algorithm of activities that is repeated each year with the grant cycle. The methods described in this chapter summarize the essence of the lessons learned from seven consecutive grant cycles by a center director and suggest a common algorithm that can be reapplied as needed to biotechnology public-private partnership efforts elsewhere.

1 *www.cccewd.net*

2 *www.bio-link.org, also discussed in this volume*

THE CENTRAL COAST BIOTECHNOLOGY CENTER

The story of economic development in biotechnology at the community colleges of California anecdotally starts in an unlikely sphere—with the animation industry. As computerization and gaming developed in the 1980s, digital alternatives to hand drawn cartoons were clearly in demand. The problem was that computer technical education had not kept pace, despite the fact that the computer industry was being invented in California at the time. The result was that the average entry-level digital animator at the time was educated out of state. Ironically, there was also the paradox of significant unemployment in California. The animation industry petitioned the California legislature for support for technical training. This led to the establishment of a statewide economic development network (ED>Net) at the community colleges in the 1980s which later became the Economic and Workforce Development Program (EWD) in the new millennium.[3] Biotechnology was added to this statewide mandate in the mid-1990s. Robert Renger, Kim Perry and Mary Pat Huxley have been successive statewide directors for the EWD initiative now know as Applied Biotechnology Centers. Collectively the six regional centers and statewide coordinator are collectively funded with roughly $1.5 million from the EWD. It is expected that center directors seek external funding beyond this seed funding for technology curriculum development.

In the case of the Central Coast Biotechnology Center (CCBC), resources were acquired and generated in the past seven years through partnership with biotechnology companies Amgen, Baxter, Ceres, Dako, Integrity Biosolutions, Invitrogen, Alliance Protein, Alzheimer's Institute at CSUCI, Fziomed, Hardy Diagnostics, Coastal Marine Biolabs, Technical Associates, and Promega, During this time frame, collaborative grants were arranged with Amgen (3-D projection), California State Universities at Channel Islands and San Luis Obispo (grant development and review), College of the Canyons (126 Biotech Corridor), and

3 *www.cccewd.net*

UCSB (California Institute of Regenerative Medicine – stem cells). Despite these intensive efforts, the acquisition of an emerging transformational convergent biotechnology which would fundamentally alter basic college instruction and simultaneously provide industry training benefits was elusive and would wait until further collaborations developed as described below.

As an aside, it is important to note that other technical training initiatives, (multimedia, advanced transportation, competitive technologies, and health) are among the palate of EWD initiatives. The EWD mission in brief is to advance California's economic competitiveness through a well-trained workforce. However, the method(s) used to achieve this aim are worth noting as they can provide significant direction to those with similar challenges. Implicit within the algorithm for biotechnology public-private partnership is the goal of describing the basic methodology for generating resource development (equipment, material and funding) to augment the meager support for high technology education.

THE CCBC CORE ALGORITHM

The CCBC has operated for over a decade with a core algorithm that starts each year by renewing partnerships with businesses and key industry advisors early in the fall. Because the center operates during the summer months, it is prepared for the regular networking events that take place in business circles starting in September. Educators typically underestimate the importance of informal regional business meetings and likely don't have the time, or have scheduling conflicts with attendance. In California there are many professional forums that provide opportunities for networking, including the MIT enterprise forum, Biobrew, IEEE, and regional biotechnology organizations (SoCalBio, BayBio, Biocom). Other avenues for networking include small business innovative research meetings (SBIR) and trade shows which offer combinations programs for investors and scientists (Biotechnology Industry Organization, LARTA). In contrast to technical meetings common at universities, these industry organizations provide

The CCBC Core Algorithm

1. Renew a broad set of partnerships annually
2. Informally and formally survey businesses faculty and individuals
3. Define regional needs with a core of advisers
4. Strategically address the need and incrementally improve the regional curriculum.

the opportunity to meet a wide diversity of people from different fields, including representatives from the U.S. Patent Office.

Beyond the networking aspect of the algorithm for generating public-private partnerships is the practical need to generate a core of advisors. Face to face meetings to advise a biotechnology education program are not as important as the individual relationships that a center director develops. Also, in keeping with the high-risk business model, many collaborative ideas with advisors fail, but this should not impede reformulation and refinement of the basic collaboration with the representative from industry. The main goal of collaboration with an advisor from industry is to find out what type of employee that person would hire. Then, implement at least one technology training module for that hiring need in a classroom, independent study, or workshop. This involves considerable finesse when dealing with faculty across a region. Again, since this is done on a yearly cycle, the retirement of unneeded or less desired aspects of the training curriculum is critical. This opens the grant deliverables and makes readdressing of industry needs each year possible, with new deployment modules. Many studies have been written on common skill sets needed for industry. The best way to find out what training is needed locally or regionally is to ask your advisors directly. Using this method, exceptional lab modules were developed for atomic force microscope, formulations, protein stability, cell cultivation, bioreactor, and fluorescent protein expression in prokaryotes and eukaryotes by transfection and virus infection. Offsite modules in HPLC, structural biology, and other labs involving extensive instrumentation were performed at industry sites using their equipment.

The next activity in the yearly algorithm is formulation of a survey. Major surveys require a great deal of time and money and should only be undertaken when a major shift in the program or local industry need is expected. In the case of the CCBC, a major survey was undertaken in 1998, prior to Amgen's massive expansion, Baxter's opening of a biosciences manufacturing suite, and Biosource's (now Invitrogen) extensive new hiring. The chapter on the Moorpark Program, elsewhere in this volume, illustrates a training program developed from specific industry polling. Minor surveys can be as simple as a quick phone call to human resource departments and lab support companies, assessing which jobs are in demand.

Most hiring managers realize that within a class of students, they will probably only want to view several of the best resumes. For this reason, the center director encourages educational modules such as resume writing wherein a company in need of employees can come and teach a section on the fundamentals of preparing documents specific to their company.

Beyond minor and major surveys is the need to coordinate local needs with statewide or national employment need trends. For this reason, the CCBC became involved in the California Governor's life sciences initiative that surveyed all major biotechnology companies, educators, venture capitalists and economic development/labor specialists simultaneously. Four documents were produced which collectively define a roadmap for biotechnology economic development in California. These documents predict that business formation and research growth will occur primarily along the north-south coastal belt, while manufacturing and expansion will take place along the east-west corridors that connect the coasts with the central valley and deserts. These crucial documents can be found at *www.monitor.com* and are closely linked to articles from Michael Porter on technology cluster model theory. In brief, the cluster model suggests that new emerging startup companies will have the greatest entry level training needs (like animation in the 1980s). These startup companies grow more frequently near larger existing companies—during times of distress in the larger compa-

ny, employees who want to stay in the region typically start their own ventures near the parent company. These small companies have special needs that can be met by small community college training programs.

One of the great success stories of CCBC is that Ventura College placed some of the first employees at Amgen, when it was a little tiny company in what is now known as Building 1. In the 1980s, Amgen's fate was not assured and each hire was critical. At that time a former Ventura College student named Timothy Osslund became one of the first employees. There was no university in Ventura County at the time so companies like Amgen relied on relationships with community college programs for entry-level employees. This early partnership illustrates a judicious use of resources by the college. In the 1980s, Ventura College began offering biotechnology modules as part of regular college courses. This led to full program development later in the 1990s.

New technologies have specific training needs that entail bringing faculty into the company for apprenticeship and training. This was encouraged during the mid-1990s and allowed faculty to return to the classroom with an appreciation for the goal of introducing specific curriculum into existing courses. Many of the skill sets are now taught as part of a research programs at the university. As community college programs with biotechnology faculty develop certificate programs and articulations with universities, the need for annually renewing partnerships and defining new needs is vital. For this reason, it is suggested that like Ventura College, schools elsewhere should offer courses which provide the public and non-majors the opportunity to hear a new lineup of biotechnology related speakers. The second key aspect of the Ventura College program is a lab skills course that affords those with a basic biological sciences background as well as those with a university degree (and no lab skills) the opportunity to learn lab technique directly from industry employees. Many of the instructors are former students. The founder of the program, William Thieman, is currently publishing the second edition of a biotechnology text used in the program. Terry Pardee continues

to lead coordination of the industry sponsored laboratory instruction course he authored with considerable assistance from Marta deJesus and occasional input from the CCBC director.

Courses where students, faculty, and industry employees interact are the perfect environment to try out new curriculum ideas. The center director can develop new courses to test deploying emerging technologies, either by inviting industry directly to the classroom, or vice versa. In the case of the emerging curriculum described below, a representative from Cepheid flew into town with a suitcase one evening and spent an hour demonstrating the portability, convenience, and speed of a new portable real-time PCR (RT-PCR) product—all attributes that were highly sought in developing transformational curriculum modules.

The regional goal of the CCBC is to foster development of biotechnology at all the community colleges in the proximal coastal region. Because the current CCBC director had also participated in the development of the Moorpark Program in its first semester in the lab at CSUCI (with Marie Panec and Dr. Maureen Harrigan), there was awareness that it had considerable internal inertia and was highly capable of guiding its own development. The contribution of the CCBC to Moorpark has been an on-call relationship to provide resources when needed and to participate as an occasional lab instructor. The CCBC director contributed several chapters to the Moorpark-NSF Industrial Biotechnology text, particularly to encourage testing for *Mycoplasma* by PCR. Baxter quickly adopted this training locally in its QA/QC processes for producing factor VIII for hemophilia.

From 2002-2007, the CCBC algorithm of searching for business needs was extended to community colleges throughout the Central Coast region from San Luis Obispo to Ventura and eastward to Lancaster. This assigned region followed the state of California economic development map. Partnerships were developed or renewed with community college science programs and biotechnology-related businesses at various stages of the CCBC project. The CCBC regularly interacted with regional universities, including Cal Poly SLO (for review of faculty grants with

Susan Opava), UCSB Department of Neurosciences (for stem cells infrastructure development with Dennis Klegg), and the newly developing CSUCI in Ventura County (for the business and technology partnership committee and for the Master's Program in Biotechnology with Wayne Davies and Dr. Ching-Hua Wang among others). Each of these partnerships with colleges and universities involved layers of contacts from industry and education. A significant effort was developed in partnership the Gold Coast Innovation Center (for alternative energy) which resulted in a pilot biodiesel plant at the Hueneme Naval Base in Ventura and a $4 million biogas facility built by Onsite Power at UC Davis. Collaborators for alternative bioenergy included the National Park Service, County of Ventura, VCEDA, NFESC (U.S. military), Biodiesel Industries, and CCBC.

Perhaps the most fortuitous partnership the CCBC inherited from predecessors was with a non-profit organization, VCBio, that attracted the interest of a successful businessman and investor, Gary Clark. VCBio functioned under Clark to network the biotechnology interests of the Ventura, Santa Barbara, and San Luis Obispo from 2001-2004 and resulted in many industry-training partnerships. Unlike traditional academic program development, this training was directed at industry representatives. The discovery of this executive need led to the closure of the full cycle of the algorithm described in this article.

A difficult aspect of the CCBC algorithm as described (which correlates to a grant workplan) is understanding where to initiate the effort to upgrade the curriculum with new technology. Over the years, various efforts have included a vast number and spectrum of individuals in combination with technologies. The core question that continued to be asked was: *How is the center going to acquire a truly transformational emerging technology and succeed in its adoption throughout the college curriculum?* Through careful one-on-one surveys information it was discovered that many Amgen entry-level research technicians had been trained in microbiology lab skills at a community college prior or during employment. The CCBC then focused on the ubiquitous microbiology labora-

tory class as the common denominator to introduce a universally applicable curriculum.

FOCUS ON TRANSFORMATIONAL TECHNOLOGY

The CCBC realized that if the technologies were the emerging part of the economic equation that related to the EWD mission, it could simply pick a transformational technology that met specific criteria (speed, portablility, convenience, computerization, sensitivity, genetic-basis) and train everyone with it. The answer came from an unlikely source in a partnership with a geographic information system (GIS) grant authored by William Budke. The CCBC was asked to consult on detection of bacteria. Initially, gel boxes, PCR machines, and other aspects of traditional methodology were considered. Then the labor was analyzed. The existing technology would involve constant monitoring, mentoring, and an ongoing commitment to interpreting bands on gels results. This existing technology would require intense time commitments. As described previously, the CCBC arranged demonstration of a specific implementation of portable RT-PCR product manufactured by Cepheid. The GIS project required detecting and mapping bacterial contamination in streams, which could lead to beach closure. This is a huge seasonal problem in California. The RT-PCR technology passed the initial review for inclusion in the grant, which was ultimately approved. The project seemed to be in trouble because the steep price of the technology meant that the purchase required college district board approval. With a one-year grant cycle, months of waiting can spell disaster for workplan timelines. Program officers monitoring the grant become impatient, and in this case there was also pressure to show grant progress before the state governor's election in November. In this case however, the real tragedy was that the spinach – *E. coli* 0157:H7 outbreak in Salinas killed and injured over a dozen children, and that hit Westlake, CA-based Dole foods very hard. The Cepheid technology was used to track down the source of the outbreak in partnership via a New Mexico testing lab and this was broadcast

all over the news. A key question was, *Why was a California technology was being deployed out of state to solve a problem at home?*

In September, the real-time PCR machine arrived, months behind schedule, but in time to contribute to a very relevant story. The technology was very sturdy—it had been developed on a DARPA SBIR grant—and was deployed in over 1000 post office sorting areas for detection of anthrax following the often forgotten letter incidents after 9/11. In fall 2006 the real-time PCR unit, being portable, was put in a suitcase and traveled all over the state for workshops. The reagents did not need to be refrigerated and, using a simple of the protocol, the product was able to detect the genetic signature of specific bacteria in as little as 12 minutes—in contrast with conventional bacterial identification methods, which can take experts 24–48 hours or more. This real-time PCR technology was portable and could also be used by a nurse in the hospital to swab a new mother for a bacteria (GBS) that could potentially cause meningitis in her newborn. Alternatively, screening all incoming hospital patients for the dangerous MRSA bacteria is now feasible. The inventors also implemented FDA level stringency to tests performed with the units. Furthermore, transforming basic microbiology laboratory curriculum from the existing Koch-Pasteur methodologies to a contemporary 21st century genetic signature methodology seemed to be feasible. The curriculum adoption of this key Nobel Prize-winning technology after so many years of waiting finally seemed feasible. It was easy to use; simpler than a cell phone.

The CCBC took every opportunity to demonstrate the Cepheid RT-PCR technology. Often the audience would consist of people without lab experience who would be fascinated that they could accomplish an advanced molecular biology experiment within an hour. After years of pushing projects along, one module and one instructor at a time, students were actively seeking training in the Cepheid RT-PCR technology. One of CCBC's key problem solving technicians, Robert Shieman received a full scholarship to Stanford. Others like Dwylene Zapparelli, Steven Ekman, Thrace Allen, Maribel Aguilera, Nikki Geluz and Norma

Villalon participated as a team in deploying the technology in workshops for industry employees at hotels and labs in the region. In one session for the Integrity Biosolutions manufacturing team, we were able to utilize Gram staining, RT-PCR, gel electrophoresis to confirm bacterial identities in 3 hours! Furthermore, Robert, Maribel, Steven and myself cloned and sequenced bacterial PCR fragments demonstrating proof of principle that this particular technology could also revolutionize the traditional curriculum in microbiology lab instruction. Central Coast region colleges Ventura, Moorpark, College of the Canyons and Oxnard all include a detection module at some point during the year.

Convergent technologies like the Cepheid RT-PCR product involve combinations of biotechnology, nanotechnology, computer science and cognitive science. The cognitive science part is difficult to grasp, but is facilitated by software of an exceptionally good design. There will be many other technologies that are expected to follow this same development path. These technologies will in themselves create training needs for industry.

CONCLUSION

New technology deployment also roughly follows the Thomas Kuhn paradigm. The problem in microbiology is that from the top down, methodologies to determine bacterial species are standardized around biotechnical protocols that originated with Pasteur and Koch and were perfected in the first half of the 1900s. A new technology that incorporates previous capabilities of existing technology and resolves anomalies (the need for regulatory approval by FDA, EPA and DOD) is expected to generate some resistance by those supporting a simple and cheap biochemical curriculum. The college faculty are ready to make the transition. There is a strong awareness that a true transformation of the diagnostic approach to keying bacteria with a combination of genetic and traditional biochemical methods is now within reach. A RT-PCR platform that has a set of protocols that are regulatory approved will promote its adoption in pathways leading to MLT (medi-

cal laboratory technician) or CLS (clinical laboratory technician). The microbiology and biotechnology course infrastructure could make a significant contribution to training for those who could monitor food safety and water quality, check the health of hospital admissions, monitor bioreactor cultures and provide diagnostics at point of care. Many platforms are competing in this sector, but an implementation that is sturdy enough to also be used in training has been missing. California is currently sending many healthcare samples out of state for determination of bacterial identity. The delays, increased healthcare costs, and degradation of patient care this entails are simply unacceptable.

California's biotechnology industry is expected to greatly simplify other complex technologies such as gas chromatography – mass spectroscopy (GC-MS), microarrays, DNA sequencing and lab-on-a-chip PCR. As instructors, economic development partners, industry consultants, and program developers, center directors must anticipate the simplification and convergence of emerging technologies so as to animate the region with new ideas for education.

The ability to popularize and institutionalize novel emerging and transformational technologies will determine California's success in competing globally. The work plan algorithm for developing and deploying these technologies is similar whether it is applied to federal, state, or foundation grants.

A strategy for developing a robust grant work plan is described here as an algorithm which involves the following steps:

1. Partnership with representatives of biotech industry, venture capital, economic development and education.
2. Formulation of informal and formal surveys to determine the evolving needs for skills training in the region.
3. Deployment of educational modules in regular courses and eventually in specialized courses. These same offerings are also offered for deployment in

the region directly to industry, venture or economic development representatives upon request.

4. Networking with the advisors in special advisory sessions that are part of larger industry specific meetings.
5. Identification of transformational, rapid and cost saving technologies that can be deployed within a single grant cycle.
6. Attraction of entry-level students to the emerging technology project to enable its deployment offsite and to the industry (because biotech involves many pieces of equipment, even when it is simplified).
7. Deployment of the student run biotechnology teaching modules for industry representatives in workshops, forums and classrooms.

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