CROs and Incubators at Educational Institutions

Webinar,
Friday, January 27, 2017: 1:00-2:30 EDT

Click here to watch the webinar recording

Deborah Davis, Abbe Kesterson, Mary Nelson, Elizabeth Boedeker & Tyler Drake

Moderator

Sulatha Dwarakanath, PhD
Director, Biotech Dept. Austin Community College
Bio-Link
sdwaraka@austincc.edu

Bio-Link

- Works to increase the number and diversity of well-educated technicians in the bioscience workforce
- Our members are workforce-oriented college & high school programs, instructors, industry, students
- Bio-Link.org

Presenters

Deborah R. Davis, PhD
Acting Biotechnology Coordinator
Co-PI, AC2 Bio-Link Regional Center
Bluegrass Community and Technical College
deborah.davis@kctcs.edu

Abbie Kesterson
Bluegrass Community and Technical College
abbe.kesterson@kctcs.edu

Mary Nelson, Ph.D
Director of InnovaBio & STUDENTfacturED
Salt Lake Community College
mary.nelson@slcc.edu

Presenters

Elizabeth Boedeker
Coordinator
BioBench CRO
St. Louis Community College
EBoedeker@stlcc.edu

Tyler Drake, Ph.D
Director,
Bioscience Incubator
Austin Community College
tyler.drake@austincc.edu

CSO and Incubator at Bluegrass Community College

Deborah R. Davis, PhD
Acting Biotechnology Coordinator
Co-PI, AC2 Bio-Link Regional Center
Bluegrass Community and Technical College
deborah.davis@kctcs.edu

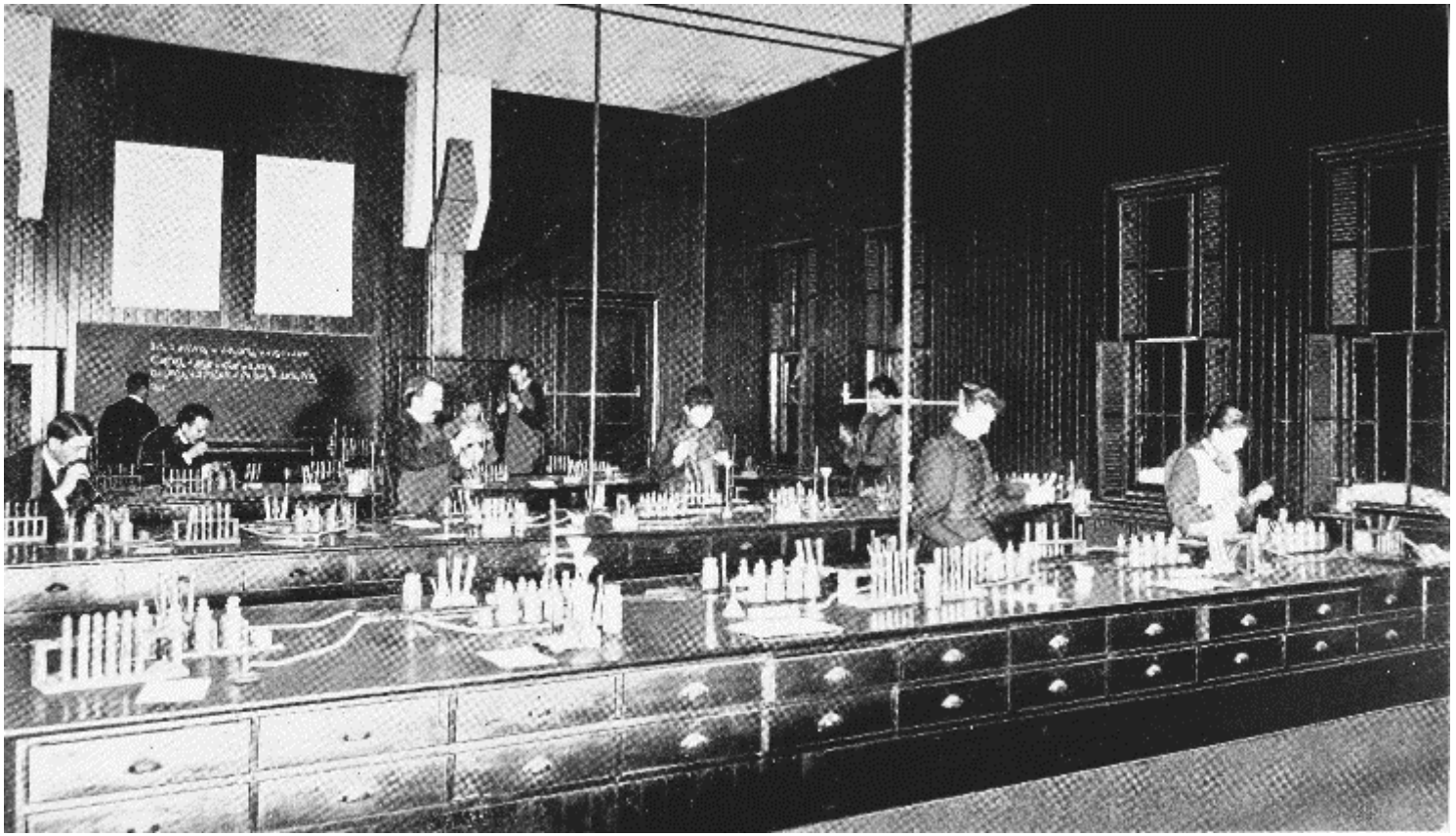
Bio-Link Webinar Series

CSOs and Incubators at Educational Institutions

Bluegrass Community and Technical College

Deborah Davis, PhD

Contract Service Organizations (CSO)



Community College CSOs

Model	CC CSO	Location	Funding Source	Services Offered	IP Share
In-house					
	InnovaBio	Salt Lake CC	Grants, State	Research & Testing	NO
	InnovaBioMd	Hagerstown CC	Grants	Research	NO
	Profile Genetics	Merrit College	Grants	Library & Array prep, robotic colony picking	NO
Incubator/Accelerator					
	BioBench	St. Louis CC	Grants, State, College	Rent-a-Bench, Research, Interns	NO
	Pasadena Bioscience Collaborative	Pasadena City College,	State, College	Full Incubator Services + Interns	NO
Co-Localization					
	Florida Institute for Food Safety	Florida State College	Grants, College	Testing	NO
Work Experience					
	Most Colleges	Various	College, Company	Internships	NO

http://bio-link.org/home2/publication/bio-link-cxo-summit-report-2012

Challenges & Solutions

- **Wet Lab Space**
- **Equipment**
- **Trained Personnel**
- **Intellectual Property**

- **Valid Work Experience**
- **Jobs/Careers**
- **Community & Industry Support**
- **(Lack Understanding)**

Solution

Low Cost Space

Equipment

Low – No Cost Trained Personnel

College/Company Collaboration

Safe Intellectual Property

Kentucky Future Plans
Science & Technology Building

Kentucky Future Plans Curriculum

Students

Learning Laboratory

+

Faculty

Project Management

=

Company

Fully Trained Personnel

Access to Fitted Wet Lab Space

Access to Equipment

Safe IP

Student/College

Authentic Work Experience

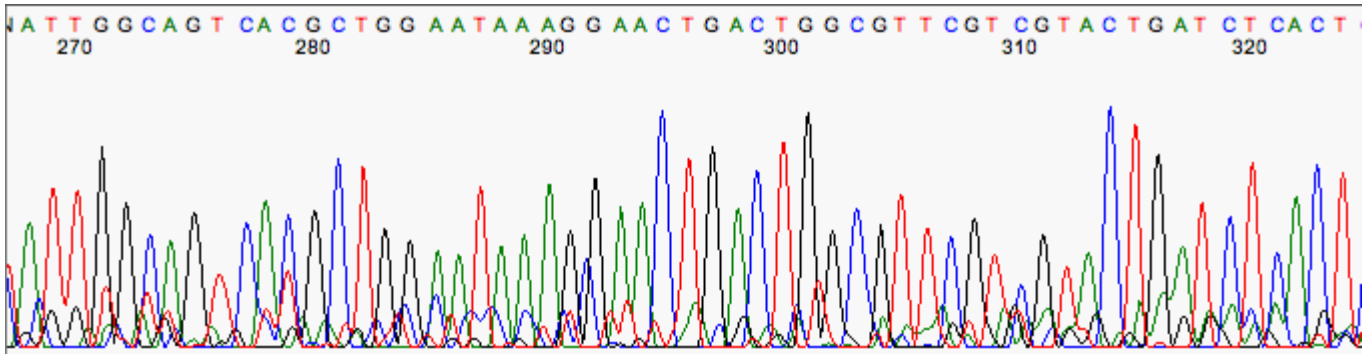
Increased Employability

Industry Collaboration

Community Recognition

Additional Revenue Stream

Accomplishments



CSO Summit: Community Colleges as Drivers for Regional Economic Development

April 7 & 8, 2017

Austin Community College

http://ac2.bio-link.org/upcoming-events

CSO and Incubator at Salt Lake Community College

Mary Nelson, Ph.D
Director of InnovaBio &
STUDENTfacturED
Salt Lake Community
College
mary.nelson@slcc.edu

Salt Lake Community College

Biotechnology Program

INNOVABiO®

INNOVATIONS IN CONTRACT RESEARCH AND SERVICES

STUDENTfacturED®

Made by STUDENTS for STUDENTS

Bio-Link CSO Webinar

Mary L. Nelson Ph.D.

mary.nelson@slcc.edu

Medical Devices

INNOVABiO®
INNOVATIONS IN CONTRACT RESEARCH AND SERVICES

- Initial Funding: NSF Advanced Technical Education (ATE) Grant Awarded in 2005 (DUE# 0402497)

- On-going funding provided by the State of Utah

Salt Lake Community College

INNOVABIO®
INNOVATIONS IN CONTRACT RESEARCH AND SERVICES

Core Philosophy

- Real Projects
- Real Scientists
- Real Equipment

- Intern Expectations:
  - Ask questions
  - Learn from your mistakes
  - Become independent scientists & work in teams
  - Project presentation

Salt Lake Community College

INNOVABIO®
INNOVATIONS IN CONTRACT RESEARCH AND SERVICES

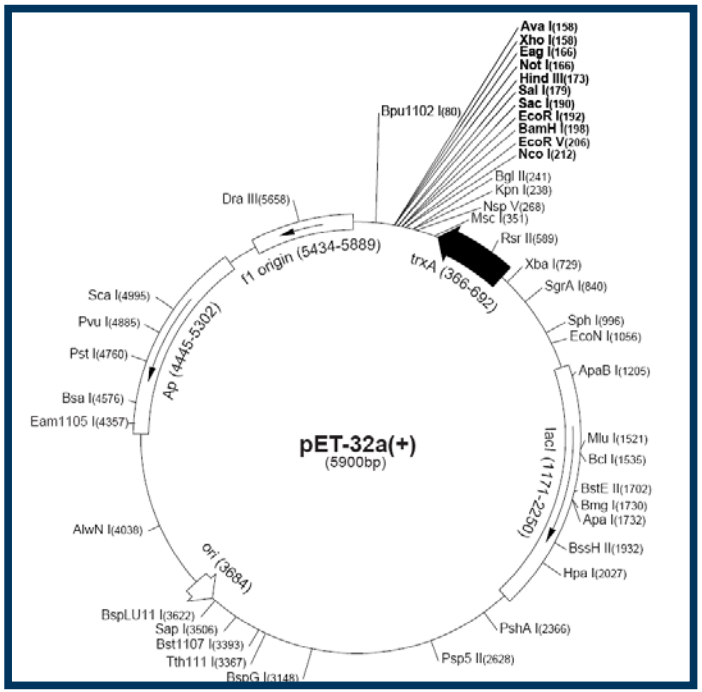
- Mary Nelson Ph.D. Director
- Kate Slessor Ph.D. Scientist and Mentor
- Alejandro Pabon M.S. Project Manager

- Intern Sources
  - Volunteer (Incumbent workers)
  - High School: JATC, Itineris & (NU)AMES
  - SLCC
  - UVU
  - Part-time paid
- Currently averaging 10 new interns each semester
- Trained over 540 interns since 2006

Salt Lake Community College

Intern Training Curriculum

- Training Packet: Interns work in a self-directed manner
- Interns demonstrate experimental molecular biology skills with plasmid pET 32a
  - Transformation (SOP)
  - 5 mL Culture (DIY)
  - Mini Prep (kit)
  - QC -Restriction Digest
  - QC –PCR
  - *E. coli* protein expression



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Intern Training Curriculum

- Interns demonstrate conceptual skills and abilities
  - Designing primers for restriction digest cloning
  - Read and report primary literature
  - Periodically evaluated regarding job skills:
    - Attendance and reliability
    - Critical thinking and comprehension
    - Problem solving
    - Lab citizenship
    - Independence
    - Communication

Advanced Curriculum: Client Projects

Real and relevant CRO projects for clients (low priority)

Salt Lake City, UT

Provo, UT

- Interns present their work at InnovaBio and at client locations

Salt Lake Community College

SLCC Contract Considerations

- SLCC Risk Management modified an existing document
  - Obligations of college and client
  - Intellectual property and confidentiality
  - Compliance with laws, rules and regulations
- All contracts and contract changes need VP approval
- Note 1: SLCC has no interest in intellectual property.
  - Client owns contracted work and lab notebooks.
- Note 2: InnovaBio® has interns who are minors.
  - No legally binding confidentiality agreements
  - Client risks are mitigated by restricting access

Salt Lake Community College

Lessons Learned by Trial and Error

- InnovaBio® only charges for lab consumables.
- InnovaBio® does not provide incubator space.
  - All spaces may also be used as classrooms.
  - All projects are directed by InnovaBio staff.
- In general, interns are not paid.
  - Earn college credit
  - Gain experience and letters of recommendation
  - SLCC Biotech supports part-time paid project leaders
- One multi-year contract for several projects.
  - Client approves project specific experimental outlines.

Salt Lake Community College

Collaborations with NSF Grant Funded Companies

- NSF-Small Business Innovation Research (SBIR) Phase II Community College Supplemental Funding

Salt Lake Community College

STUDENTfacturED®

Biomanufacturing

Training Enterprise at

Salt Lake Community College

STUDENTfacturED® Support

A student-run non-profit biomanufacturing company

- Conceived and established by Vivian Ngan-Winward
  - NSF ATE program
    - Awarded $909,443.00 in 2010
  - Launched in January 2012
  - Ongoing support from SLCC biotech program July 2016

STUDENTfacturED

*Made by **Students** for **Students***

Salt Lake Community College

Supported by the National Science Foundation under Grant No. 1003292.

STUDENTfacturED®

Where science, education and business meet…

*Made by **Students** for **Students***

Training enterprise, source for educational supplies

Design & development of biotech products

“Regulated” biomanufacturing company

STUDENTfacturED®

Salt Lake Community College

Collaboration:

~~School of Business:~~

~~Business~~

~~Marketing~~

~~Accounting~~

Biomanufacturing

program

Balancing business and education is not easy.
Real application is better than“simulation.”

STUDENTfacturED®

Salt Lake Community College

~~School of Business:~~

~~Business~~

~~Marketing~~

~~Accounting~~

Biotechnology

Program

~~Biomanufacturing~~

~~program~~

Students are the foundation. You need a clear mission.

STUDENTfacturED®

- Interns/Students
  - High School, SLCC &UVU
    - Similar to InnovaBio
  - Volunteer (Med Device students)

- Products:
  - Plasmids: BTEC 1015: SLCC and Concurrent Enrollment
  - Agar Plates: SLCC Microbiology

Photo credit: Steve Speckman

STUDENTfacturED® Products

Biotech education supplies:

Cheek Cell DNA Kit

Plasmid Identification Kit

Agar Plates (SLCC Micro)

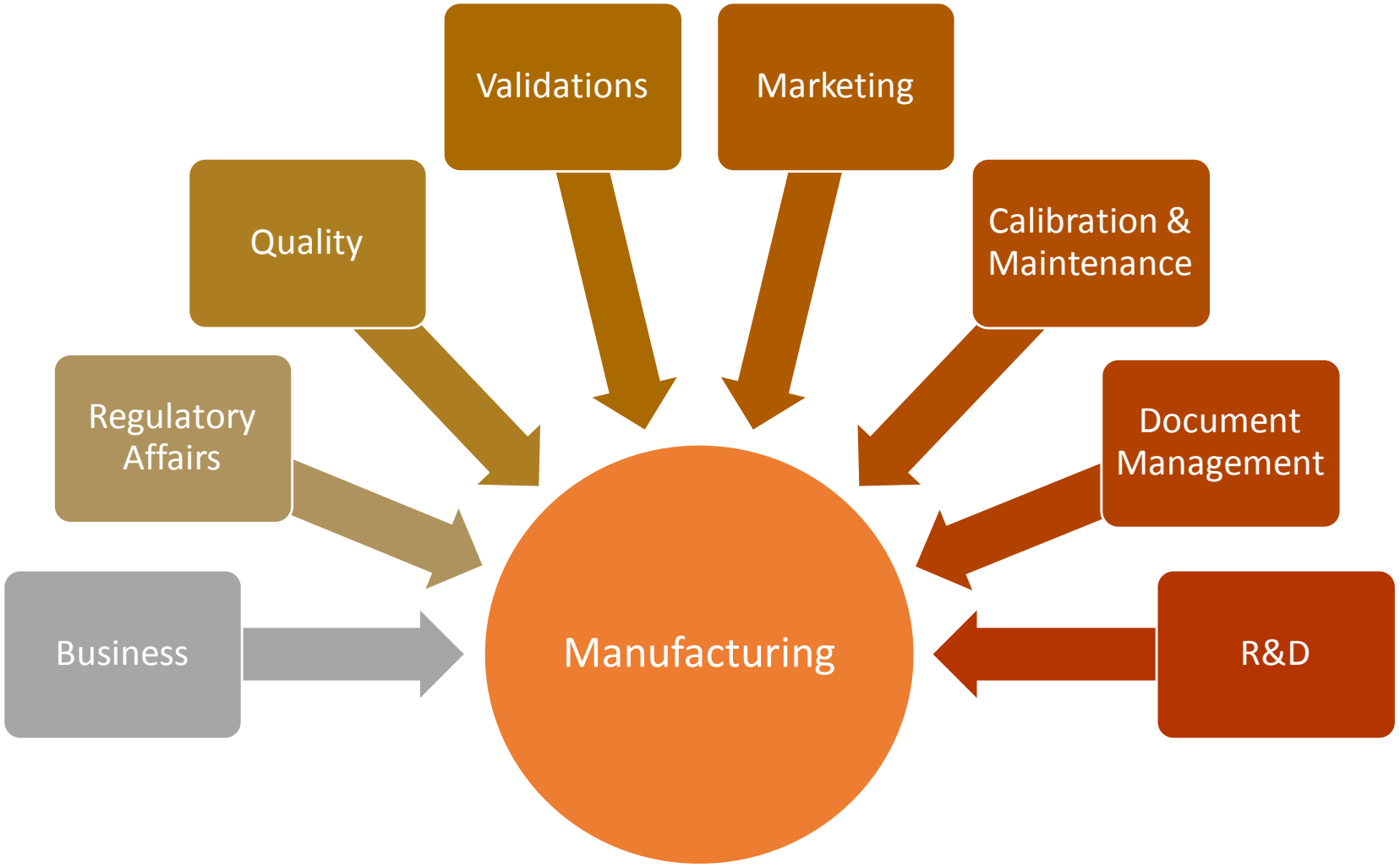
Salt Lake Community College

STUDENTfacturED® Curriculum

- Relevant training in real production processes using Lean manufacturing & GXPs
- Quality standards
  - Design controls
  - QMS (21 CFR 820/ ISO 13485)
  - MasterControl – document management
  - Production and process control
- Self-driven learning guided by experienced & knowledgeable mentors “empower” students
- Access to experience all functions of a company promotes entrepreneurial thinking

Salt Lake Community College

Many Functions in an Enterprise



STUDENTfacturED® Mentors

Vivian Ngan-Winward Ph.D. -Former PI/Director

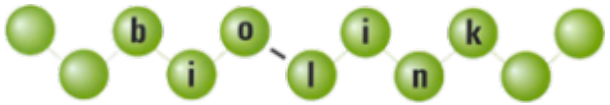
Mary Nelson Ph.D. -PI/Director

Bo Price -Peer mentor (limited to one year)

?? -Production Manager

Salt Lake Community College

QUESTIONS SO FAR?



Elizabeth Boedeker
Coordinator
BioBench CRO
St. Louis Community College
EBoedeker@stlcc.edu

CSO and Incubator at St. Louis Community College

BioBench Contract Research Organization

Elizabeth (Betsy) Boedeker
Senior Research Scientist, CRO Coordinator
Adjunct Biotechnology Faculty Member
January 27, 2017

Location

- Located within an Industry Building
  - BioResearch and Development Growth Park (BRDG Park)
  - STLCC Center for Plant and Life Sciences (CPLS)
  - 10,500 square feet, 1st floor (great visibility)

CORTEX
innovation community

- Close to much regional Biotechnology Industry
  - Monsanto
  - Danforth Plant Science Center
  - Washington and St. Louis Universities
  - Helix Center
  - Cortex (Central West End)

Center for Plant and Life Sciences / BioBench Role

- Education is **Number 1**

- Promote STEM and Biotechnology
  - Life Science Lab Assistant Program
  - Biotechnology Program
  - Outreach to Area Schools (Middle and High School)
    - Educational Specialist
    - More in-depth high school research opportunities G Park
      - Dual credit to high school students
      - Great way to build interest and enthusiasm

  - Teacher Education

BioBench Role (continued)

- Promote Industry, Life Sciences, Biotechnology
  - Limited and Full Lab Use agreements
    - Access to individual equipment
    - All access
  - Project Support
    - Sequencing
    - Danforth
      - Transfections
      - Western Blot
  - Personnel
    - Internship assignments
    - Paid by grant support

Define Success

- Initial expectation
  - Self-sustaining
  - Cost of space, salaries, equipment service agreements
  - Not realistic

- Not possible to be self-sustaining
  - Most equipment dual purpose (cannot separate)
    - Teaching support
    - Industry support
  - Industry setting very important
    - Very costly ($$)

Redefine - We are Successful

- Success ≠ self-sustaining

- Biotechnology Students (college)
  - > 30% biotech interns hired by internship-providing company
  - 91% placement rate of biotechnology students in industry jobs
  - Increase in program enrollment

- Industry
  - Provide resources for very small start up companies
  - No part of intellectual property (deal breaker)
  - By helping when small
    - Prove concept
    - GROW
    - Remain local
    - Employ local

Poll Question:

Do you feel that your organization would be flexible (or at least open) in their definition of Contract Research Organization Success?

Yes

No

Maybe

NewLeaf Symbiotics Story

- Pink Pigmented Facultative Methylotrophs (PPFMs)

- Beneficial bacteria that grow on plants
- Initially started in our lab space Jan 2012
  - Only lab space
  - 3 interns requested to work with their lead scientist

- Proof of concept, into field studies same year
- Jan 2013
  - $7 million in funding
  - STAYED in St. Louis for trained workforce
  - Hired former interns as full-time employees

More NewLeaf Symbiotics

- Built out space within BRDG Park building!
- Summer 2014 received another $17 million!

- Expanded their facilities
  - Added some production
  - Added Research and Development
- Currently
  - Seven graduates of STLCC biotechnology progr
  - Many former interns
  - Total head count >30 people

Challenges

- Many similar as when we started
- Within Center for Plant and Life Sciences
- Very limited ability to increase headcount
  - Full-time senior scientist (me!)
  - Full-time catch-all
    - Invoicing
    - Business aspects (marketing, budgeting)
    - Lab (very limited, time-permitting)
  - Part-time lab support
    - Project support
    - Internship assistance
    - High School research

- Small but devoted staff, limited resources – accomplish a lot!

Recognition Locally

- Recent Podcast (early Jan)
  - Entrepreneurially Thinking
  - One of three panelists
    - Nice story

- Arcus Award Nominee Finalist
  - St. Louis Regional Chamber
  - St. Louis organizations “championing a better tomorrow for our region”
  - 2013 and 2017 in Biosciences

Recognition Nationally

- Bellwether Awards Nominee Finalist
  - Community Colleges FUTURES Assembly
  - 2015, 2016
  - Programs and Industry pipeline

- Public Television Series
  - James Earl Jones
  - Behind the Scenes
  - Airs later this year

How can we broaden our impact?

- Community College Contract Research National Consortium
  - Abbe K's GREAT idea!

- Provide a helping Network
  - Help high schools teach science
  - Provide vectors/bacteria/*C. elegans*/guidance
  - Resource limited right now

- Open to many other ideas

Poll Question:

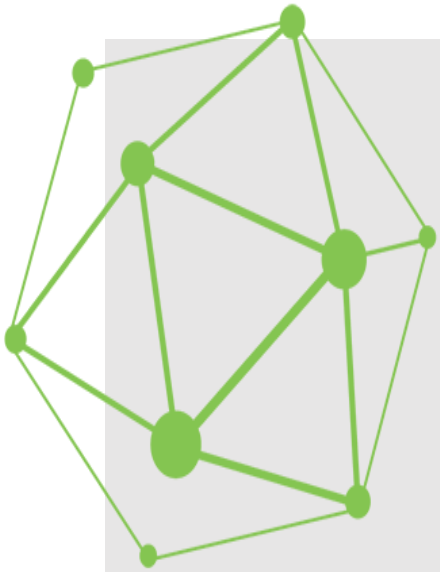
If you were managing a Contract Research Organization, would you be interested in participating in a consortium to share resources or expand capabilities?

Yes

No

Tyler Drake, Ph.D
Director,
Bioscience Incubator
Austin Community College
tyler.drake@austincc.edu

CSO and Incubator at ACC



AUSTIN COMMUNITY COLLEGE

BIOSCIENCE INCUBATOR

CENTRAL TEXAS HAS A PROBLEM

The region lacks wet lab space and a skilled workforce for its growing biotech industry

ABI HAS A SOLUTION

ABI MISSION

AUSTIN COMMUNITY COLLEGE
BIOSCIENCE INCUBATOR

The ACC Bioscience Incubator aims to establish a permanent wet lab facility and business incubator to accelerate Central Texas' biotechnology economy while training a skilled workforce

ABI HISTORY

AUSTIN COMMUNITY COLLEGE
BIOSCIENCE
INCUBATOR

- ACC has a long-term commitment to community economic success
- Over the past several years, the ACC Biotechnology Program has piloted biotech acceleration services with local start-ups
- Companies utilizing ACC interns and equipment have saved time and money during product development
- ACC was awarded a $4.9M grant from the State of Texas to expand the wet lab capacity of the region

AUSTIN COMMUNITY COLLEGE
BIOSCIENCE
INCUBATOR

- ABI bridges the gaps in the “research to product” cycle
- Creates an innovative work environment for life science entrepreneurs

ABI FACILITY

AUSTIN COMMUNITY COLLEGE
BIOSCIENCE INCUBATOR

Grand Opening January 31st!

10,000 SF renovation of the historic Highland Mall

WHY USE ABI?

AUSTIN COMMUNITY COLLEGE
BIOSCIENCE INCUBATOR

- Leasable Wet Lab Space
- Startup Business Development
- Core Laboratory and Instrumentation
- Workforce Education
- Private-Public Partnership
- Staff
- Collaborative Space
- Contract Research

ACCEPTANCE CRITERIA

AUSTIN COMMUNITY COLLEGE
BIOSCIENCE INCUBATOR

Profit-focused, bioscience/life science entity taking a proprietary product to market and positioned to scale
Technology can be commercialized; at least a prototype/alpha product; credible business model
Financial considerations – • Seed/pre-seed stage; funding under $10 million • Private company • Not yet revenue positive
Activities compatible with facility and align with ACC resources
Willing to engage in mutually beneficial collaborations • Willing to work collaboratively with ACC faculty • Willing to use ACC bioscience or other interns • Willing to work with ACC to develop diverse entrepreneur ecosystem
Texas presence; need for less than eight people in incubator space
Mature firms or non-profit research organizations can enter into short-term leases, if space available

ABI LEADERSHIP

AUSTIN COMMUNITY COLLEGE
BIOSCIENCE INCUBATOR

TYLER DRAKE, PH.D.
Director, ACC Bioscience Incubator

NANCY LYON
Coordinator, ACC Bioscience Incubator

LINNEA FLETCHER, PH.D.
Department Chair, Professor
ACC Biotechnology

CINDY WALKERPEACH, PH.D.
Director, ATI Health/Biosciences
IT^2 Institute, UT Austin

MICHAEL G. DOUGLAS, PH.D.
Executive Director, Texas Life-Sciences Collaboration Center

ABI PARTNERS

AUSTIN COMMUNITY COLLEGE
BIOSCIENCE
INCUBATOR

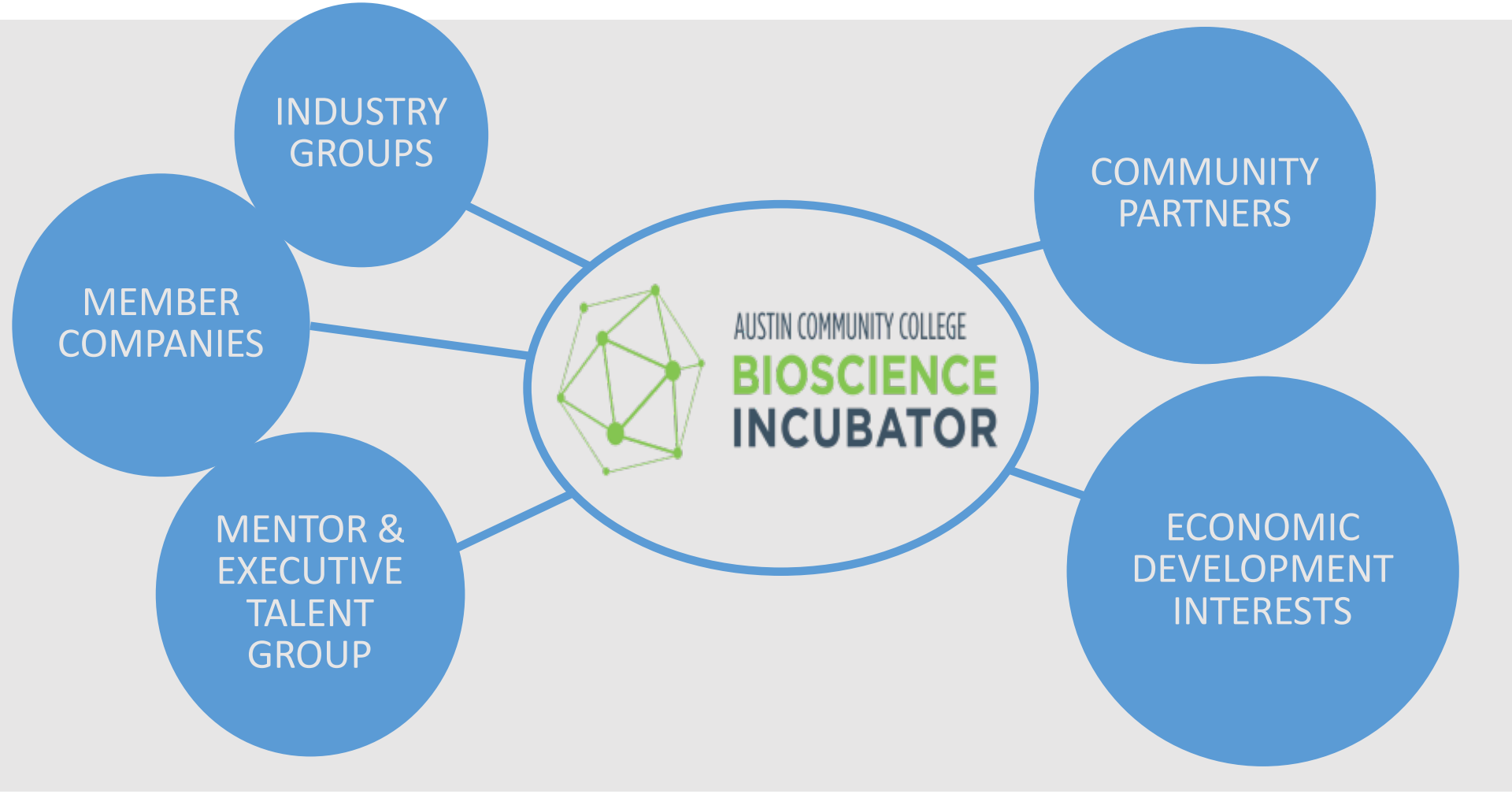
ati austin technology incubator
iC² INSTITUTE • THE UNIVERSITY OF TEXAS AT AUSTIN

TEXAS
LIFE-SCIENCES
Collaboration Center

ACC
AC2 BIO-LINK
REGIONAL CENTER

ABI NETWORK

AUSTIN COMMUNITY COLLEGE
BIOSCIENCE
INCUBATOR



EARLY ACHIEVEMENTS

AUSTIN COMMUNITY COLLEGE
BIOSCIENCE INCUBATOR

- Wet lab space at TLCC (Georgetown, TX) completed
  1,500 SF wet lab, 2 cell culture rooms and training room
  $440K equipment
- 7 CSO contracts currently in the space
- Supported Speragen, Inc. in successful STTR proposal ($225k)

MEMBER COMPANIES

AUSTIN COMMUNITY COLLEGE
BIOSCIENCE INCUBATOR

macmillan learning
lab solutions

KJ SCIENTIFIC

FABRICO TECHNOLOGY

CELLING BIOSCIENCES

HALO

EQ
Environmental Quality Operations

kinetoch
em

CASE STUDY

AUSTIN COMMUNITY COLLEGE
BIOSCIENCE INCUBATOR

Problem: Required wet lab space & equipment to complete proof-of-concept studies surrounding novel biological monitoring techniques in aquatic environments

CSO Solution: ABI was able to supply required infrastructure

Results: Successful proof-of-concept; Technology is now launched and company is actively soliciting contracts; CEO/Founder worked with ACC faculty & led class on qPCR.

Cost Savings:

- Equipment – Leased ACC equipment = $89,000
- Wet lab facility – Company was quoted $70k to build out 700 SF

Total Savings = $156,000 and 2 months

Founder worked with faculty member to develop curriculum based on company's technology

CASE STUDY

AUSTIN COMMUNITY COLLEGE
BIOSCIENCE INCUBATOR

Problem: Required wet lab space and cell culture equipment to conduct R&D surrounding decellularization of tissues (DOD SBIR Phase II)

CSO Solution: ABI was able to supply wet lab space, equipment, and 2 interns

Results: Completed Phase II research; Found new applications for technology in brain tissue and skin; Supported intern for job interviews and references

Cost Savings:

- Equipment – Leased ACC equipment = $79,000
- Personnel – Internships; 560 hours x $12.50 = $7,000
- Wet lab facility – Company was quoted $150k to build out 500 SF

Total Savings = $230,000 and 2-3 months

Principal scientist served as reference for interns when applying for jobs

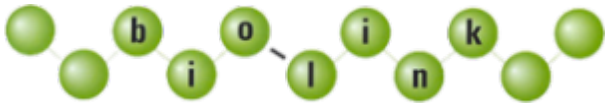
APPLY TO JOIN THE BIOSCIENCE INCUBATOR AT ACC:

sites.austincc.edu/incubator/apply

CONTACT THE DIRECTOR OF THE BIOSCIENCE INCUBATOR AT ACC:

tyler.drake@austincc.edu
515-233-7163

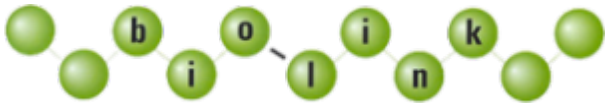
QUESTIONS?



Bio-Link Resources

- Biotech-Careers.org
- Bio-Link.org
- Links to archived webinars
- Summer Fellows Forum – June 7-10th
- Sign up for our newsletter

TIME FOR THE SURVEY



THANK YOU!