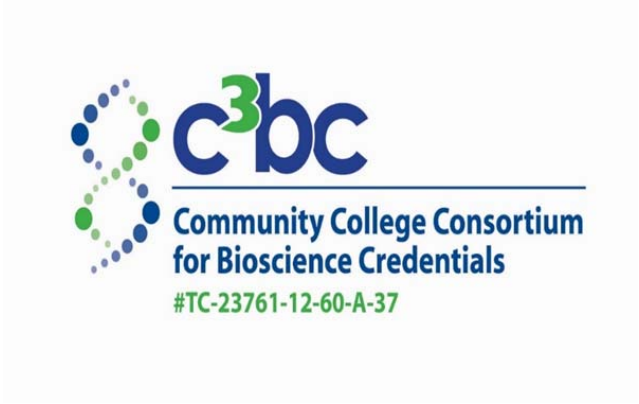


c3bc Panel
What did we do & learn?

San Francisco

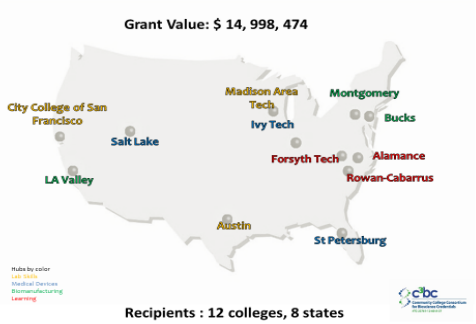
June 6, 2016

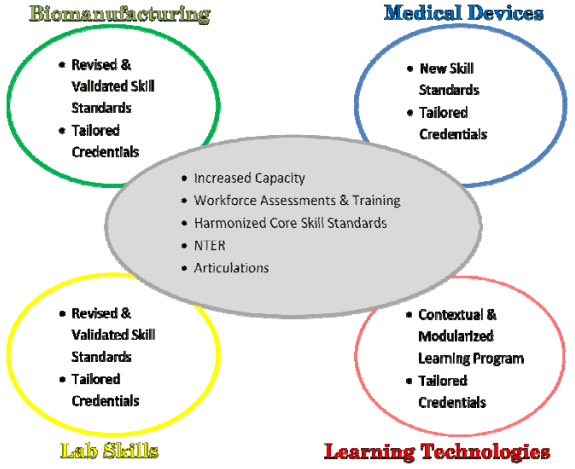
Russ H. Read, Sengyong Lee, Elaine Johnson, Sonia Wallman, Michael Ayers, Steve Dahms

c3bc- Mission

- What did we set out to do?
- What did we accomplish?
- What did we learn?

The Players & Plan






600
GRANT

Addressing HS students at the NCBW

National Approach

c3bc
Community College Consortium for Bioscience Credentials
#TC-23761-12-60-A-37


SLCC StudentFactured program

- Increase capacity by building new programs - credit & short non-credit programs for technicians
- Build Bioscience Harmonized Skill Standards. Create Medical Device Skill Standards.
- Remove barriers to achieving training (flexible labs, simulations & gaming programs)
- Industry Advisory Council's input on credentials & program development
- Promote seamless articulations from 2-year schools to 4-year schools = 2+2 and back to 2-year from 4-year schools and beyond for hard skills training
- Promote internships


Capstone Boot Camp Students

LAVC Bridge Class

Accomplishments

Austin CC students

- Completed expansion of upgrades on equipment and training capacity at multiple colleges
- Created the first set of industry-validated Medical Device Skills Standards for training entry-level technicians
- Created industry-validated Core Bioscience Skill Standards
- Delivered a modular and open resource approach to learning the biosciences and a novel Science Skills Laboratory
- Well into the process of uploading grant products to the virtual entities of NTER & Skills Commons.org for universal access
- Bioscience training opportunities were provided to over 3,000 displaced workers and students and a successful LAVC Bridge Program
- c3bc colleges created multiple new certificates, programs and degrees to accelerate students completion
- The unique BioNetwork Capstone experience has been offered to 35 students from across the country

Austin Veteran Grad

Accomplishments

Bucks CC student

- The National Advisory Council has met to review the progress of the grant either virtually or in person several times for guidance and input
- The Manufacturing Institute(MI) has teamed up to produce case histories of work with employers and job training placements of c3bc graduates
- The Abt Evaluation team has been proactive with the sites and has tapped into some of the great partnerships occurring between colleges, workforce and industry
- The grant is actively disseminating information through IMPACT magazine, MI & conference presentations & posters & Skills Commons
- The grant has undergone 6 budget modifications to meet the needs of the twelve participating colleges and two successful site visits by the US DOL

Sengyong Lee- Medical Devices Hub

What did we do ? What did we learn?

- Medical Devices Skills Standards

Dissemination of Medical Device Skill Standards

San Francisco, CA

June 5, 2016

Funded by DOL #TC-23761-12-60-A-37

Sengyong Lee Ph.D.

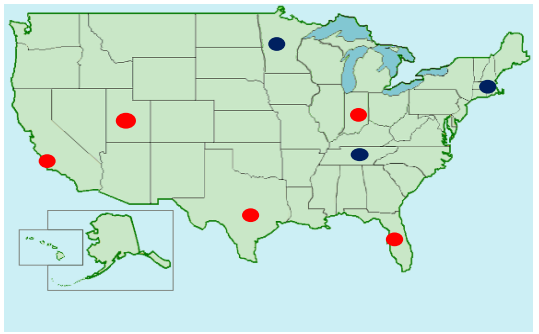
Medical Device Hub Leader

Professor & Program Chair

Biotechnology

Ivy Tech Community College Bloomington

✓ *The Medical Device Hub Partner Colleges*



Anoka Ramsey Community College in MN

Austin Community College in TX

College of the Canyons in CA

Ivy Tech Community College in IN

Moorpark College in CA

Mount Wachusett Community College in MA

Saint Petersburg College in FL

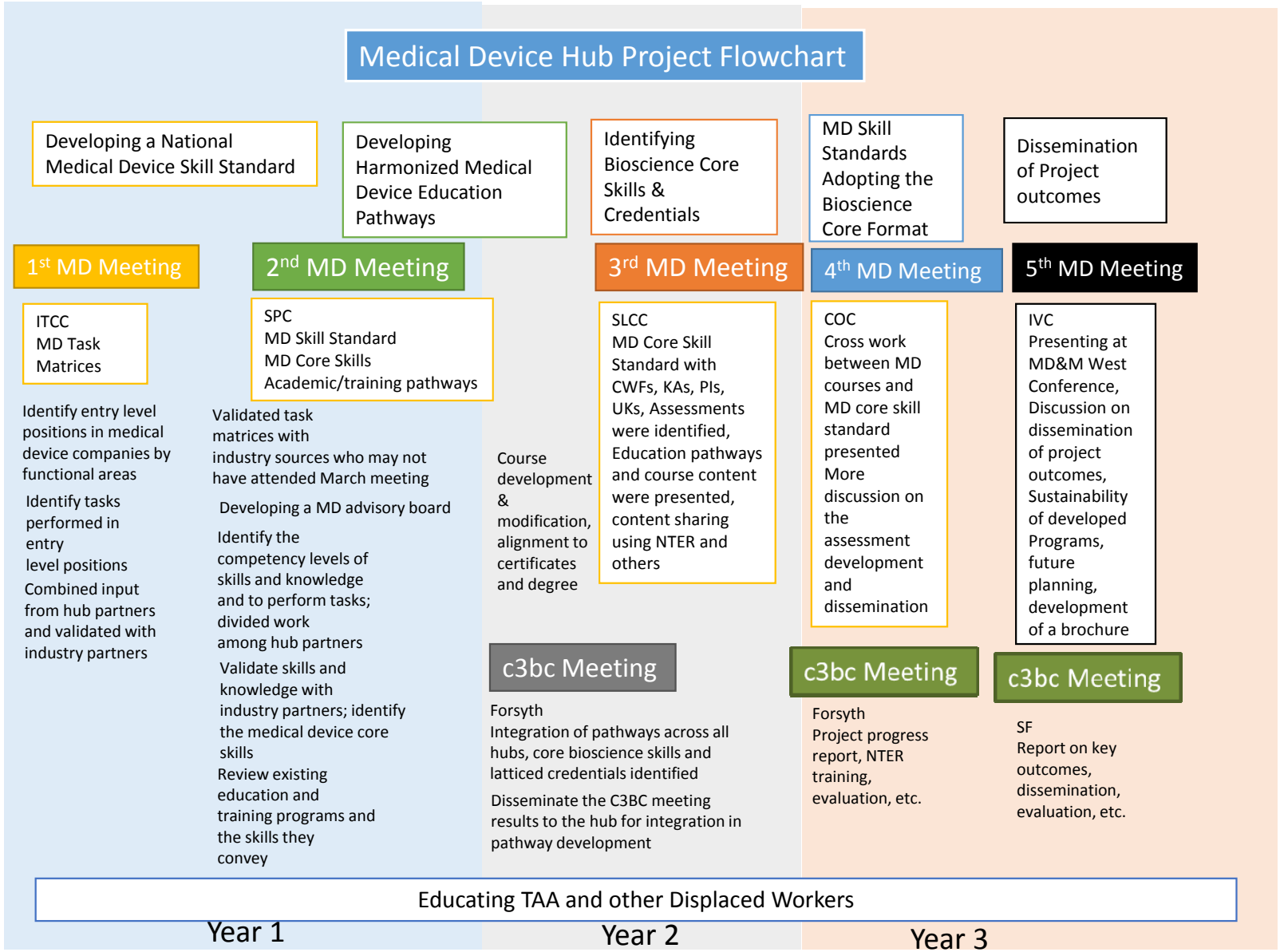
Salt Lake Community College in UT

Southern California Biomedical Council in CA

Ventura County Community College District in CA

William Moor College of Technology in TN

**** The Grant Funded Colleges were italicized.***


Medical Device Hub Project Flowchart
Developing a National Medical Device Skill Standard
Developing Harmonized Medical Device Education Pathways
Identifying Bioscience Core Skills & Credentials
MD Skill Standards Adopting the Bioscience Core Format
Dissemination of Project outcomes
1st MD Meeting
2nd MD Meeting
3rd MD Meeting
4th MD Meeting
5th MD Meeting
ITCC
MD Task Matrices
SPC
MD Skill Standard
MD Core Skills
Academic/training pathways
SLCC
MD Core Skill Standard with CWFs, KAs, PIs, UKs, Assessments were identified, Education pathways and course content were presented, content sharing using NTER and others
COC
Cross work between MD courses and MD core skill standard presented
More discussion on the assessment development and dissemination
IVC
Presenting at MD&M West Conference, Discussion on dissemination of project outcomes, Sustainability of developed Programs, future planning, development of a brochure
Identify entry level positions in medical device companies by functional areas
Identify tasks performed in entry level positions
Combined input from hub partners and validated with industry partners
Validated task matrices with industry sources who may not have attended March meeting
Developing a MD advisory board
Identify the competency levels of skills and knowledge and to perform tasks; divided work among hub partners
Validate skills and knowledge with industry partners; identify the medical device core skills
Review existing education and training programs and the skills they convey
Course development & modification, alignment to certificates and degree
c3bc Meeting
Forsyth
Integration of pathways across all hubs, core bioscience skills and latticed credentials identified
Disseminate the C3BC meeting results to the hub for integration in pathway development
c3bc Meeting
Forsyth
Project progress report, NTER training, evaluation, etc.
c3bc Meeting
SF
Report on key outcomes, dissemination, evaluation, etc.
Educating TAA and other Displaced Workers
Year 1
Year 2
Year 3

IVY TECH COMMUNITY COLLEGE

c3bc Community College Consortium for Bioscience Credentials #TC-23761-12-60-A-37

- ✓ ***Main Project Outcomes from the MD Hub***
  - *Development of the first skill standards for the entry level jobs in the Medical Device industry*
  - *Education program alignment and development based on the new skill standards*
  - *Disseminating instructional materials for courses and modules*

- ✓ ***The Medical Device Skill Standards***
  - *The first skill standards for the entry level jobs in the medical device industry*
  - *Developed by the industry SMEs through so many regional and national meetings*
  - *Describe entry level jobs, critical work functions, key activities, performance indicators, underlying knowledge and assessments*
  - ***Provide guidelines to develop education & training programs for medical device industry careers***

✓ *Education Program Development and Implementation*

- *Partners colleges utilized the new skill standards in their courses, certificates, and degree programs*
  - *Austin CC – Framework for a new MD manufacturing program*
  - *Ivy Tech CC – New RA certificate & plastics program*
  - *Salt Lake CC – New MD certificate program strongly endorsed by their local employers*
  - *St. Petersburg C – New Biomedical Equipment Technician I Certificate program highly valued by local hospitals*
  - *"Course sharing" between Anoka Ramsey CC and Ivy Tech CC*

✓ *Disseminating Courses and Instructional Resources*

- *"Courses in a box" project - Disseminate all necessary instructional materials to teach a course or a topic (syllabus, lesson plans, a cross-walk between the course content and the skill standards, lecture slides, assignments, assessments, instructor's qualification requirement, necessary equipment and supply list, etc.)*
  - *Quality Practices Course – aligned with ASQ's CQIA & CQPA*
  - *Metrology Course – calibration, inspection, quality audits, etc. in the MD manufacturing environment*
  - *Product Life Cycle Course – MD product life cycle based project scenarios*
  - *Root Cause Analysis Module – key problem solving tools*

✓ *Benefitting Educators and the Industry*

- *"The final publication for the c3bc work looks great and has been very helpful. I am preparing to offer the quality class for the first time in the Fall and the course materials help tremendously!" - Emalee MacKenzie, Irvine Valley College*
- *" It is an excellent publication... our companies will find extremely useful, and administrators of post-secondary education should find invaluable!! Congratulations on successfully completing a monumental task!" - Kathy Heuer, Executive Director, Indiana Medical Device Manufacturing Council, Inc.*
- *" I know the people involved were happy to help and I am glad their contributions were of help to you. Thanks to you and your team for all the hard work." – Pete Yonkman, President, Cook Medical*

✓ List of Industry Participants

Abt Associates *- Judy Alamprese, Hannah Engle*

Alfred Mann Foundation *- Joe Schulman*

Alpha Training & Consulting *- John Lee*

AMEDICA Corporation *- Bill Jordan*

Bard Access Systems *- Jessica Smith*

BayCare Health System *- Walter Barrionueve, Randell Orner, Carlos Villafane*

BD Medical *- Jacob Morrill, Corey Thayer*

BioFlorida, Inc. *- Michael Van Butsel*

BioFire Diagnostics, LLC *- Kelly Hunter, Paul Murphy, Quinn Whitlock*

BioUtah *- Peter Knauer*

Boston Scientific Corporation *- Brian Sills, Robert Wilson*

Bovie Medical Corporation *- Dan Cavaliere*

Cain Consulting, LLC *- Meraleen Cain*

Chapman Lake Instrument, Corp. *- Mike Kiser*

Cook Medical *- Ray Amos, Eric Bomba, David Chadwick, RuthAnn Dubois,Jay Freund, Rich Granquist,Jim Koontz, April Lavender, Chris Kilander, Shawn Lawson, Bruce Miller, Dan Peterson, Jim Pope, Jim Ragsdale, Kim Roberts, Don Rodda, David St. John, Alyson Tews, Troy Wingler*

Cook Polymer Technology *- Spencer Leiter, Deb Schwanke*

Echelon Biosciences Incorporated *- Xin Morrow*

Edwards Lifesciences Corporation *- Santosh Bhagat, Karen Jones*

Fresenius Medical Care *- David Lockridge*

Grace Medical *- Alfred Chung*

IVY TECH COMMUNITY COLLEGE

c3bc Community College Consortium for Bioscience Credentials #TC-23761-12-60-A-37

✓ List of Participants

Haemonetics Corporation *- Jesse Kryger*
HDE Technologies, Inc. *- Merelee Engel, Simon Engel*
ICU Medical, Inc. *- Scott Peters*
Indiana Medical Device Manufacturers Council *- Peggy Welch*
Kinamed Incorporated *- William Pratt*
Lantheus Medical Imaging, Inc. *- David L. Hyde*
Lumenis *- Jace McLane*
MasterControl, Inc. *- Jeff Brown*
Medical Machining Specialists *- Tim May, Jeff Shepherd*
Medtronic *- Stan McKee*
Medtronic Minimally Invasive Therapies (formerly Covidien Plc.) *- Jan Flegeau*
Megadyne Medical Products, Inc. *- Balaji Sudabattula*
MichBio *- Stephen Rapundalo*
National Institute for Metalworking Skills, Inc. *- James Wall*
Nelson Laboratories Inc. *- Tina May*
Ocular Systems, Inc. *- Lynn Knight*
Operon Resource Management *- Steve Sawin*
Rhein Medical, Inc. *- Chris Gahles*
Second Sight Medical Products, Inc. *- Ted Randolf*
Southern California Biomedical Council *- A. Stephen Dahms*
The Calibration Solution *- Tom Bartunek*

IVY TECH COMMUNITY COLLEGE

c3bc Community College Consortium for Bioscience Credentials #TC-23761-12-60-A-37

✓ *List of Participants*

The KPI System *- Rai Chowdhary*

The Manufacturing Institute *- Gardner Carrick*

Utah STEM Action Center *- Tami Goetz*

University of California, Irvine *- Mark Bachman*

Ventura County Workforce Investment Board *- Cheryl Moore*

Vivid Ngenuity, LLC *- Vivian Ngan-Winward*

Wencor Group *- Jennifer Bolander*

Elaine Johnson- Laboratory Skills Hub

What did we do? What did we learn?

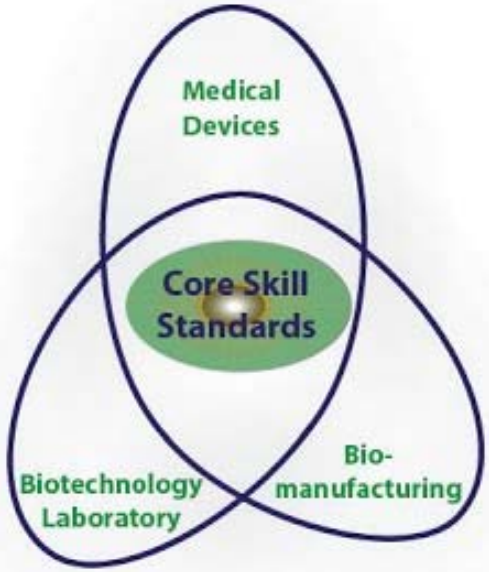
- Bioscience Core Skills Standards

LAB SKILLS HUB

Elaine Johnson, PhD
Lab Skills Hub Leader
Representing
City College of San Francisco
Austin Community College
Madison Area Technical College

Lab Skills Hub Goals

- Produce Revised & Validated Core Lab Skill Standards
- Disseminate Core Lab Skill Standards
- Work with hubs to determine Core Bioscience Skill Standards
- Contribute assessment tools for Core Bioscience Skill Standards
- Tailor Stackable Credentials
- Provide assessment resources for educators available through web-based portal, webinars, workshops, presentations, and publications
- Share information with stakeholders
- Create an environmental monitoring program at CCSF
- Train students
- Place students in jobs and internships


Medical
Devices
Core Skill
Standards
Biotechnology
Laboratory
Bio-
manufacturing

Why this effort to define Core Skills?

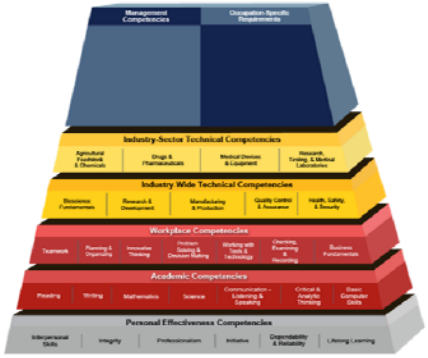
- Give educators the tools to develop courses, certificates, modules, etc.
  - Assessments
- Define skills and knowledge necessary for entry level positions
  - Students know and can articulate what they know
  - Industry recognizes what students know
  - Means to measure learning outcomes
- Possibly develop credential based on those core competencies

Draft of Core Skill Standards based on:

2007 Biotechnology and Biomedical Skill Standards; Copyright 2007

http://www.bio-link.org/home/shoreline-community-college/biotecl ndards

Bioscience Competency Model: U.S. Department of Laborwww.careeronestop.org/COMPETENCYMODEL/pyramid.aspx?BIOS



Other Skill Standards served as important references

Organization of Skill Standards

- **Critical Work Functions**
  - Major responsibilities of the job
- **Key Activities**
  - Activities needed to accomplish a critical work function
- **Performance Indicators**
  - Concrete, visible ways that we will know the individual is doing the activity correctly
- **Underlying Technical Knowledge**
  - Knowledge that technician must have to excel
- **Assessment**
  - Determination of proficiency

Critical Work Functions

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

Key activities for one Critical Work Function: Perform measurements/tests/assays

- Collect samples according to established procedures and applicable sampling plans
- Prepare samples according to established procedures
- Follow appropriate test procedures/instructions
- Document data & results according to established procedures
- Interpret and/or analyze data & results as appropriate

US DOL-TAACCCT– CCSF – Environmental Monitoring Program

Trade Adjustment Act (TAA) Workers; Other Displaced Workers; Veterans; Other students

Courses in Laboratory Skills/Instrumentation

1. Field Instrumentation/handhelds
2. Environmental Monitoring
3. Microbiology; EPA methods
4. Wet Chemistry; Instrumentation ICP, GC-MS, IC
5. QA/GLP – documentation?
6. LIMS?

Internships; Job Placement

Laboratory Analysts/Technicians

Courses in water operations/quality?

1. Math (contextualized to water operations)?
2. Chemistry (contextualized)?
3. Engineering?
4. Test Prep for state certification?

Internships; Job Placement

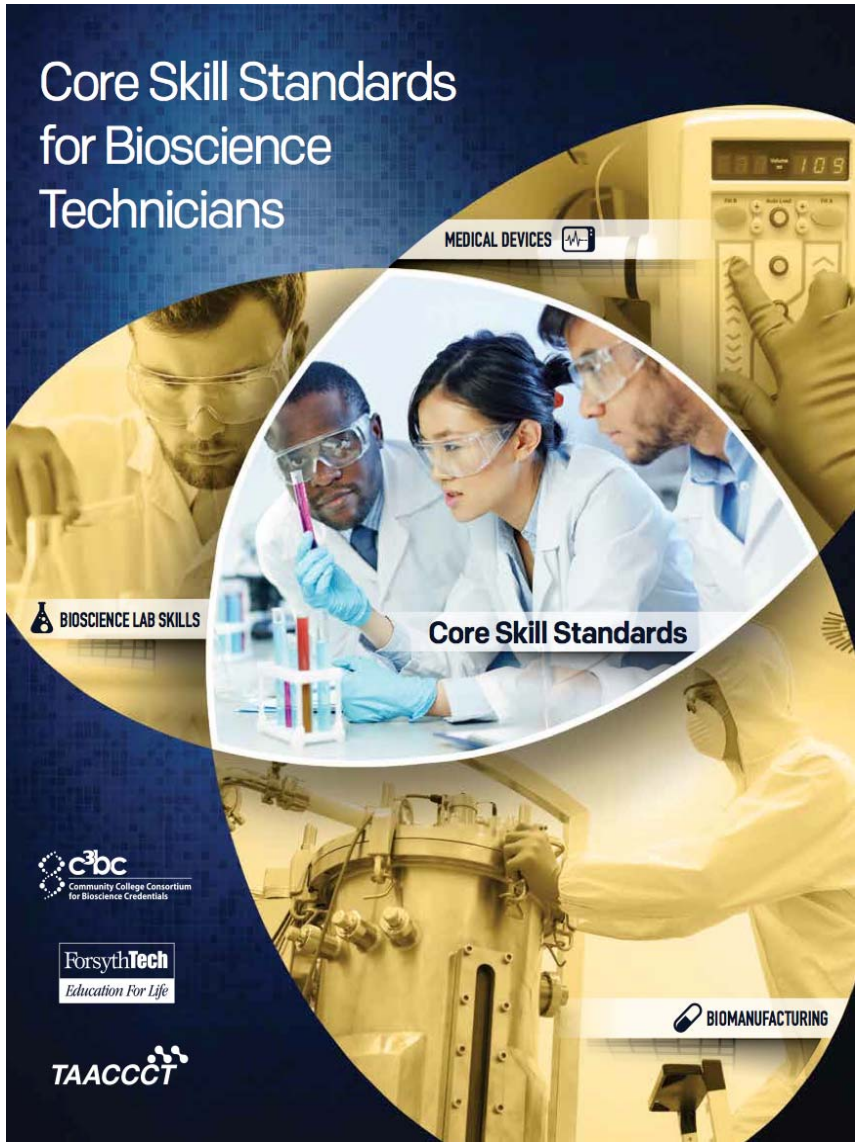
Water operator/quality

Reflections and Conclusion:

The Lab Skills Hub (CCSF, MATC, ACC) continue to value collaboration and leveraging resources.

The Bio-Link network, curriculum and instructional materials clearinghouse, and robust interactive web communication tools offer value to TAACCCT.

Core Skill Standards for Bioscience Technicians



c³bc
Community College Consortium for Bioscience Credentials

ForsythTech
Education For Life

TAACCCT

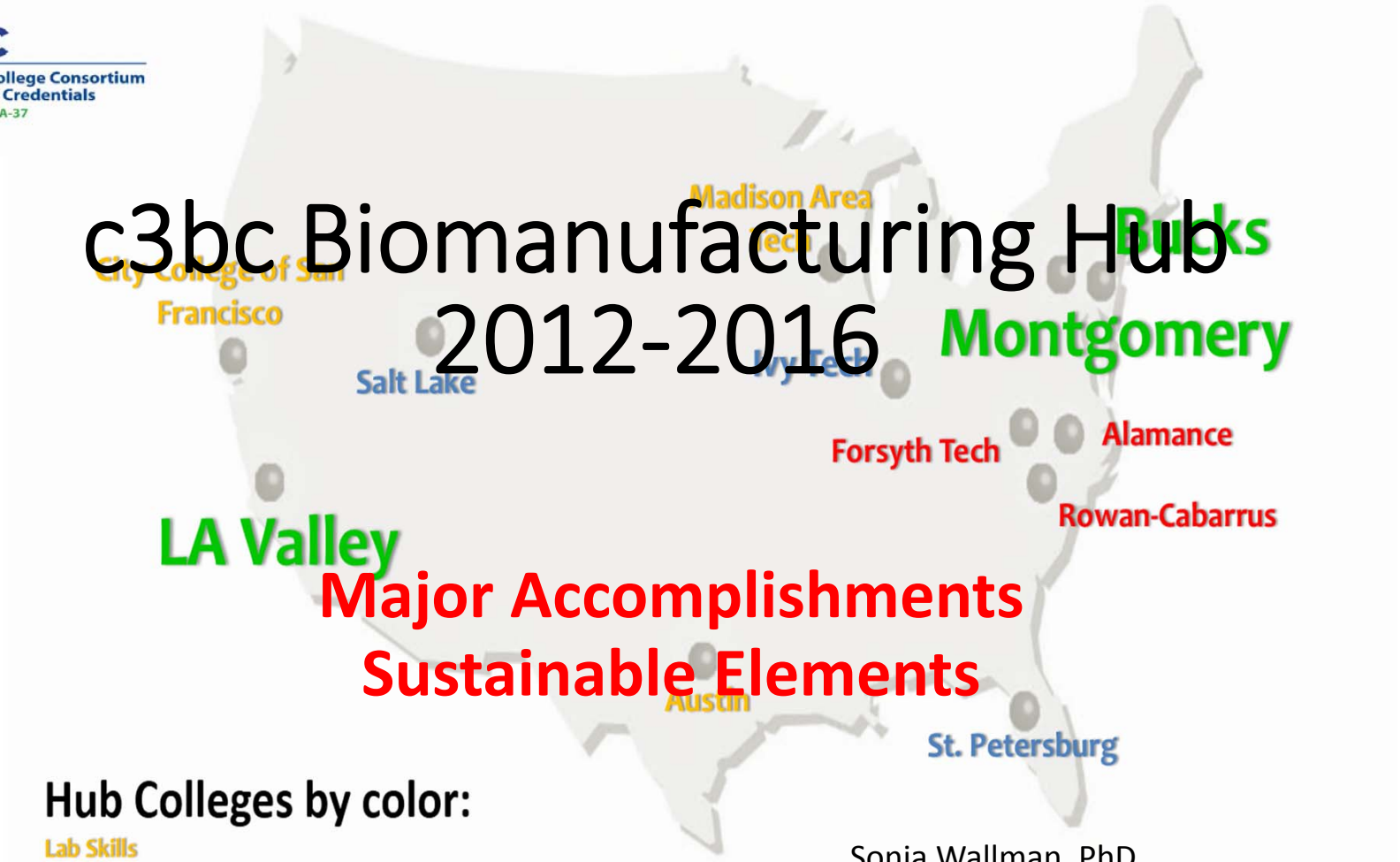
Sonia Wallman- Biomanufacturing Hub

What did we do? What did we learn?

- Downstream processing module

c3bc
Community College Consortium for Bioscience Credentials
#TC-23761-12-60-A-37

c3bc Biomanufacturing Hub 2012-2016



Major Accomplishments
Sustainable Elements

Hub Colleges by color:

Lab Skills
Medical Devices
Biomanufacturing
Learning

Sonia Wallman, PhD
Biomanufacturing Consultant NBC2
c3bc **Biomanufacturing** Hub Lead

The Biomanufacturing Hub People

- Montgomery County Community College (MC3)
  - Sonia Wallman, PhD, Biomanufacturing Hub Lead
  - Margaret Bryans, PhD, Faculty
  - John O'Neill, PhD, Project Director
  - Jason McMillan, BS and MBA, Career Coach and Laboratory Manager
- Bucks County Community College (Bucks)
  - Linda Rehfuss, PhD, Co-PI
  - Ciana Cooper, PhD, Bioscience Grant Coordinator
- Los Angeles Valley College (LAVC)
  - Lennie Ciufo, Job Training Director
  - Chander Arora, PhD and Pamela Byrd-Williams, Co-PIs
  - Keri Luna, Career Coach
  - Sara Lamog,

LAVC People and Program

Los Angeles is home to biopharmaceutical manufacturers Baxter, Grifols, Prolacta, and Baxalta, companies engaged in downstream processing of valuable human products and proteins. These companies are expanding in the LA area; they need local biomanufacturing technician help.

Because of Lennie Ciufo's connection to industry and understanding of workforce needs plus the use of his proven methods for developing public interest, along with the creation of contextualized training in the form of a (14 unit/150 hour non-credit) Biotechnology/ Biomanufacturing Skills Certificate, the LAVC program placed the greatest number of graduates into the local, growing biomanufacturing industry. The certificate program is co-led by Dr. Chander Arora and Pamela Byrd-Williams, professor in the biological sciences department. Lennie Ciufo oversees the biotech bridge academy in the job training department at LAVC and is aided by Keri Luna, manager and Sara Lamog. instructor

LAVC's Biomanufacturing Team
Dr. Chander Arora and Professor Pamela Byrd-Williams in the Biological Sciences department with Keri Luna, Sara Lamog and Lennie Ciufo of the Biotech Bridge Academy

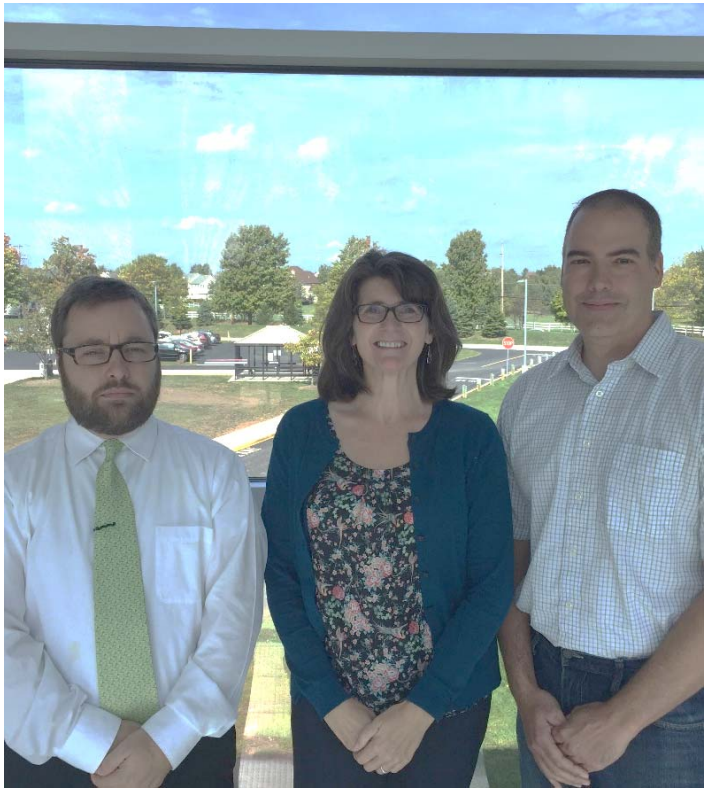
Montgomery CCC People and Program

Margaret Bryans joined MCCC in 2006, serving first as NBC2 Project Manager and from 2009 to 2012 as NBC2 Principal Investigator. Maggie is Assistant Professor and Director of the MCCC Biotechnology program.

John (Jack) O'Neill, c3bc Program Director for the Biomanufacturing Hub, and Jason McMillan, c3bc Laboratory Manager and Career Coach, joined the c3bc Biomanufacturing Hub at MCCC in early 2013.

The new 16 credit Biotechnology and Biomanufacturing certificate program has preferred provider status in Montgomery County. The certificate has served a variety of students including TAA workers, veterans, students with Bachelor's and Master's degrees, incumbent workers and those pursuing an Associate's degree.

The region's BigPharma industry suffered job losses during the great recession. Contract research, development and manufacturing organizations (CSOs or CXOs) sprouted in the area to work on BigPharma projects. These companies need biotechnicians *already* skilled in *hands-on* biotechnology/biomanufacturing in the areas of production and quality control and in the *behaviors* required in the stringent regulatory environment of biopharmaceutical (bio)manufacturing.



Bucks CC People and Program

Linda Rehfuss, Ph.D. came from a research position in BigPharma to Montgomery County Community College as professor and program director for biotechnology/biomanufacturing. She became Dean of Math and Sciences in 2006.

In 2009, Dr. Rehfuss moved to Bucks County Community College to develop a hands-on biotechnology and biomanufacturing education and training program at the college to help serve Pennsylvania's BigPharma region.

Cianna Cooper, Program Director, joined the c3bc Biomanufacturing Hub in 2012.

Buck's new 16 credit stand alone Cell and Tissue Culture certificate program and Biology AA degree has preferred provider status in Bucks County. Students find ready employment because they have skills identified by manager and technician Subject Matter Experts from the biomanufacturing industry. On-the-job skills that have been identified include about 36% hands-on production and analysis, with the majority of skills needed relating to the regulatory environment of the industry: 'if you didn't document it, you didn't do it'.

Biomanufacturing Hub Program
Montgomery County Community College

Biotech and Biomanufacturing Certificate – 16 Credits

BIT 120 (4 Credits)
Introduction to Biotechnology

BIT 123 (4 Credits)
Techniques and instrumentation for

BIT 220 (4 credits)
Biotechnology Research

BIT 232 (4 credits)
Biomanufacturing

Biotech and Biomanufacturing AAS Degree – 60 Credits

The Certificate is integrated into the Montgomery CCC Biotechnology and Biomanufacturing AAS Degree

Certificate graduates can be immediately employed without further education.

Biomanufacturing Hub Program
Bucks County Community College

Cell and Tissue Culture Certificate – 16 Credits

BIOT 125 (**4 credits**)
Biotech Methods and Techniques

BIOT 205 (**4 credits**)
Cell and Tissue Culture

BIOT 221 (**4 credits**)
Biomanufacturing

CHEM 121 (**4 credits**)
Chemistry 1

Biotechnology Associate Degree – 60 Credits

The Certificate is integrated into the Bucks Biotechnology Associate Degree

Certificate graduates can be immediately employed without further education.

Biomanufacturing Hub Program
LA Valley Community College

Biotech Bridge Academy

200 hours non-credit

Biotech Academy	
Curriculum Breakdown	
Manufacturing Principles	30 hours
OSHA SAFETY	6 hours
Attitude /Emotional Intelligence / Preparing for Workplace Success	24 hours
Business Writing/Verification	6 hours
Science for the Workplace / Fractionation	12 hours
Lab Techniques	24 hours
Math for the Workplace	18 hours
Biology & Chemistry for the Workplace	12 hours
Critical Thinking/Problem Solving	6 hours
Effective Communication	6 hours
Integrity/Values Ethics	6 hours
Stress Management	6 hours
Time Management	6 hours
Cultural Diversity	6 hours
Necsc$w Employee Application Process	6 hours
Interviewing skills/New Hire Activities	24 hours
Graduation	2 hours

Baxter, Baxalta, Shire, Grifols

Manufacturing Tech I

Strong relationship with global biopharmaceutical companies hiring a great many employees as a result of expansion.

Companies such as Baxter (then Baxalta then Shire), Grifols Biologicals and Eastman Chemical are partners.

Relationship Guarantees Employment as Manufacturing Tech I, sometimes Manufacturing Tech 2 or lab, environmental monitoring or quality roles

Biomanufacturing Hub Programs
LA Valley Community College

Biotechnology/Biomanufacturing Skills Certificate – 14 Credits

Biotech 1 (3 Units)
Fundamentals of Bioman & Biotech

Biotech 2 (3 Units)
Biomanufacturing I

Biotech 3 (4 Units)
Biomanufacturing II

Biotech 4 (4 Units)
Biomanufacturing III

or

Biotech 5 (2 Units)
Environmental Control & Support

and

The Bridge Academy and the Skills Certificate are two different programs. People who have completed the Skills Certificate are either already employed at Baxalta and Grifols or are high school students currently pursuing transferable college credit. The Skills Certificate is for credit; the Bridge Academy is not for credit.

Biomanufacturing Workforce Roundtables Create Partnerships for Education and Jobs

LOS ANGELES, CA LOCALE

LA Valley College c3bc Staff and Faculty

LA Valley Employee Development Department

SoCalBio

WIB (Los Angles/Orange County)

WIB (LA) Career Services Director

America's Job Center of California (AJCC)

Salvation Army Haven

Veteran's Administration

Baxter

Baxalta

Shire

Grifols Biologicals

Eastman Chemi

Parexcel

Naval veteran Ron McGee receives congratulations from Baxter Human Resource Manager Dean Arnold (left), Valley College President Dr. Sue Carleo, and WorkSource Services Division Chief Michael Dolphin.

PHILADELPHIA, PA LOCALE

Montgomery County CC c3bc CoPI, Staff and Faculty

Project Manager TAACCCT 2 Grant MC3

Director of Testing and Placement MC3 and Bucks

Director of Grant Development MC3

WIB (Montco) Recruitment Supervisor

WIB (Montco) Career Services Director

Montgomery County Development Corporation (MCDC)

Bucks County CC c3bc CoPI, Staff and Faculty

WIB (Bucks) Employer Service Supervisor

WIB (Bucks) Business Service Representative

WIB (Bucks) TAA Specialist

WIB (Bucks) WIA Director

GSK

Merck & Co., Inc.

Teva Pharmaceutical Industries

Rockland Immunochemicals

Rockland Antibodies and Assays

Meso Scale Discovery

KVK Tech

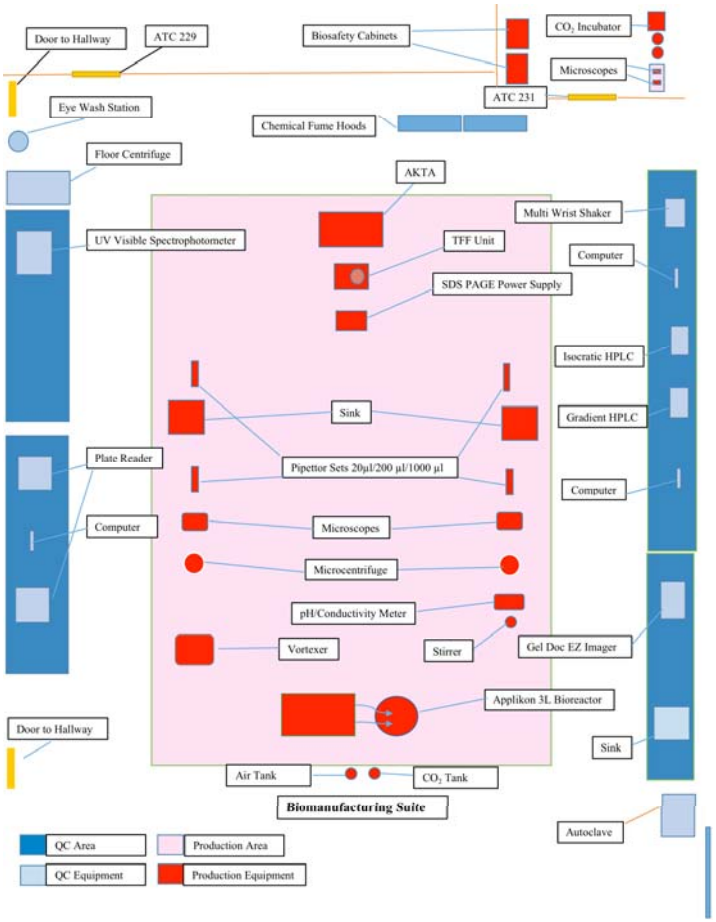
VWR Scientific

Jansen

WuXi AppTec

JLL, Inc.

Biomanufacturing Suite with Equipment



Core Laboratory Equipment

Pipettors

Microfuge

pH/Conductivity Meter

Stirrer

Shaker

Vortexer

Computer

Production Upstream

Autoclave

Biosafety Cabinet

CO2 Incubator with Magnetic Stir Plate and Spinner Bottles

Applikon 3L Bioreactor

Microscope

UV Visible Spectrophotometer

Centrifuge

Tangential Flow Filtration Unit

Production Downstream

Bio-Rad LP Liquid Chromatography System

GE AKTA LP Liquid Chromatography System

Biomanufacturing Laboratory Manual

Biomanufacturing Laboratory Manual
Table of Contents

Metrology: SOPs for lab-scale equipment
Validation: SOPs for autoclave
Quality Assurance: cGMP, SOPs, Batch Records, Equipment Logs
Quality Control Microbiology:
Environmental Monitoring SOPs
Upstream Processing:
CHO recombinant for human Interleukin 8 (IL-8) SOPs
Centrifugation SOPs
Tangential Flow Filtration SOPs
Downstream Processing:
Chromatography of IL-8 from CHO Cell Culture SOPs
Quality Control Biochemistry:
SDS-PAGE SOPs
IL-8 ELISA SOPs

Montgomery County Community College
340 DeKalb Pike
Blue Bell, PA
Page 1 of 1

Document Number: 22.01.01
Revision Number: 0
Effective Date: 99/99/9999

SOP: Applikon ez-Control Bioreactor Controller Operation

Figure 1. Applikon ez-Control Bioreactor Controller and Bioreactor

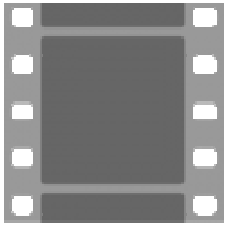
Virtual Downstream Processing

Monoclonal antibody proteins (or mAbs) are the single largest class of recombinant biological drugs to date and represent about a third of the total biopharmaceutical market. The recent success of monoclonal antibodies for a wide range of disease therapies has led to the development of industrial production operations that manufacture pharmaceutical-grade mAbs both efficiently and safely. The following modules introduce a typical mAb bioprocessing workflow, detailing the equipment and processes used in biomanufacturing within a regulated environment.

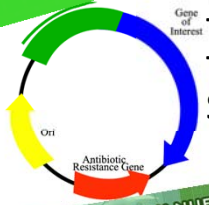
http://faculty.mc3.edu/downstreamprocessing/story.html

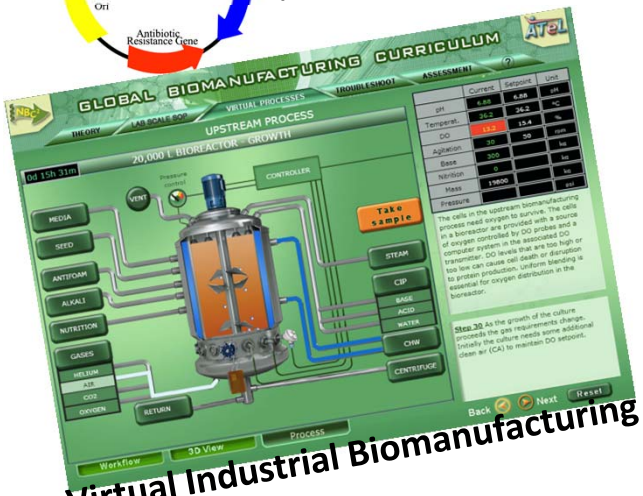
Online Biomanufacturing Resource www.biomanufacturing.org/

CHAPTER 1 INTRODUCTION
ENGINEERING UNIT OVERVIEW
CHAPTER 2 FACILITIES
CHAPTER 3 METROLOGY
CHAPTER 4 VALIDATION
CHAPTER 5 ENVIRONMENTAL, HEALTH, AND SAFETY (EHS)
CHAPTER 6 OPERATIONAL EXCELLENCE
QUALITY UNIT OVERVIEW
CHAPTER 7 QUALITY ASSURANCE
CHAPTER 8 MICROBIOLOGICAL CONTROL
CHAPTER 9 QUALITY CONTROL
BIOCHEMISTRY
PRODUCTION UNIT OVERVIEW
CHAPTER 10 UPSTREAM PROCESSING
CHAPTER 11 DOWNSTREAM PROCESSING
CHAPTER 12 PROCESS DEVELOPMENT
APPENDIX A MASTER GLOSSARY



Michael Cicio - Today's Biologics: From Bench Top to Bottle.
Tags: Keynote Speeches, Bioman 2006





Career Pathway Data Collection: Students and Graduates

STUDENT DATA COLLECTED	PA	LA	TOTAL
Total Number Unique	139	189	328
Male	60 (43%)	134 (72%)	194 (60%)
Female	79 (57%)	52 (28%)	131 (40%)
Average Age	30.5	36.5	33.5
Employed at Start of Class	18 (13%)	156 (82%)	174 (53%)
Associate, Bachelor, Graduate Degree	46 (33%)	91 (48%)	137 (42%)
Veterans/Spouses/Dependents	6 (4%)	16 (8%)	22 (7%)
Disability	7 (5%)	2 (1%)	9 (3%)
TRA/WIA	13 (9%)	3 (2%)	16 (5%)
Biotech/Bioman Credential	45 (32%)	156 (82%)	201 (61%)
Biotech/Bioman Job	18 (13%)	156 (82%)	174 (53%)
Transfer to Higher Education	6 (4%)	0	6 (2%)
Percentage of Placements	53%	100%	76%
Hourly Wage	N/A	$14.76	$14.76

Career Pathway Data Collection: Job Titles of Some Program Graduates

- Environmental Monitoring Technician
- Laboratory Automation Scientist
- Laboratory Technician
- Manufacturing Associate I
- Manufacturing Tech I
- Manufacturing Tech 2
- Process Improvement Leader
- Quality Assurance Associate
- Quality Analyst
- Quality Control Analyst
- Quality Operations Product Release Coordinator l
- Research Associate
- Research Scientist
- Research Technician
- Senior Laboratory Technician
- Senior Scientist
- Technical Writer
- Technical Writer/Scientist III

Career Pathway Data Collection: Companies Hiring Program Graduates

- WuXi AppTec
- Baxter
- Baxalta
- Shire
- Grifols Biological
- Eastman Chemical
- JLL, Inc.
- NewAge Clinical
- Merck & Co., Inc
- Teva Pharmaceutical Industries
- Rockland Immunochemicals
- Rockland Antibodies and Assays
- Meso Scale Discovery
- KVK Tech
- VWR Scientific

Michael Ayers- Learning Technologies Hub

What did we do? What we did learn?

- Science Skill Labs
- Modular Learning

Steven Dahms- NAC Chair

What did we do?

- What did we learn?
- What's next ?