ID # 12-W-08-UT

Please provide the following information, adding space as necessary:

State: ___Utah_______________

Assign Program Category (applicant): Infrastructure and Economic Development
Program Name: BioInnovations Gateway
Administering Agency: Utah Science Technology and Research
Contact (Name and Title): Suzanne Winters, Executive Director
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1. How long has this program operated (month and year)?  **Opened in October 2009**
2. Describe the program:
   - Why was it created?

BioInnovations Gateway was created to solve 2 problems: Problem 1: Most life science start-up companies do not have access to affordable laboratory space and expensive, sophisticated instrumentation and equipment. They also require extensive coaching and mentoring to create high potential growth and investment opportunities. Problem 2: An appropriately trained workforce in biomanufacturing is required for the Utah life science sector to grow. On-the-job training/education of workers in this FDA regulated industry is expensive and inefficient for the companies to conduct post employment. No programs are available in Utah to prepare the workforce in the skills to enter and advance in the Biomanufacturing industry.

BiG is a concept which brings together individuals from the public and higher education and business communities. Each of these sectors “speaks their own language”, has their own agendas and traditionally have operated in an almost exclusive and independent basis. The success of this model has been completely dependent upon engaging the correct individuals with fully supportive administrators within each organization.

Utah, being a very entrepreneurial culture, ranks very high in the number of start-up companies in the nation. Unfortunately, the success of these companies five years after start-up is pretty discouraging and life science companies struggle disproportionately because of the high cost of research facilities and instrumentation required to conduct that research.

Additionally, in order to grow, a business must have access to a well skilled and abundant workforce. An appropriately trained workforce in biomanufacturing is required for any life science sector to grow.
On-the-job training/education of workers in this FDA regulated industry is expensive and inefficient for companies to conduct post employment.

Business incubation is a program, not just a facility. Access to BiG facilities removes a substantial hurdle but the services provided to the resident companies has been demonstrated to significantly increase the odds for success. A study conducted by Grant Thornton for the U.S. Economic Development Administration stated “that investments in business incubators generate significantly greater impacts in the communities in which they are made than do other project types.” In fact, the national return on investment in business incubators reports that for every dollar of public investment, $30 are returned to the community in the form of local tax revenue. Additionally, the likelihood of business success for these incubated companies is around 87% compared to less than 30% without participation in an incubation program. And 84% of incubator graduates stay within the local community. (Source: Business Incubation Works, 1997; 2006 State of the Business Incubation Industry)

- Why is it a new and creative approach or method?

The concept of combining workforce and business incubation economic development began in a grant proposal to the U.S. Department of Labor in 2007. Following receipt of the DOL grant, a partnership between Salt Lake Community College, Granite School District and the Utah Science Technology and Research initiative (www.innovationutah.com) was developed to create a shared use facility. No other Biomanufacturing programs in the US engage high school students in this kind of training. Additionally, BiG is a key player in the Utah STEM initiative to attract more students into STEM careers. High school students earn concurrent enrollment for college credit.

Currently, both high school and college level classes are conducted at the Granite Technical Institute and share laboratory space with BiG. Students have the opportunity for hands-on learning on sophisticated laboratory instrumentation, not generally available to the high school and undergraduate student population. The Biomanufacturing curriculum including Good Manufacturing Practices, Good Laboratory Practices, Product Design Control and Integrated Product Development was developed with significant industry input to ensure students graduating from the program have the skills and education required to meet the needs of industry. Biomanufacturing students have the opportunity to intern with resident life-science start-up companies within BiG.

- What are the specific activities and operations of the program in chronological order?

Activities of BiG fall into two categories: business and education with some overlap.

BiG incubator client companies are screened prior to entry for commitment to educational mission and “suitability”. Business and technical metrics and milestones are established with quarterly assessments for each company. Monthly CEO lunches are held for training purposes as well as addressing shared laboratory concerns/issues. Depending upon the stage of development of the client’s technology/business model, specific mentoring/coaching is conducted to prepare the company for the next stage of development Assistance is provided to the companies in financial and market analysis, business models and strategy and technical expertise is offered where appropriate.

The Biomanufacturing training program uses a 3-Tiered model:

Biotechnology and Biomanufacturing students have the opportunity to work and learn in shared labs with resident start-up companies and then intern with them within BiG. Since completion of the first year of the Biomanufacturing two-year curriculum in June 2010, BiG has placed 6 interns with resident companies and, in fact, one of these interns has since been hired as a full time employee of the company. Currently, both high school and college level classes are conducted at BiG and share laboratory space with BiG company clients. Students have the opportunity for hands-on learning on
sophisticated laboratory instrumentation, not generally available to the undergraduate student population.

The Biomanufacturing curriculum (Tier 1) including Good Manufacturing Practices, Good Laboratory Practices, Product Design Control and Integrated Product Development was developed with significant industry input to ensure students graduating from the program have the skills and education required to meet the needs of industry. Upon graduation, efforts are made to place these students in outside companies which reimburse for higher-education tuition.

BioInnovate is a program within BiG which provides the second tier of student training opportunities. Through research, development and manufacturing projects for real companies, students learn not only the technical skills necessary to conduct the project but also learn about team work, deliverables and schedules, contracting and entrepreneurship. All BioInnovate projects are carried out under FDA regulatory compliance which forms the basis of the Biomanufacturing training. For example, BiG has developed a partnership with Intermountain Health Care, a major health care provider in Utah, to develop ideas and inventions from its physicians and nurses for development as student projects. In essence, this is a student-run contract R&D organization.

BiG has recently initiated a student-run assembly and distribution unit that serves a resident company. Student interns are offered full-time, paid summer employment while learning GMP manufacturing skills while contributing to the success of the resident company and producing a medical device.

The third and highest level of student training is serving as interns with BiG resident companies. To date, BiG has placed 9 with client companies as well as several in businesses outside of BiG. As part of the Biomanufacturing training, students learn to operate and in some cases, calibrate and validate (for FDA compliance) all research-grade equipment increasing their skills and value to resident companies

- Is it effective? Provide tangible results and examples.

The Benefits of BiG are many. By partnering with several organizations, BiG has created a synergy significantly greater than its parts. The model was created to provide benefits for students, faculty, the life science industry sector and the State of Utah.

**Benefits to Students and teachers**
- Internships/Experiential learning
- Advanced skills on advanced equipment
- Improved employability
- Professional development
- Networking with entrepreneurs
- Networking with Chief Scientists

**Benefits to the State of Utah:**
- High wage job growth
- New company formation
- Skilled life science workforce
- Pipeline of students into research universities
- Outlet for university technology
- New technology development
- Tax Base growth
Benefits to Start-up Companies

- Affordable office/laboratory space
- Access to capital intensive equipment w/o capital outlay
- Availability to skilled interns
- Grooming of potential employees
- Access to contract research capabilities
- Collaborative environment

The BiG resident companies have stated that having access to the laboratory and prototyping facilities at BiG has provided efficiencies and cost savings enabling significantly faster technical and market development. The mentoring and business/market analysis available to them has helped provide access to and readiness for presentation to potential investors. Resident companies have raised a total of nearly $12 million of investment capital and hired an additional 30 employees since the BiG opening.

Metrics

- Number of new jobs created by resident companies: 34
- Amount of investment dollars in resident companies: ~$12 Million
- Number of new federal grants awarded to resident companies: 6
- Number of interns placed into resident companies: 9
- Number of graduating companies and follow-on data: 1 (Graduation scheduled for May 21, 2012)
- Number of students participating in the biomanufacturing program: 1250
- Percent of students enrolling for 2nd year biomanufacturing program: ~70% (includes 1000 9th graders)
- Number of students graduating from the biomanufacturing program: 240
- Number of students applying for internship with resident companies: 16
- Number of students participating in BioInnovate student projects: 8-10 at any one time (depending upon the current projects)

Did this program originate in your state? If YES, please indicate the innovator's name, present address, telephone number, and e-mail address. **YES**

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3. Are you aware of similar programs in other states? If YES, which ones and how does this program differ?

There are several, mostly new programs within the U.S. involving Community Colleges with beginning Biomanufacturing programs but none of the model with co-located start-up companies and on-site internship opportunities. In fact, the National Science Foundation recently sponsored a meeting, the Bio Link Summit on the economic and educational impacts of biomanufacturing programs where BiG was featured as a novel example. However, we are aware of only one other program with a similar dual mission and that program engages ONLY college level students and does not encourage student entrepreneurship through contract research and development. Introducing marketable skills, education and the experience of life-science entrepreneurship to high school students is unique in the U.S.
4. What limitations or obstacles might other states expect to encounter when attempting to adopt this program?

BiG is a concept which brings together individuals from the public and higher education and business communities. Each of these sectors “speaks their own language”, has their own agendas and traditionally have operated in an almost exclusive and independent basis. The success of this model is completely dependent upon engaging the correct individuals with fully supportive administrators within each organization.

The BiG partnership was initially difficult to implement until all involved recognized and accepted that the goal was mutual between them. However, without the partnership, BiG would have been impossible. No single entity, neither academic nor business, has the capacity, resources and competencies to successfully develop and implement such an innovative program.

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Use these as guidelines to determine the appropriate Program Category for your state’s submission and list that program category on page one of this application. Choose only one.

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