

# New Core Skill Standards for Bioscience Technicians: Making them Work for Us

[Click here to watch the webinar recording](#)

Webinar,  
Friday, February 17: 3:00-4:30 EDT

Lisa Seidman, Ph.D.

Jeanette Mowery, Ph.D.

Linda Rehfuss Ph.D.

Linnea Fletcher Ph.D.





# Moderator



Elaine Johnson, PhD  
Bio-Link, CA.  
City College of San  
Francisco



# 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



Jeanette Mowery, Ph.D  
Madison College, WI  
Leadership Team, Bio-Link



Lisa Seidman, Ph.D  
Madison College, WI  
Co-PI Bio-Link



Linda Rehfuss Ph.D  
Bucks County Community  
College  
NBC2



Linnea Fletcher Ph.D  
Dept. Chair, Austin Community College, TX  
PI, AC2 Bio-Link Regional Center

## Now, Tell Us About You!

- What is your primary affiliation?
  - a) 2-year community/technical college
  - b) 4 year college or university
  - c) High school educator
  - d) Industry
  - e) Other

## How many are participating today?

- a) Myself
- b) 2-4 persons
- c) 5-7 persons
- d) 8-10
- e) More than 10

# AGENDA

- Introduction; reproducibility in science, a contemporary hot topic
- The New Core Skill Standards
- Teaching Resources
  - Bio-Link
  - NBC2
  - Other
- Now that we have them, what do we do with them? Lessons from Texas

## Cancer reproducibility project releases first results

An open-science effort to replicate dozens of cancer-biology studies is off to a confusing start.

**Monya Baker & Elie Dolgin**

18 January 2017

## SHARE



3K



61



342



DAVIDE BONAZZI

## Rigorous replication effort succeeds for just two of five cancer papers

By Jocelyn Kaiser | Jan. 18, 2017, 1:00 PM

# Science

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0

**Jocelyn Kaiser**

*Science* 20 Jan 2017:  
Vol. 355, Issue 6322, pp. 234-235

## Mixed results from cancer replications unsettle field

# **Reproducibility Project only Partially Able to Validate Findings of Prominent Cancer Studies**

Jan 19, 2017 By Randi Hernandez

# What are these Headlines about?

- 2012, Amgen researchers reported failure to replicate 47 of 53 landmark cancer papers
  - Why this really matters
- The Reproducibility Project: Cancer Biology launched 2013
- First results from 5 studies announced January 19, 2017
  - Replicated two out of five studies
  - One study not replicated
  - Two studies were inconclusive

# Why is this a Big Deal?

- Consequences for patient treatments/prevention
- Huge financial implications
- Affects the public's view of science
- Strikes at the heart of what science is all about

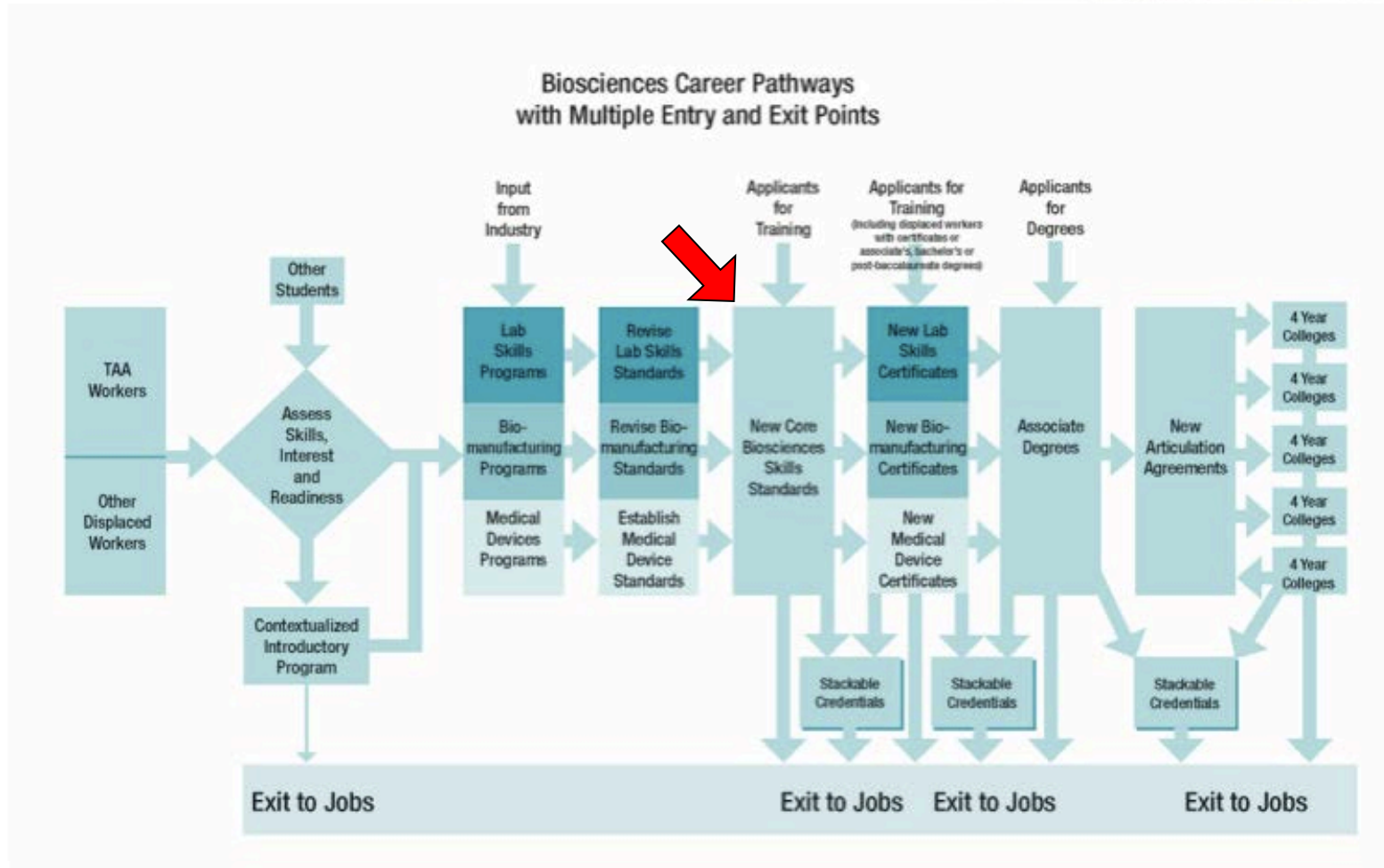
# Journalists' Response

- Journals have already responded by adding much more detail in research reports

# Now Let's Introduce the Core Skill Standards



# DOL TAACCCT Grant



Trade Adjustment Assistance Community College Career Training

# Forsyth Tech Community and Technical College



## Organization of the 12 College Consortium:

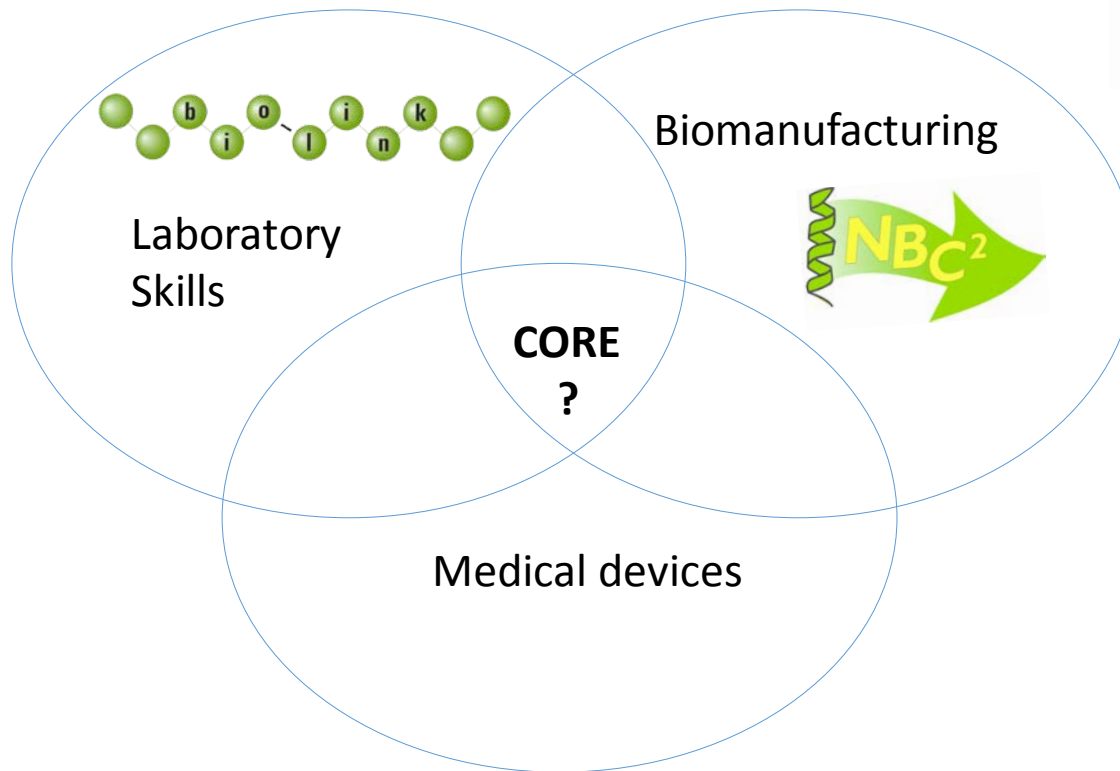
<b>Biomanufacturing Hub</b>	<b>Bioscience Lab Skills Hub</b>	<b>Medical Devices Hub</b>	<b>Learning Technologies Hub</b>
Led by <b>Dr. Sonia Wallman, NBC2</b> Montgomery County CC, PA	Led by <b>Dr. Elaine Johnson, Bio-Link</b> City College of SF, CA	Led by <b>Dr. Sengyong Lee</b> Ivy Tech CC, IN	Led by <b>Michael V. Ayers</b> Forsyth Tech CC, NC
Bucks County CC, PA	Madison Area Technical College, WI	Salt Lake City CC, UT	Alamance CC, NC
LA Valley CC, CA	Austin CC, TX	St. Petersburg CC, FL	Rowan-Cabarus CC, NC



# Grant Strategies to Assist TAACCCT Workers

- Improve and expand recruitment
- **Harmonize a set of bioscience core skills**
- Accelerate completion time in credentialing programs
- Build capacity for bioscience education

# What does "harmonization" mean?



## What skills are held in common?

# Why focus on *CORE* skill standards?

- **Tremendous Diversity of Entry Level Technician Positions**
  - Define skills and knowledge necessary for entry level positions
  - Students know and can articulate what they know
  - Industry recognizes what students know
  - Provide a framework for developing curriculum and courses
  - Provides the means for measuring student performance
- Facilitate process to award credit for prior learning
- Possibly develop credential based on those core competencies

# PROCESS

Biomanufacturing	Laboratory Skills	Medical Device	CORE Skill
Accesses and uses SDS (MSDS) and LOTO	Find and Use SDS (MSDS) and other information resources	Locate and Apply MSDS (SDS) in material handling (2.2 Prod)	Locate and Use MSDS (SDS) and other information sources
Works with hazardous/biohazard materials	Follow institutional policies relative to hazardous materials and biohazard	Adhere to safety requirements (OSHA), blood borne pathogen and FDA requirements (7.4 Eng)	Comply with safety requirements (institutional, regulatory agency, etc)
Records data and documents activities (paper hard copy and electronically)	✓	✓	

# Components of Core Skill Standards

- Critical Work Functions
  - Major responsibilities of the job
    - Example: “Provide routine facility support”
- Key Activity
  - Essential task performed to accomplish the CWF
    - Example: “Maintain inventory of raw materials, parts, components, and/or equipment”
- Performance Indicator
  - Concrete, visible ways that we will know the individual is doing the activity correctly
    - Periodic inventory of stock taken in compliance with established procedures; Materials are stored appropriately; Expired materials are discarded
- Underlying Technical Knowledge
- Assessment
  - Exercise to determine proficiency

# Industry Input and Recognition

- Core Team Experience

- Dr. Linda Rehfuss
- Dr. Vivian Ngan-Winward
- Dr. Jeanette Mowery



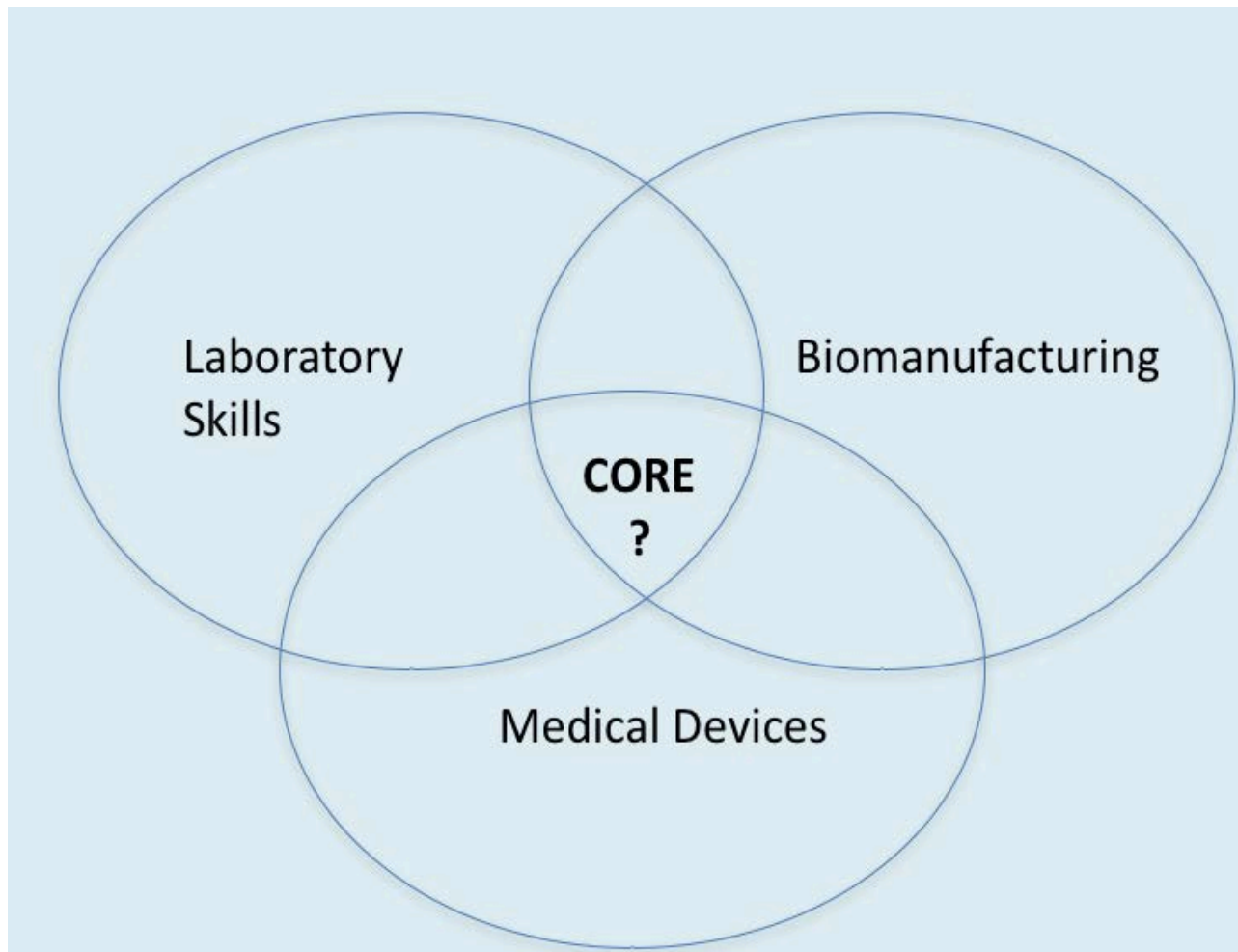
- Face to face meetings

- National Advisory Council for c3bc Consortium

- Online Survey

- Industry Supervisors of Entry-level technicians
  - 22 Industry supervisors from across the 3 industry subsectors gave feedback

# CAVEAT: Necessary but NOT sufficient



# Where to find the Core Skill Standards



- Bio-Link web site:
  - <http://www.bio-link.org/home2/publication/core-skill-standards-for-bioscience-technicians>
- National Center for the Biotechnology Workforce
  - <http://www.biotechworkforce.org/>
- Skillscommons.org
- Email us for electronic or paper copies
  - [jmowery@madisoncollege.edu](mailto:jmowery@madisoncollege.edu)

# Return to the Reproducibility Studies

- Reproducibility is fundamental to laboratory research and all laboratory testing
- Reducing variability is also fundamental to all production
  - Biomanufacturing
  - Medical devices
- So it is not a surprise that the core skill standards address reproducibility/reducing variability

# CORE CRITICAL WORK FUNCTIONS

- Provide routine facility support
- Perform measurements/tests/assays
- Comply with applicable regulations and standards
- Manage and communicate information
- Perform mathematical manipulations
- Maintain a safe and productive work environment

# CRITICAL WORK FUNCTION: Provide routine facility support

## Key Activity: Monitor, maintain, and troubleshoot equipment

### Performance Indicators:

- Preventative maintenance is performed and equipment logbook is maintained
- Monitoring activities are performed and documented according to established procedures
- Basic equipment troubleshooting is performed

### Underlying Knowledge:

- Maintenance requirements of different pieces of equipment
- Proper documentation practices

## Key Activity: Use equipment correctly according to manufacturer's guidelines

### Performance Indicators:

- Equipment performance is verified prior to use
- Recommended operating conditions of the equipment is used
- Initialization and shutdown of equipment is performed correctly


### Underlying Knowledge:

- Concepts of calibration, verification, qualification, validation
- General principles of metrology
- Use of calibration standards and traceability


# CRITICAL WORK FUNCTION: Perform measurements / tests / assays

## Key Activity: Follow appropriate test procedures/ instructions

### Performance Indicators:


- Tests are performed according to established procedures
- Appropriate measurement/ test tool(s) is(are) chosen for the application
- Measurement/ test tool(s) is(are) used correctly 

### Underlying Knowledge:

- Appropriate use of applicable test equipment
- Types and causes of measurement error 
- Distinction between accuracy and precision
- Relevant measurement range and resolution of different tools
- Uncertainty in measurement

## Key Activity: Document data and results according to established procedures

### Performance Indicators:

- Lab notebook is maintained properly 
- Batch records are completed properly
- Information is entered correctly in an electronic database


### Underlying Knowledge:

- Importance of proper documentation practices

# CRITICAL WORK FUNCTION: Comply with applicable regulations and standards

## Key Activity: Follow established policies and procedures

### Performance Indicators:


- SOP or procedure is executed correctly and completely
  - Deviations are handled appropriately
- 

### Underlying Knowledge:

- Familiarity with applicable current federal, state, local and industry regulations and standards
- Familiarity with the FDA (e.g. history, enacted laws/ promulgated regulations, organizational structure, premarket approvals, etc.)
- Consequences of noncompliance
- Types of documents (quality manual, quality policy, standard operating procedures, work instructions, etc.)
- Policy/ procedures for deviations

## Key Activity: Exercise proper document control

### Performance Indicators:

- Changes to documents are made in accordance to established change control system
- 

### Underlying Knowledge:

- Concepts related to document changes, approvals, and distribution/controlled documents

# CRITICAL WORK FUNCTION: Comply with applicable regulations and standards



## Key Activity: Adhere to traceability principles

### Performance Indicators:

- Items (e.g. raw materials, in-process product, final product, samples, etc.) are labeled appropriately
- Material lot numbers/ equipment identification numbers are recorded

### Underlying Knowledge:

- Concept and importance of traceability within the bioscience workplace
- Traceability of materials, documentation, and training

## Key Activity: Participate in validation activities

### Performance Indicators:

- Draft procedure is tested and feedback to author is provided

### Underlying Knowledge:

- Types of validation: equipment (IQ, OQ, PQ), methods, process

# CRITICAL WORK FUNCTION: Comply with applicable regulations and standards

## Key Activity: Adhere to control principles in accordance with the established quality system

### Performance Indicators:

- Knowledge of change control is demonstrated
- Knowledge of purchasing controls are demonstrated
- Knowledge of production and process controls is demonstrated
- Knowledge of labeling and packaging controls are demonstrated
- Knowledge of materials management/ control is demonstrated

### Underlying Knowledge:

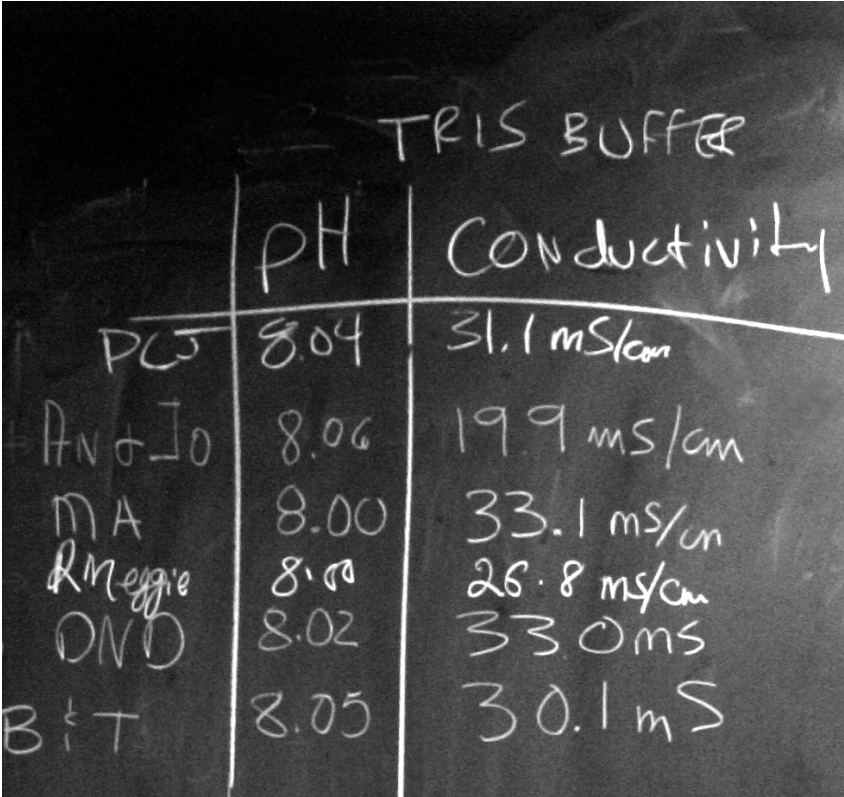
- General change control philosophy
- Potential consequences that may arise when change is not controlled
- Supplier relationships, supplier agreements, supplier qualifications, supplier management, supply chain management, purchasing documentation, traceability, and approvals
- General philosophy with consideration of materials, methods, machine, man, and environment; monitoring program; material control and traceability; established procedures and compliance with them; equipment monitoring, inspection, maintenance, and repair; personnel with appropriate and current training; facility and environmental control for product/process quality/ consistency
- Label integrity, appropriate label information content, inspection of labeling, storage and controlled issuance for use, packaging selection considerations
- Incoming raw materials handling (quarantine, acceptance or rejection after inspection/ QC testing, storage for use or disposition of rejected material), FIFO (first in first out), inventory, purchasing

# What is Required to Reduce Variability/Promote Reproducibility?

- Journalists' solution is to print details
- Educators' solution is....education

# Data to Consider

1 M Tris Buffer, pH 8.0



A handwritten table on a chalkboard titled "TRIS BUFFER". The table has two columns: "pH" and "Conductivity". The data is as follows:

	pH	Conductivity
PC5	8.04	31.1 mS/cm
Ant + Jo	8.06	199 mS/cm
MA	8.00	33.1 mS/cm
R Meggie	8.00	26.8 mS/cm
DND	8.02	33.0 mS
B & T	8.05	30.1 mS

# What Does this Mean?

- Cannot assume that individuals have these core skills
- Education is critical
- We can address core skills explicitly in our classes
  - Next topic


**QUESTIONS?**

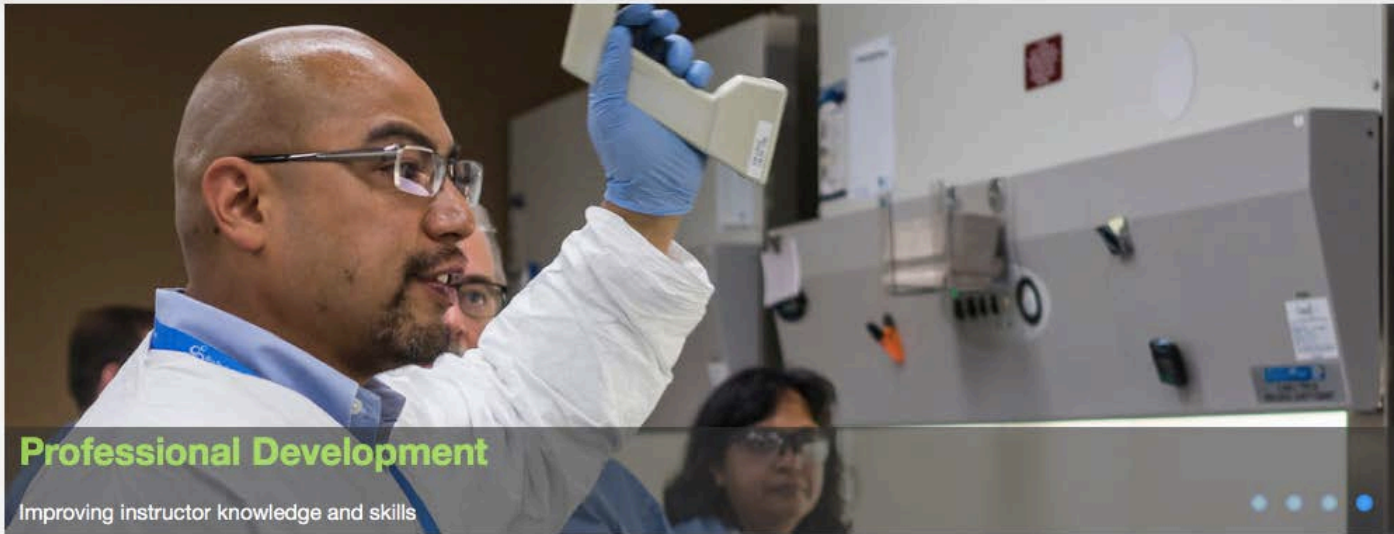
# RESOURCES

- [Bio-Link.org](http://Bio-Link.org)
- NCBionetwork: [NCBionetwork.org](http://NCBionetwork.org)
- NBC2: [Biomanufacturing.org](http://Biomanufacturing.org)

# Bio-Link: COURSES IN A BOX



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**Professional Development**  
Improving instructor knowledge and skills

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- Learn about biotech careers
- Find programs in your area

**FOR INSTRUCTORS**

- Learn how Bio-Link helps
- Learn about Courses in a Box

**FOR EMPLOYERS**

- Learn about skills taught
- Recruit interns and employees



# Course-in-a-Box

## The Courses

### Basic Laboratory Methods in a Regulated Environment

Submitted by Lisa Seidman on Sun, 2011-03-06 19:04

Biotechnology transforms knowledge that emerges from life science research into technology, the creation of products of value to people. Beginning biotechnology students therefore need to develop a strong foundation in laboratory science that is integrated with an ... [Read more](#)

### Cases in Industry Practice in Biotechnology

Submitted by Jeanette Mowery on Wed, 2012-01-04 14:26

Cases in Industry Practice in Biotechnology (CIPB)

Authors : V. Celeste Carter and Kristen Hershbell Charles

These instructional materials were developed in collaboration with industry partners and utilize a case-method approach with hands- ... [Read more](#)

### Embryonic Stem Cell Course (Stanford)

Submitted by Jeanette Mowery on Wed, 2011-07-20 11:46

These instructional materials were developed with support from the National Science Foundation and have been used in embryonic stem cell courses at Stanford and at San Francisco State University. Materials include Laboratory Protocols for both mouse and human embryonic stem cells, Lectures, ... [Read more](#)

### Hazardous Materials

Submitted by Mary Ellen Kraus on Fri, 2015-07-10 07:29

Welcome to the Hazardous Materials course-in-a-box. This course is not designed as a safety training course. The educational philosophy of this course, like that of most of the courses in the Biotechnology Laboratory Technician Program, is that properly educated technical students will have the ... [Read more](#)

### Laboratory Math for Biotechnology

Submitted by Mary Ellen Kraus on Fri, 2012-09-28 07:50

Bench work in the biotechnology laboratory requires that technicians possess certain fundamental math skills and the ability to apply these skills. Beginning biotechnology students often need a "refresher" of basic algebra, scientific notation, logarithms and graphing. They also need practice ... [Read more](#)

### Mammalian Cell Culture

Submitted by Jeanette Mowery on Sun, 2012-09-09 13:36

This course, from City College San Francisco, teaches the techniques necessary to maintain mammalian cells in culture. The course includes a laboratory exercise using mouse embryonic stem cells (takes 3 weeks to complete). Laboratory exercises provide instruction in basic techniques of routine ... [Read more](#)

### Quality Regulations and Standards

Submitted by Jeanette Mowery on Mon, 2012-11-19 09:02

Survey of Quality, Regulations, and Standards for Biotechnology

This Course-in-a-Box is about teaching quality and regulatory affairs. "Quality" products in this context means products that are suitable for their intended use and are free of defects and variability. Many vital ... [Read more](#)

# EXAMPLE COURSE

## Basic Laboratory Methods in a Regulated Environment

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Biotechnology transforms knowledge that emerges from life science research into technology, the creation of products of value to people. Beginning biotechnology students therefore need to develop a strong foundation in laboratory science that is integrated with an understanding of product quality. This course provides students with a foundation in basic concepts and techniques necessary to work as effective professionals in a biotechnology laboratory or small scale production facility. The course emphasizes metrology (the study of measurements), solution preparation, performing assays, and basic biological separation methods. These fundamental laboratory techniques are essential for student success in later molecular biology, cell culture, bioprocessing, analytical, and other specialized courses. Throughout the course the principles of product quality systems (e.g., Good Manufacturing/Laboratory Practices and ISO 9000) are integrated as students explore documentation, calibration, accuracy and precision, error reduction, trouble-shooting, verification and validation of assays, and other quality concepts. Integrating a "quality-mindset" into their laboratory work is important both for students who plan to work in a biotechnology company and for students who some day aspire to generate meaningful results in a research environment.

Submitted by Lisa Seidman (LSeidman@MadisonCollege.edu) and Jeanette Mowery (JMowery@MadisonCollege.edu)

Published Textbooks:

- Required: **Basic Lab Methods for Biotechnology** by Lisa Seidman and Cynthia Moore and **Laboratory Manual for Biotechnology and Laboratory Science** by Lisa Seidman, Mary Ellen Kraus, Diana Brandner and Jeanette Mowery.
- Recommended: **Basic Laboratory Calculations for Biotechnology** by Lisa Seidman

### Additional materials\*

- Syllabus
- Classroom Activities
- Lectures - video
- Lectures - Power point
- Sample of class discussion - video
- Instructors' notes for laboratory manual (part I)
- Instructors' notes for laboratory manual (part II)
- Instructors' notes for laboratory manual (part III)
- Sample Final Exam

**\*Course in a Box access:** The additional materials and supplementary materials listed above are available to **Bio-Link faculty-admin members**. You must log in to view these materials. The open material attachments can be downloaded without logging in.

# Additional material

View

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## Direct Links to Materials

- Syllabus ([syllabus.docx](#), 102 KB)
- Classroom Activities ([all\\_activities\\_in\\_one\\_file.pdf](#) 434 KB)
  - Kelsey Case Study ([kelsey\\_activity\\_2011.pdf](#) 334 KB)
  - How to Access the Code of Federal Regulations ([access\\_cfr\\_activity.pdf](#) 145 KB)
  - Reading GMP Regulations ([read\\_regulations\\_activity.pdf](#) 147 KB)
  - Quality Control in the M & M Factory ([qc\\_m\\_and\\_ms\\_activity.pdf](#) 115 KB)
- Lectures - Videos and Power point - click on the first word for the video version of the lecture; click on the ppt link for the power point version.
  - Workplace ([workplace ppt](#). 3.72 MB)
  - Quality parts I and II ([quality\\_parts\\_i\\_and\\_ii.ppt](#) 2.36 KB)
  - Documentation ([documentation.ppt](#) 2.86)
  - Brief Intro to Descriptive Statistics ([brief\\_intro\\_descriptive\\_statistics.ppt](#) 3.17MB)
  - Metrology ([metrology.ppt](#) 6.41MB)
  - Weighing ([weighing.ppt](#) 6.13 MB)
  - Volume ([volume.ppt](#) 8.53 MB)
  - pH ([pH.ppt](#) 3.61 MB)
  - Solutions 1 ([solutions\\_1.ppt](#) 6.45 MB)
  - Solutions 2 ([solutions\\_2.ppt](#) 121.5 KB MB)
  - Solutions 3 ([solutions\\_3.ppt](#) 2.63 MB)
  - Spectrophotometry ([spectrophotometry.ppt](#) 3.69 MB)
  - Filtration ([filtration.ppt](#) 1.06 MB)
  - Centrifugation ([centrifugation.ppt](#) 552 KB)
  - Summary of the Semester ([summary.ppt](#) 53.5 KB)
- Sample of class discussion - [Download Video](#) 500 MB
- Instructors' notes for laboratory manual
  - part I ([notes\\_to\\_instructors\\_part\\_i.pdf](#) 3.11 MB)
  - part II ([notes\\_to\\_instructors\\_part\\_ii.pdf](#) 13 MB)
  - part III ([notes\\_to\\_instructors\\_part\\_iii.pdf](#) 20 MB)
- Example Final Exam Questions ([sample\\_final\\_exam\\_questions.pdf](#) 448 KB)

FranklinBiologics.org

Kevin Turner  
QC Analyst

FRANKLIN  
BIOLOGICS

## Making the Call:

QUALITY IN BIOMANUFACTURING

See how the decisions of three employees of a fictional biotech company effect its prospects.

Corinne Lawton  
Upstream Technician

Aseem Komani  
Upstream Supervisor

PELLET

bioblink

# NCBionetwork.org



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Chromatography

Clinical Research Study Management

Comparing Title 45 and Title 21

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Deliberate Documentation

Determining Glassware Accuracy

Drug Development Overview

Environmental Monitoring

Fermentation

Filtration

Filtration Simulator

Gas Chromatography (GC)

Good Laboratory Practices (GLP)

Good Manufacturing Practice (GMP)...

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### Sterile Gowning Procedures

Sterile Gowning Procedures is a serious game that teaches the steps for proper sterile gowning and gloving.



### Job Interviewing

Getting ready for a job interview can be a stressful task. Being prepared

**QUESTIONS?**

# NBC2: [www.biomanufacturing.org](http://www.biomanufacturing.org)

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## Protein is Cash 2017

[VIEW ARTICLE](#)

# NORTHEAST BIOMANUFACTURING CENTER and COLLABORATIVE (NBC2)



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## Textbooks & Manuals

[Introduction to Biomanufacturing](#)  
[Biomanufacturing Laboratory Manual](#)  
[Escherichia coli - GFP Core Production Manual](#)  
[CHO Cell - tPA Core Production Manual](#)  
[Pichia pastoris - HSA Core Production Manual](#)

## Resources

[Audio/Video](#)  
[Presentations](#)  
[Standard Operating Procedures](#)  
[Skill Standards](#)

# NBC2

## **Mission**

- To coordinate local and regional efforts into a national biomanufacturing education and training system to promote, create, and sustain a qualified workforce.

## **Vision**

- To be the nationally recognized center of excellence that develops a world-class sustainable biomanufacturing workforce to improve the quality of life.

# NBC2 Leadership

Dr. Margaret Bryans, PI and co-Lead, Montgomery CCC, PA

Dr. Linda Rehfuss, co-PI and co-Lead, Bucks CCC, PA

Other co-PIs and Hubs:

- Professor James Hewlett, Finger Lakes CC, NY
- Professor Mike Fino, MiraCosta College, CA
- Dr. William Woodruff, Alamance CC, NC
- Dr. Sengyong Lee, Ivy Tech CC, IN

# NBC2: Textbook



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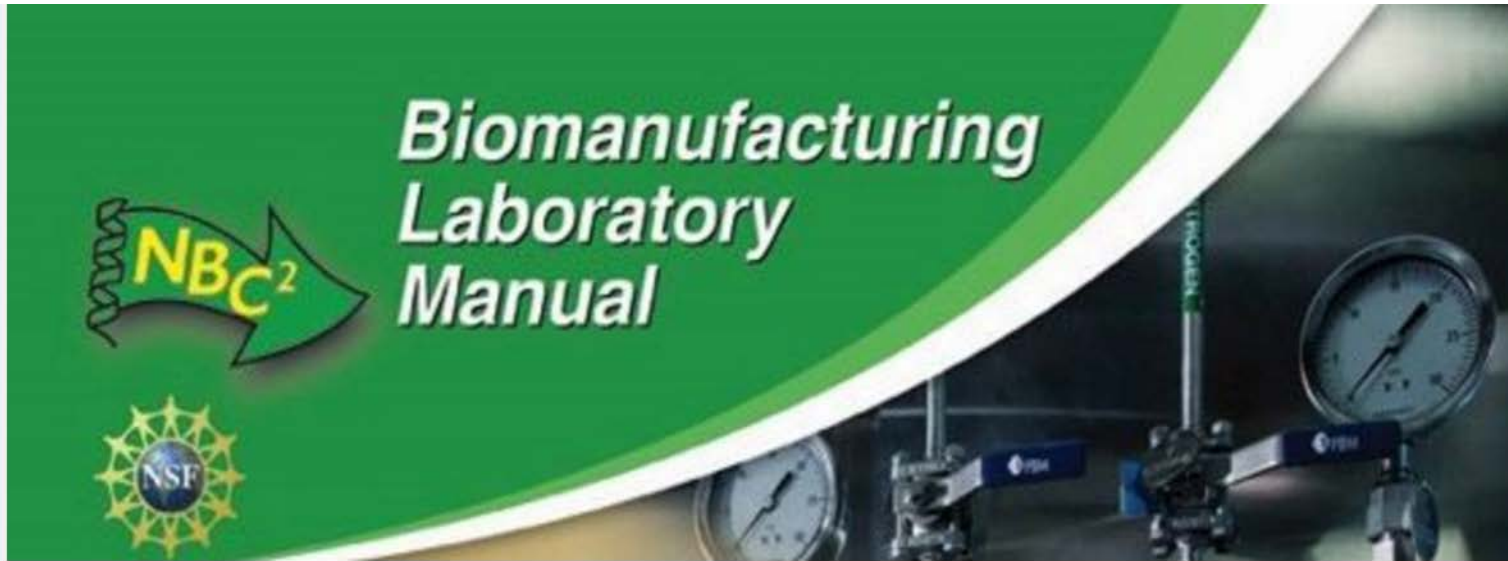


## Introduction To Biomanufacturing

by Northeast Biomanufacturing  
Center & Collaborative (NBC<sup>2</sup>)



# NBC2: Laboratory Manual



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## Biomanufacturing Laboratory Manual

# Example #1 of CWF and the NBC2 Curriculum meeting the Standards

**CRITICAL WORK FUNCTION:** Perform measurements / tests / assays

**Key Activity:** Collect samples according to established procedures and applicable sampling plans

## **Performance Indicators:**

- Samples of sufficient quality and quantity are taken

## **Underlying Knowledge:**

- Sampling procedures for the material/ product and sampling plans to be followed for testing
- Chain of custody requirements for samples

## **Suggested Assessments:**

- Have student demonstrate the collection and preparation of samples for testing according to an in-process testing procedure (provided) that has been simulated.

# Addressing CWF: Microbial ID

Montgomery County Community College  
340 DeKalb Pike  
Blue Bell, PA 19422

Document Number: QCM 7  
Revision Number: 3  
Effective Date: 18MAR14  
Page 1 of 5

## **SOP: API 20E Microbial Identification**

### **Approvals:**

Preparer: Dr. Maggie Bryans  
Reviewer: Jason McMillan

Date: 17MAR14  
Date: 18MAR14

### **1. Purpose:**

- 1.1. To perform a microbial identification assay.

### **2. Scope:**

- 2.1. This procedure is intended as a standardized identification system for *Enterobacteriaceae* and non-fastidious Gram-negative rods included in the database.

### **3. Responsibilities:**

- 3.1. It is the responsibility of the course instructor/lab assistant to ensure that this SOP is performed as described and to update the procedure when necessary.
- 3.2. It is the responsibility of the students to follow the SOP as described and to inform the instructor about any deviations or problems that may occur while performing the procedure.

### **4. References:**

- 4.1. API 20E System Brochure
- 4.2. Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – cGMP (FDA publication, September 2004)
- 4.3. United States Pharmacopeia 25
- 4.4. Gram Stain SOP
- 4.5. Bergey's Manual of Systematic Bacteriology

### **5. Definitions:**

- 5.1. *Enterobacteriaceae*: Family of Gram-negative, rod bacteria that inhabit soil, water and are commonly found in the large bowel of humans. Most common organisms isolated

# Example #2 of CWF and NBC2

validation

Previous

## Key Activity: Participate in validation activities

### Performance Indicators:

- Draft procedure is tested and feedback to author is provided

### Underlying Knowledge:

- Types of validation: equipment (IQ, OQ, PQ), methods, process

## Key Activity: Recognize and address non-conformances

### Performance Indicators:

- Appropriate corrective and/or preventative action(s) is(are) taken and documented

### Underlying Knowledge:

- Nature of specifications for raw materials and products

# Example #2 of CWF and the NBC2 Curriculum meeting the Standards

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## Validation

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### VALIDATION

#### Autoclave IQ Protocol



Example autoclave IQ protocol developed by Montgomery County Community College

### VALIDATION

#### Autoclave Monitoring Form

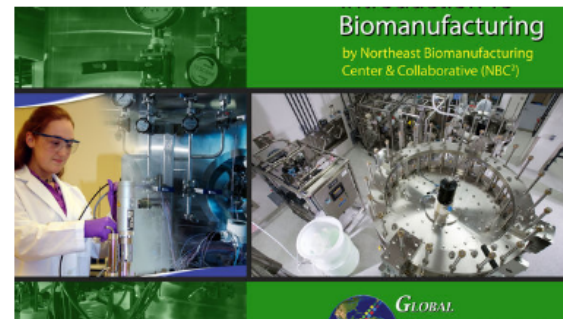


Autoclave monitoring form developed by Montgomery County Community College



## Related Content

OTHER RESOURCES



# Addressing CWF: Validation of an Autoclave- SOP

## Example of an OQ protocol for an autoclave:

### AUTOCLAVE OQ

#### Objective

To determine that the autoclave model # \_\_\_\_\_, installed in building \_\_\_\_, room \_\_\_\_ operates according to specifications, to determine the heat /steam distribution in the jacket and empty chamber and to record all relevant information and data to demonstrate it functions as expected.

#### Scope

- a) For new installation, modification, replacement, or relocation of any critical component of the autoclave.
- b) If there is a contamination problem.

To be performed after the IQ has been completed and approved.

#### Responsibility

Supervisor of the Department where the autoclave is located is responsible for writing the protocol, supervising the performance of the OQ, verifying the data and writing the OQ report.

QA is responsible for approving the protocol and reviewing and approving the data and conclusions.

#### Equipment and Documents

Example of calibration instruments required are:

thermocouples, pressure calibrator, vacuum calibrator, temperature detectors and probes, timers, temperature bath, flow meters. (Certification methods should be referenced)

SOP# \_\_\_\_: Operation, Maintenance, and Calibration of the Autoclave

# Example #3 Documentation

## BIONETWORK'S GLP TRAINING MODULE

Interactive training module on Good Laboratory Practices (GLP) from BioNetwork

BIOMAN, PRESENTATION, QUALITY ASSURANCE, BIOMAN 2013

## Biopharmaceutical Quality

PowerPoint slides from BIOMAN 2013, presented by Cynthia Sarnoski, member of the NBC2 National Visiting Committee and retired VP of Quality at Pfizer



QUALITY ASSURANCE

## cGMP Popcorn Exercise

Lab activity developed by Montgomery County Community College to introduce students to GMP processes and concepts

A collage of four images related to biomanufacturing: a green-tinted image of industrial equipment, a woman in a lab coat working with equipment, a large industrial bioreactor, and a globe with a DNA helix.

**Biomanufacturing**  
by Northeast Biomanufacturing Center & Collaborative (NBC<sup>2</sup>)

**GLOBAL BIOMANUFACTURING**

**FILE**

**Chapter 7: Quality Assurance**

Chapter 7 of Introduction to Biomanufacturing

**VIEW FILE**

# Example # 3- Documentation Practices: Popcorn GMP exercise

## **Goal:**

- Make a batch of GMP popcorn within a specified timeframe (1.5 hours).

## **Objective:**


- Understand the complexity of a GMP process.
- Gain appreciation of teamwork and cooperation of all departments.
- **How it mirrors industry:**
  - You will be frustrated at times
  - You will be rushed.
  - You will feel a sense of accomplishment once you made the batch!
- The actual time for the chemistry / fermentation / etc. is very small compared to the time it takes to get all GMP documentation in place.

# AC2 Bio-Link Regional Center



## Helping students

Catalyzing lab skills for the bioeconomy

- **2016-2017 Bio-Link webinar series!**  DUE #1507521  
Fri, Sep 30 2016 to Tue, May 30 2017
- **Bioinformatics course for instructors:** Austin TX,  
Mon, Jan 23 2017 to Fri, May 12 2017
- **CSOs and Incubators at Educational**

AC2 is a **Bio-Link** Regional Center

**Join Bio-Link Today!**



### What's New?

- Blog entry | **New HIV Self-Test -- what are the implications?**
- Blog entry | **BCTC Biotech staff and students attend IdeaFestival 2016!**
- Blog entry | **White Coat**

### Emerging Technologies

A challenge in a dynamic area like biotechnology is identifying new technologies and deciding which to include in courses and how best to teach them. Join us in the adventure!  
**[View Updates](#)**

### Undergraduate Research

To embed undergraduate research into classes within AC2 partner institutions and to foster a national mentoring network for broader implementation of undergraduate research. **[View Updates](#)**

### Entry Level Certificates

Develop and implement certificates and degrees that allow students articulated entry, at different points, into the biotechnology industry following high school or college. **[View Updates](#)**

### Contract Services (CSOs)

Create a community college Contract Service Organization (CSO) to pair industry projects with student internships and faculty externships.  
**[View Updates](#)**

### Statewide Articulation

Strong articulation partnerships create pathways that lead to academic transferability and degree completion.  
**[View Updates](#)**

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Careers

Educator Resources

Industry Resources

Grants



## Students study 3D printing

ACC students are trained to set up and maintain a Makerbot 5th generation Replicator 3D printer. [Read more...](#)



AC2 BIO-LINK  
REGIONAL CENTER

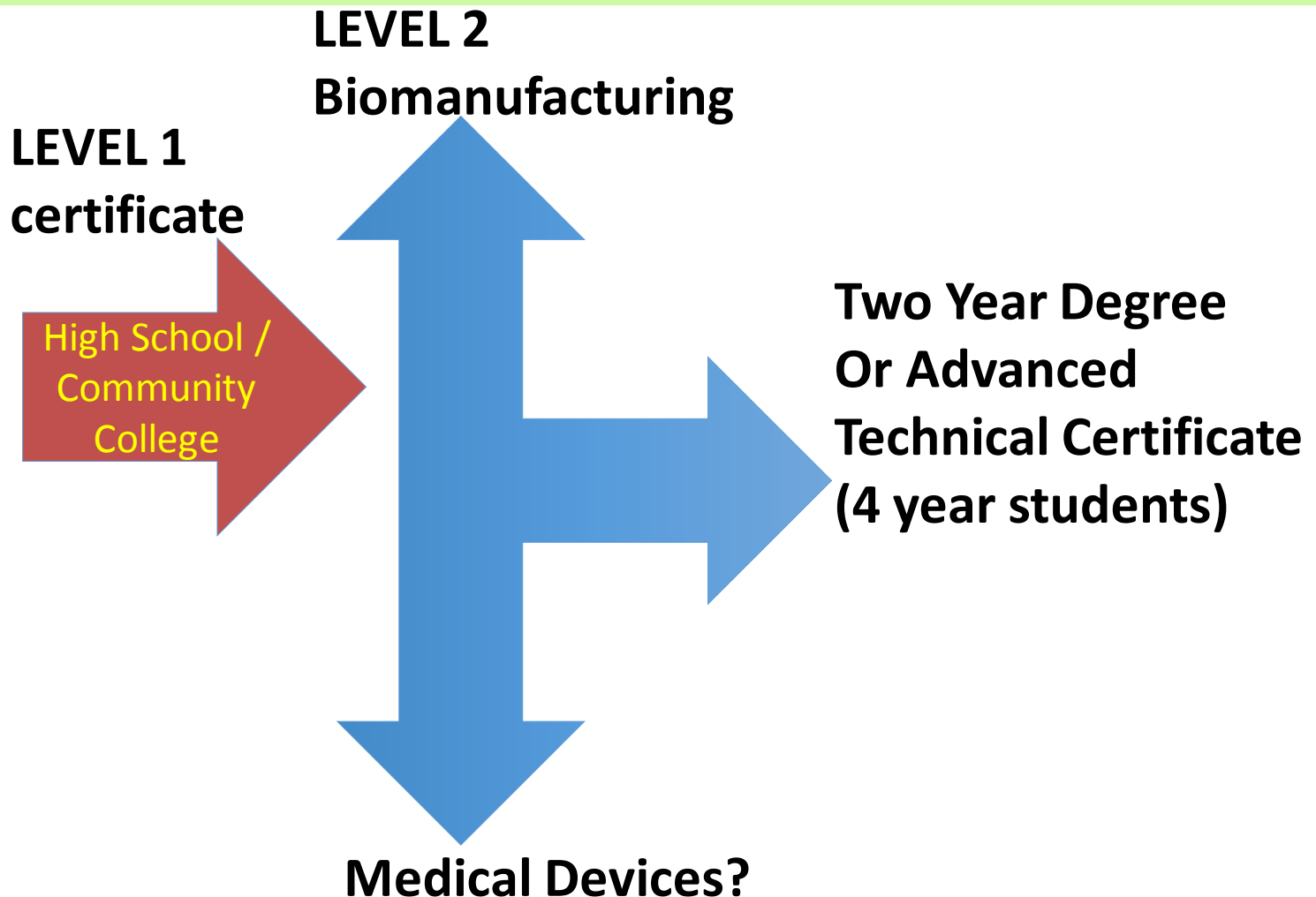


DUE #1507521

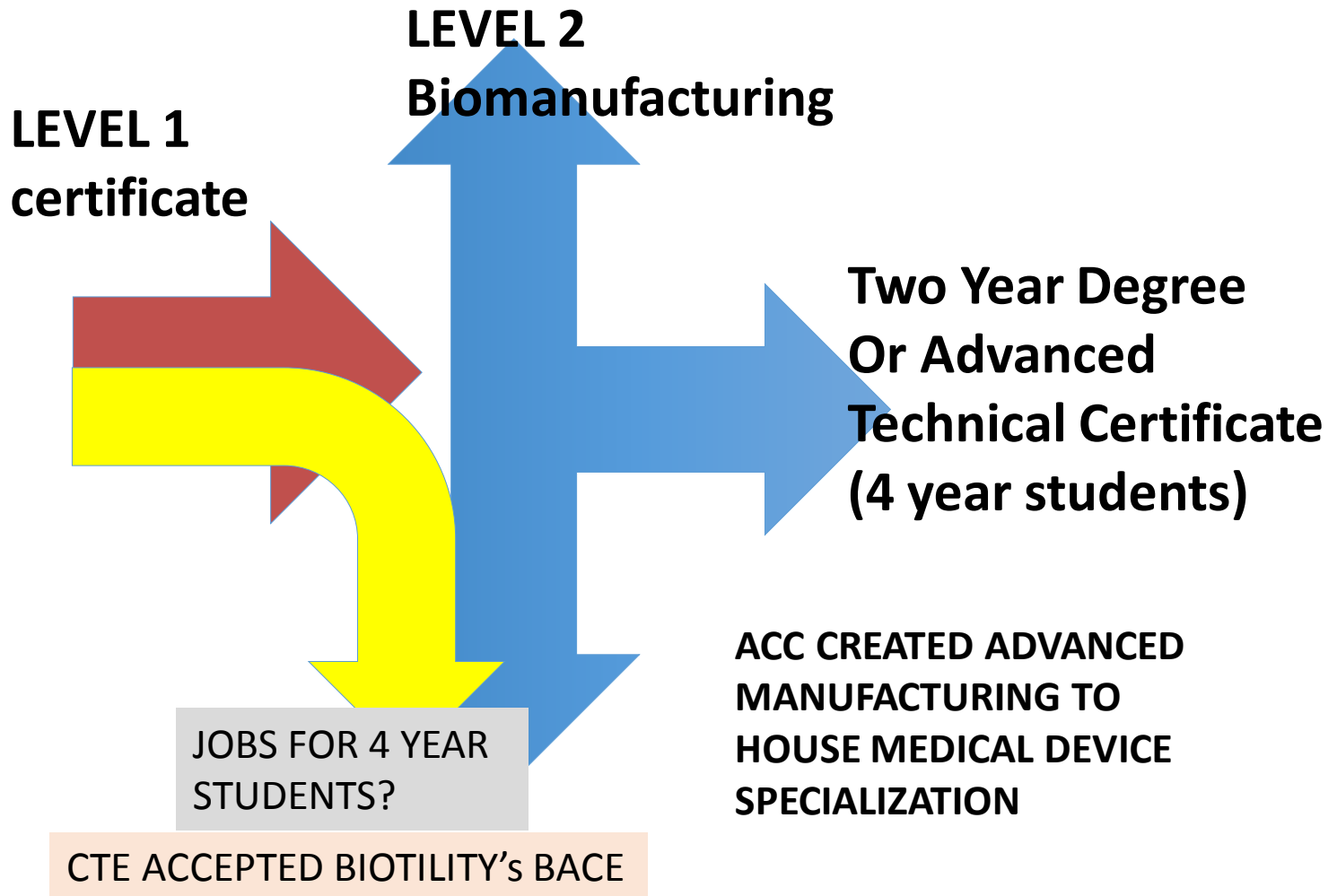
[www.austincc.edu/biotech/](http://www.austincc.edu/biotech/)

Call 512 223 5912

# A Case Study: News from Texas



# A Case Study: What Has Actually Happened So Far





# Biotechnician Assistant Credentialing Exam (BACE)

Based on foundational concepts and skills required in biotechnology-based workplace settings

- Written & Practical exam questions/skills
  - Aligned w/Academic and Performance Standards
- Industry recognition through BioFlorida
  - Accuracy, Alignment of Questions to Standards, and Representative of Industry needs
    - Biopharmaceutical, Diagnostics, Environmental
- Approved by Florida's Board of Education, Jan., 2012 for statewide articulation (A.S.) Biotechnology
- Manufacturing and Health Science Career Clusters

# Other Bio-Link Resources

- [Biotech-Careers.org](http://Biotech-Careers.org)
- [Bio-Link.org](http://Bio-Link.org)
- Links to archived webinars
- Sign up for our newsletter



# Upcoming Events

- Summer Fellows Forum
  - June 5-9<sup>th</sup>, Berkeley, CA
- HI-TEC Conference
  - July 17-20, Salt Lake City, UT



# Future Webinars

- **March TBD: Third Party Certification & Entry level Certificates**
- **TBD: 4 Year Biotech Programs**
  - At 2 year Community Colleges
    - MiraCosta, Bellevue, Solano, Miami Dade
  - At traditional 4 year colleges
    - Texas A&M Texarkana

**QUESTIONS?**

# TIME FOR THE SURVEY

[https://wsu.co1.qualtrics.com/SE/?SID=SV\\_brUGLDf2iPRo13n](https://wsu.co1.qualtrics.com/SE/?SID=SV_brUGLDf2iPRo13n)

**THANK YOU!**