

New and Innovative Industry Partnered Biomanufacturing Programs across the Nation

Sonia Wallman, PhD
CCP@BIO 2016
June 6, 2016

Location of Programs

- University of Southern Maine, Portland, ME
- Quincy College, Quincy, MA
- Bronx Community College, Bronx, NY
- Bionetwork, NC
- Santa Fe Community College, Santa Fe, NM
- MiraCosta College, Oceanside, CA

Bruce Van Dyke

Biotechnology and Compliance Program

Quincy College, Quincy, MA



Bruce Van Dyke, Professor and Chair of the program and student enrolled in the Quincy College Biotechnology and Compliance Associate in Science degree.

The first graduates in 2014, included *NBC2 Faces of Success*, Daria Kotoski, now Research Associate in Biologic Formulation Development at Takeda in Cambridge, Massachusetts.

Bruce is working with industry and organizations to develop a biomanufacturing hub for Quincy, Massachusetts.

The program is partnered with GE and Shire, making it the first in the country to train students in the use of disposables in biopharmaceutical biomanufacturing production.

Aaron Socha

Director of New York's Center for Sustainable Energy Bronx Community College, Bronx, NY

Dr. Aaron Socha started at Bronx Community College in 2011, and has directed the City University of New York's Center for Sustainable Energy since 2013. His early career focused on drug discovery where he performed structure elucidation and synthesis of several classes of naturally occurring antibiotics. The compounds were isolated from marine microbes, synthetically optimized and subsequently evaluated against clinical pathogens. As an NSF postdoctoral fellow at Brown University, Aaron researched microbial lignin catabolism and lipid biosynthesis where he developed a fascination with biodiesel fuel and green chemistry. He now works on biofuel processes involving ionic liquids and catalysts derived from biomass waste streams. He has received over \$10M in grant awards for research, teaching and infrastructure development at BCC.



Dr. Stephen Gómez

Department of Sustainable Trades and Technologies Santa Fe Community College, Santa Fe, NM

Dr. Stephen Gómez, Assistant Professor and Chair of the Department of Sustainable Trades and Technologies has worked on a wide range of biochemical projects in academia and industry covering topics from agriculture to medicine including cancer biology, asthma/COPD research, mass spectrometry, membrane biochemistry, photosynthesis, plant-nutrition stress, controlled-environment agriculture and most recently biofuels research. Dr. Gómez is involved in research collaborations with Sandia National Laboratory in reclamation of produced water from the oil and gas industry, Los Alamos National Laboratory in harvesting algal biomass for fuel production, and as a member of NM-EPSCoR is developing a citizen-scientist program with the Girl Scouts and the National Center for Genome Resources to introduce high/middle school girls to STEM educational and career pathways. He previously developed a curriculum in Green Energy as part of the engineering program at Central New Mexico Community College. Currently, Dr. Gómez is a member of the Algae Technical Educational Consortium, collaboration between the DOE/NREL and the Algae Foundation, to develop certificate and degree programs in Algae Biology, Technology and Cultivation for 2-yr colleges. In addition to his duties as chair, Dr. Gómez also teaches biology courses in the School of Health, Math and Sciences.



Michael Fino

Professor and Chair of Biotechnology

MiraCosta Community College, Oceanside, CA



Mike Fino is also Director of NBC2's Western Hub at MiraCosta College in Oceanside, California.

Mike started working with biopharmaceutical manufacturer, Genentech, a city block away from his biotechnology/bioprocessing facility in an old welding lab on the MiraCosta campus. Genentech literally helped him build his facility.

MiraCosta is also the site for one of the San Diego EDGE (Educating and Developing Workers for the Green Economy) Certificates in Biomass Production.

Last May, Mike learned that MiraCosta would have the opportunity to offer the first biomanufacturing bachelor's degree in California and one of the only bachelor's in biomanufacturing in the nation.

He recently was named Dean of Math and Science at MiraCosta Community College

Andrew Capps

Food, Beverage, and Natural Products Bionetwork, NC



Andrew Capps is the Food, Beverage, and Natural Products Education and Training Coordinator for BioNetwork. He works with food, beverage, and natural products businesses to develop customized trainings in food safety and defense, regulatory practices, laboratory methodology, and auditing and documentation practices. Additionally, he oversees a rentable test kitchen for BioNetwork.

His academic preparation began at North Carolina State University, where he earned a Bachelors of Science in Microbiology and minors in Biotechnology and Genetics. He then attended the University of North Carolina: Wilmington, where he taught a biomedically focused microbiology laboratory course and conducted research involving statistically based genetic mapping of corn populations. Prior to joining BioNetwork, Andrew served as QA Specialist, Microbiology Supervisor, and Chief Microbiologist at the NC Department of Agriculture: Food and Drug Protection Division. Andrew joined BioNetwork in 2014.

Ira 'Ike' Levine

Professor of Natural and Applied Sciences

University of Southern Maine, Portland, ME



Dr. Ira A. Levine is Professor of Natural and Applied Sciences, University of Southern Maine. Additionally, Dr. Levine is the President of the Algae Foundation, President of Professors Beyond Borders, and CEO of Algal Aquaculture Professionals, LLC. Recently awarded the 2016-2017 U.S. State Department's Distinguished Chair Fulbright award and previously, awarded a 2009-2010 U.S. State Department, Fulbright New Century Scholar Fellowship. Dr. Levine combines 30 years of applied and basic research in the molecular, physiological ecology and cultivation of algae, aquatic farming management, and aquaculture engineering. Dr. Levine's farming experience includes open-ocean and pond cultivation in Canada, China, Indonesia, Japan, Malaysia, Philippines, and USA (Hawaii, Florida, and Maine). Current efforts include algal cultivar enhancement for aquaculture and agriculture feed supplementation, human nutraceuticals, and fine chemicals.



Bruce Van Dyke

Chair: Biotechnology and Compliance

Telephone: 617.984.1669

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Connect with us on [LinkedIn](#) and [Facebook](#)

Growth in Use of Disposables in Manufacturing

Worldwide market \$3 Billion by 2019

Compound Annual Growth Rate 11.7%

Reduced

Capitol Cost 40%-50%

Operating Cost 20%-30%

Time-to-build 30%

Parrish Galliher Founder Xcellerx; CTO: GE
Pharmaceutical Technology **39** (6) 2015



Typical BioProcess Applications of Disposables

Process Step	Disposable components
Inoculation	Sterile tubes, flasks
Scale-up	Cell culture wave bags, large flasks, roller bottles
Production Fermentation	Disposable Bioreactors
Harvest	Disposable filter trains, centrifuge, TFF
Purification	Disp. Membrane (limited use)
Buffer prep, storage bags and buffer exchange	Totes, bags and Disposable TFF
Bulk fill	Bioprocess bags
Vial filling	Acerta system



Customer reports – last 5 years

Savings with Single Use versus Stainless Steel (12 users)

Company	Increased consumables	Facility CAPITAL Cost	Facility footprint	Labor	Time to build	Turnover time	Water use	Energy use	Carbon footprint	Increased capacity	Operating COGs
Consulting firm	+300%	-25%	-25%	-30%			-92%	-50%			-10%
Consulting firm	+250%		+10%								
Large pharma	+120%	-50%	-25%	-48%		-70%				+30	-57%
Large Pharma		-60%				-50%					-25%
Large Pharma						-90%					
Large biotech		-75%	-75%		-50%		-80%	-80%			-67%
Large biotech									-55%		
Large Biotech		-25%	-35%		-25%		-85%	-25%	-25%		
Small biotech	+250%			-45%	-25%						-25%
Vaccine		-75%									
CMO	+50%	-50%		-10%	-50%	-25%					-30%
CMO											-15%
average	+194%	-51%	-30%	-33%	-37%	-58%	-85%	-51%	-40%	+30%	-32%

Cost of goods includes cost of consumables, overwhelmed by these savings



Biotechnology & Compliance Program

- Associate Degree: 2 Years
 - 480 hours of hands-on lab experience
- Certificate Program: 9 Months
 - 22 weeks basic training in science
 - 300 hours of hands-on lab experience



https://www.facebook.com/QCBiotechProgram/videos?ref=page_internal

BIOMANUFACTURING LABORATORY



QUINCY COLLEGE BIOTECHNOLOGY & COMPLIANCE PROGRAM PARTNERS

MASSACHUSETTS
LIFE SCIENCES CENTER



Shire



Biogen™

MassBioEd
MASSACHUSETTS BIOTECHNOLOGY EDUCATION FOUNDATION

bioVolutions®
INCORPORATED



GE HEALTHCARE
LIFE SCIENCES

Xcellerex®



EMD MILLIPORE



Venture Development Center



MassBiologics

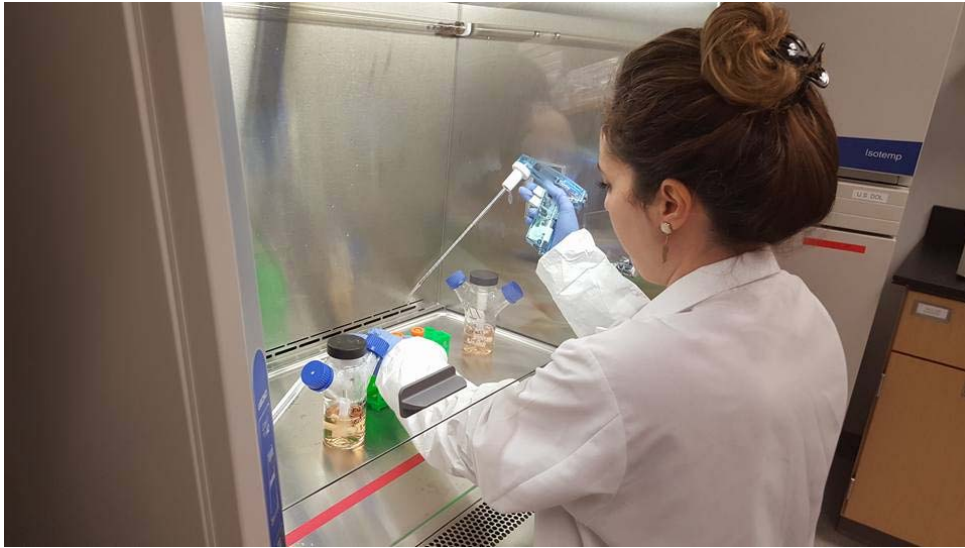
Medicine for Better Lives



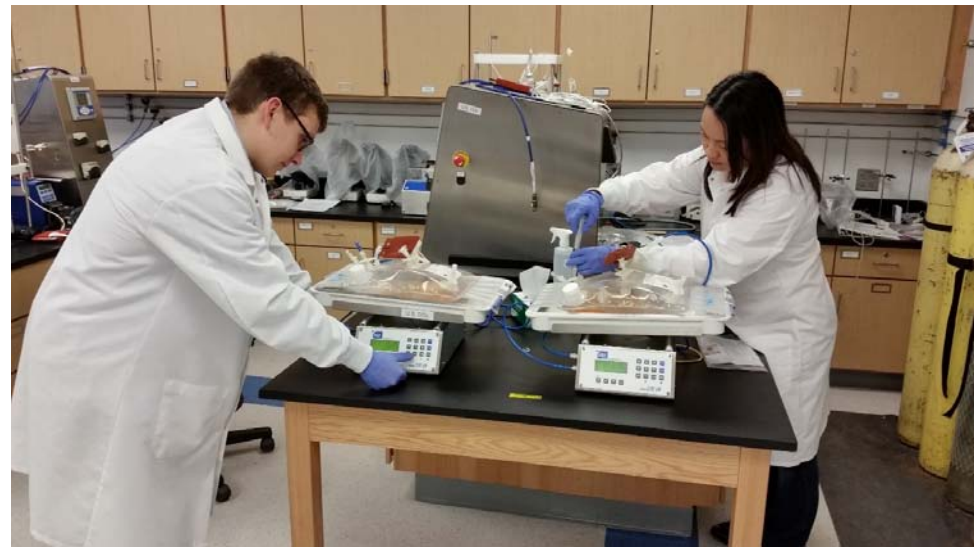
AMRI®
Albany Molecular Research Inc.

Training in Disposable Manufacturing

Aseptic Techniques



Cell Expansion in Wave Bioreactors



Single-Use Bioreactor Setup



Tangential Flow Filtration (UF/DF)



Purification (AKTA System)



Quality Control (HPLC)



Employment

93% Employed by Industry

5% Continued Education

2% ?





THE MASSACHUSETTS LIFE SCIENCES
EDUCATION CONSORTIUM

PROUDLY AWARDS TO

Quincy College

A PLATINUM ENORSEMENT OF ITS

Associate of Science in Biotechnology & Compliance

DECEMBER 2nd, 2014

Lance Hartford
Executive Director, MassBioEd
Foundation

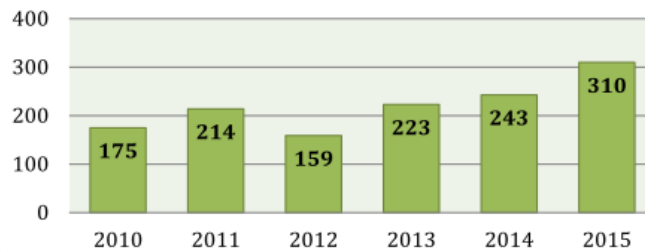


Robert K. Coughlin
Presidents & CEO, MassBio

Job Outlook Massachusetts

- **35% jump in Biopharmaceutical job postings in 2015**
- **4,325 Forecasted new jobs by May 2018**
- **87% of Employers report increased employment in the next 12 months**
- **78% of employers report more difficulty hiring now than three years ago**

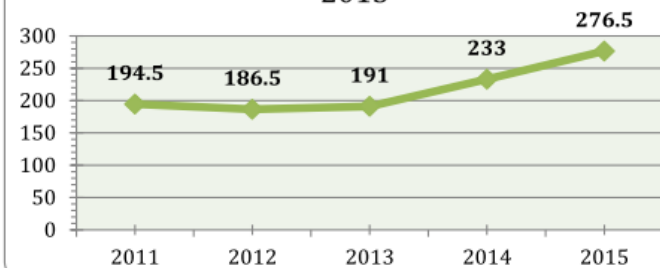
**Total Number of Core Entry Level Jobs
Requiring Associate or Less, Annually,
2010 - 2015**



Looking at the two-year moving average, we are able to discern a clearer picture of the direction of job openings for associate degrees and under in the industry over the past half-decade. At right you can see a clear upward trend in job postings.

The raw number of jobs available in this category has steadily increased in the past three years, from a low of 159 in 2012 to a high this past year of 310 – an increase of 95%. In the years 2011 through 2014, the number of annual Associate degree graduates in the state in biotechnology and life science academic programs was approximately 250 per yearⁱⁱⁱ.

**Number of Core Entry Level Jobs, Assoc.
Deg. & Under, 2-year Moving Avg., 2011
- 2015**



Virtual Biomanufacturing

<http://atelearning.com/qcbio/>

Username: Your Email Address

Password: qcbtc

Quincy College
Biotechnology &
Compliance

VIRTUAL SINGLE-USE BIOMANUFACTURING

Resources Virtual labs Assessment Help

Upstream Processing

- ☐ Tutorial
- ☐ Practice

Inoculation

- ☐ Tutorial
- ☐ Practice

Cell counting

- ☐ Tutorial
- ☒ Practice

Cell growth

Workflow Equipment Process

Xcellerex
Loading a bioprocess
bag assembly into
a XRD 2000L bioreactor

$C_i V_i = C_f V_f$, where
 C_i = Inoculum titer
 V_i = Volume of Inoculum
 C_f = Required cell titer
 V_f = X (initial volume of media)

OK Cancel

Incumbent Worker Training

ÄKTA pure Training Course



Unicorn Software

GC Training Course



OpenLab Software

High-Performance Liquid Chromatography (HPLC) Training Course



OpenLab Software

Chemical and BioEnergy Technology for Sustainability

Aaron Socha

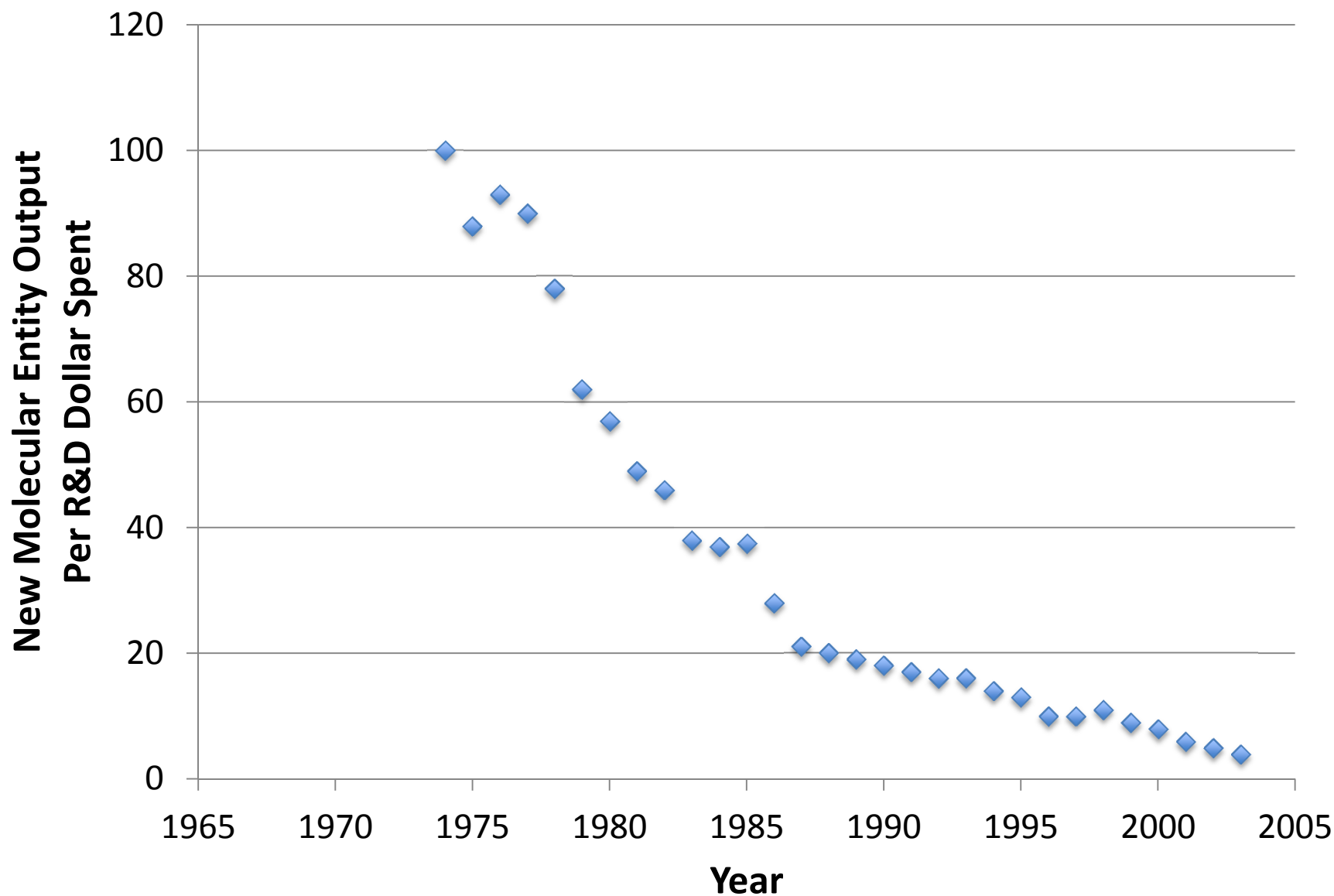
Community College - BIO

June 6, 2016

Chemical and BioEnergy Technology for Sustainability (CBETS)

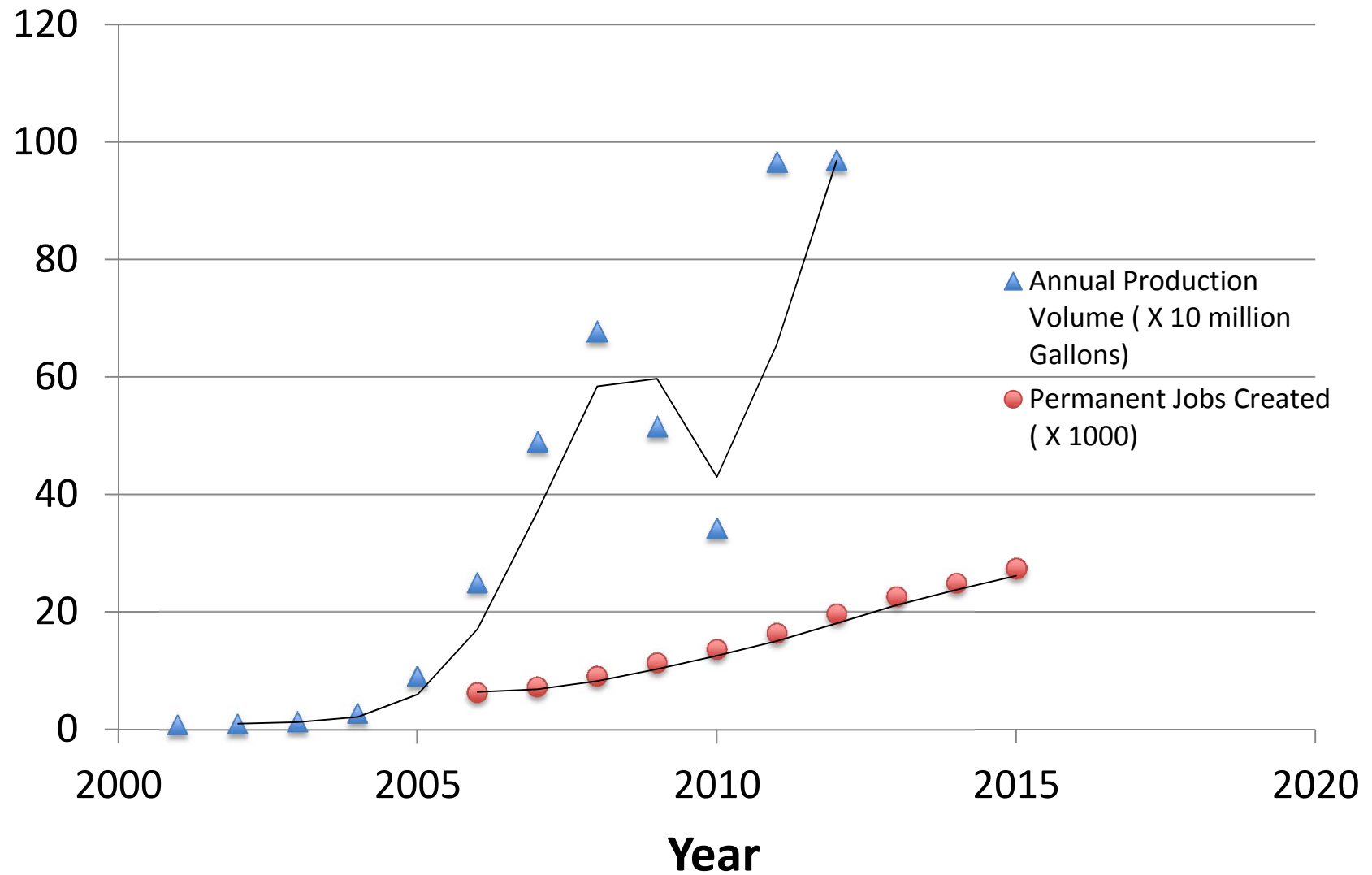
- NSF ATE Award 1601636
- June 1, 2016-May 31, 2019
- Bronx Community College – CUNY
 - Dept. Chemistry, Biology, Center for Sustainable Energy
- City College (CUNY) & Univ. New Haven
 - Depts. of Chemical Engineering

Declining Drug Discovery the U.S.



Source = IOM, Extending the spectrum of precompetitive collaboration in oncology research: Workshop Summary. The National Academies Press, 2010.

Biodiesel Growth in the U.S. Economy



Urbanchuk, J.M., *Contribution of the Biodiesel Industry to the Economy of the United States*. 2006.

BCC Demographics

Community College (12,000 students)

- 62% Hispanic, 33% African American ($n= 12,000$ students)
- Graduation rate is 14%
- 57% of graduates transfer to 4 yr school
- 12% STEM majors,
- Among lowest income congressional districts in US (31% of people below poverty line)
- College Now Program



Bronx Community College Campus



BCC Biodiesel Lab
Meister Hall 720

100L separation
funnel

Ion
exchange
column

30L
rendering
pot

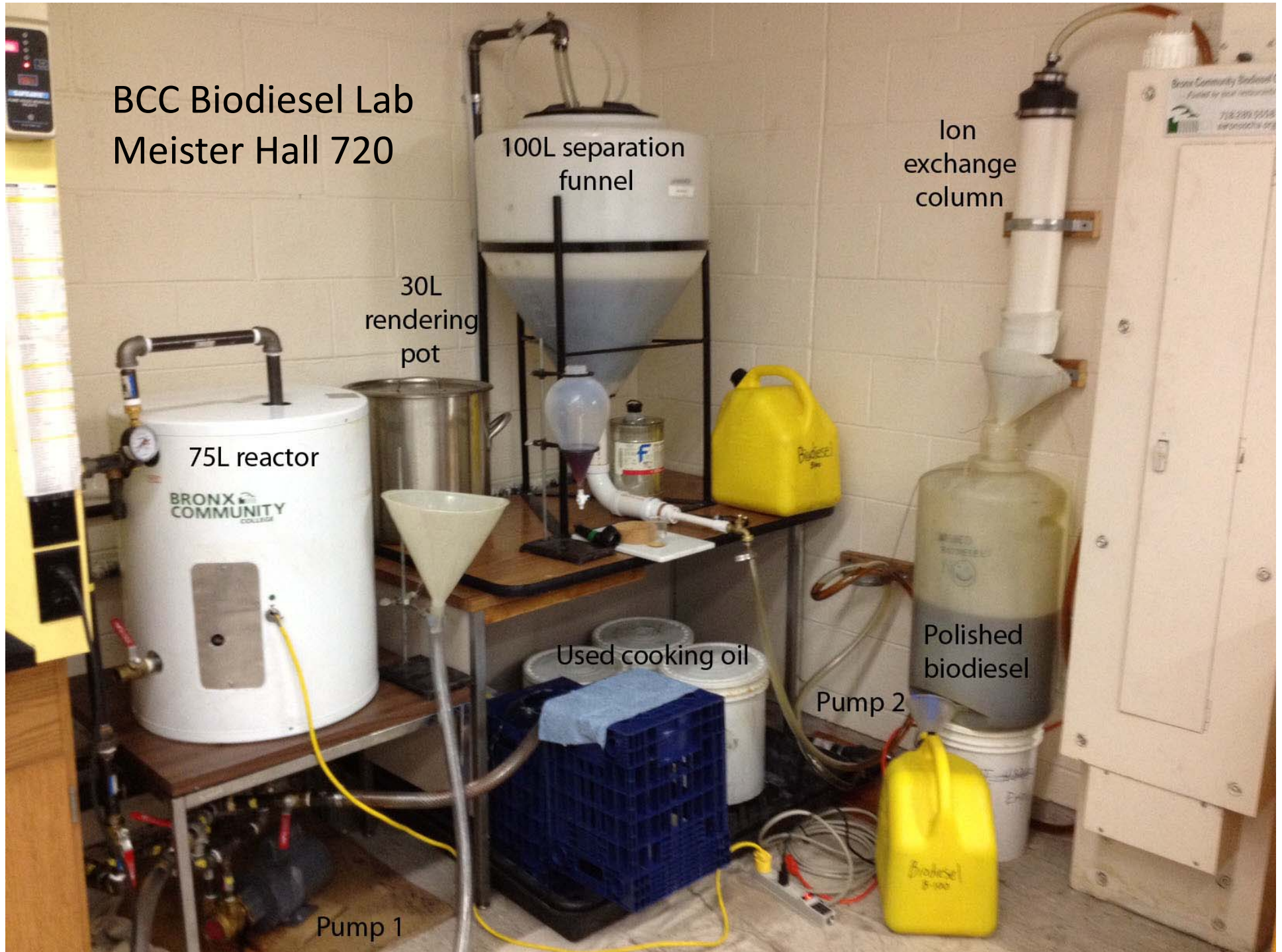
75L reactor

Used cooking oil

Polished
biodiesel

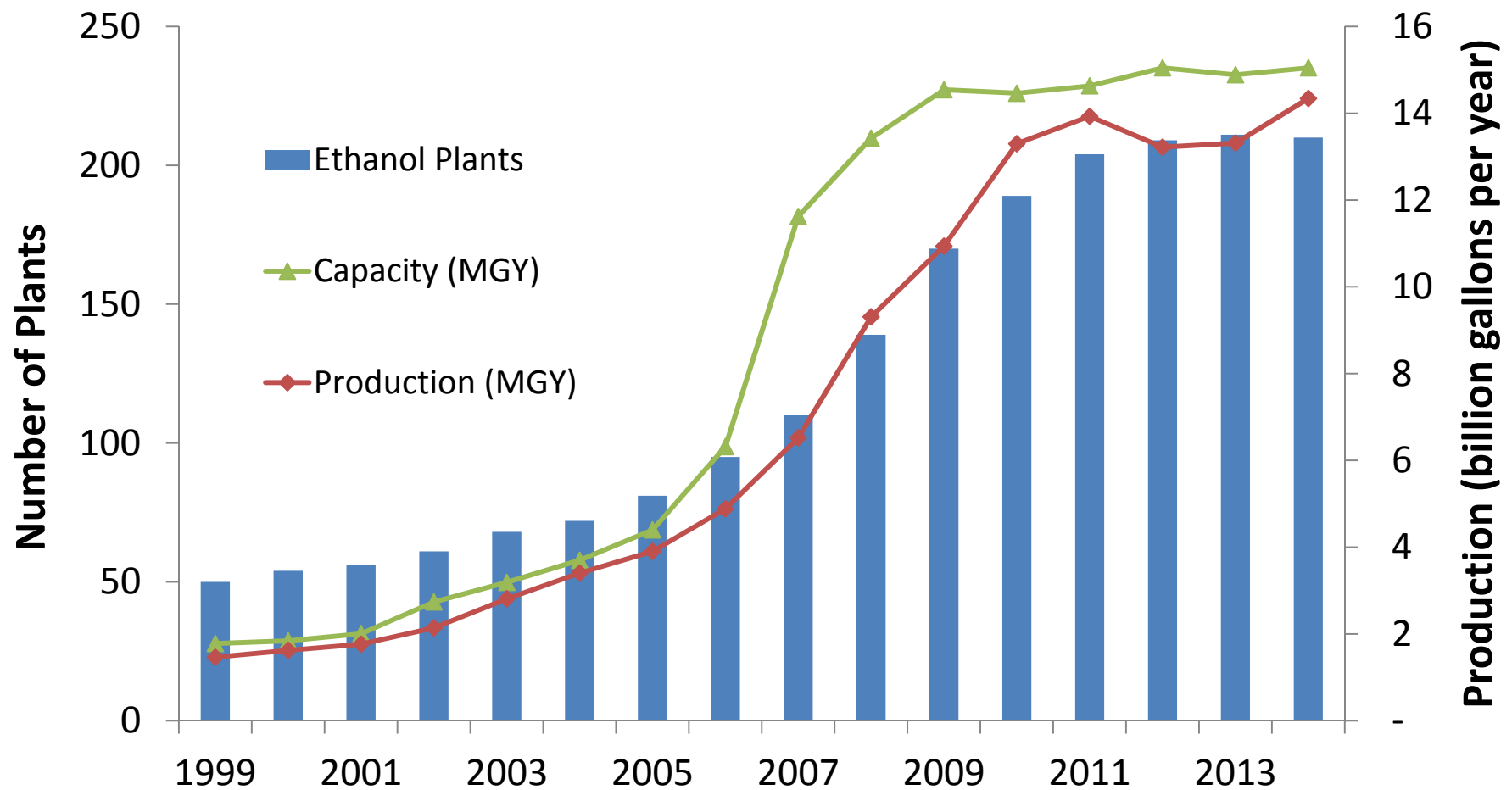
Pump 2

Pump 1



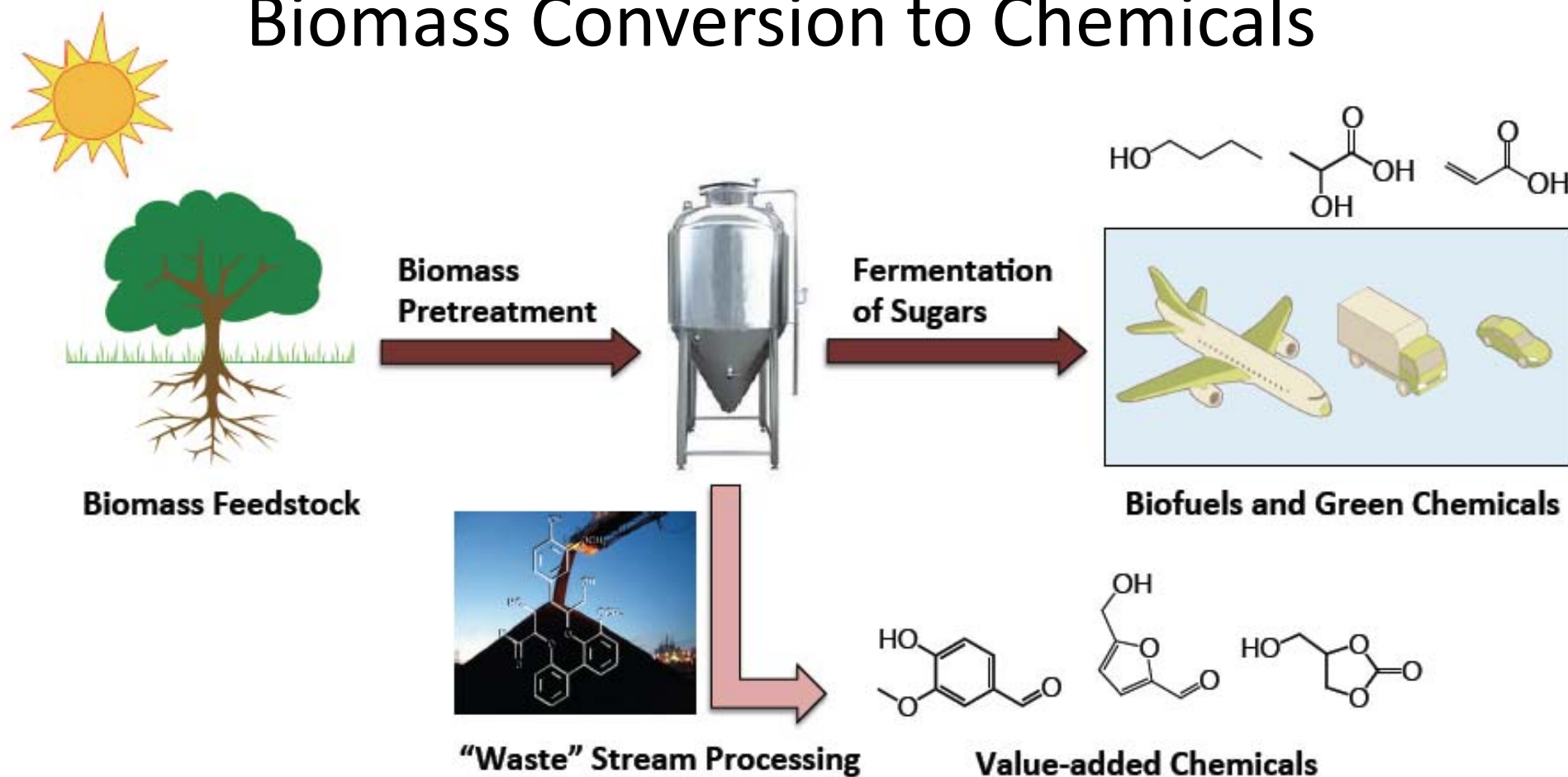


U.S. Ethanol Plants, Capacity, and Production



Source = US DoE, Energy Efficiency and Renewable Energy Alternative Fuels Data Center

Biomass Conversion to Chemicals

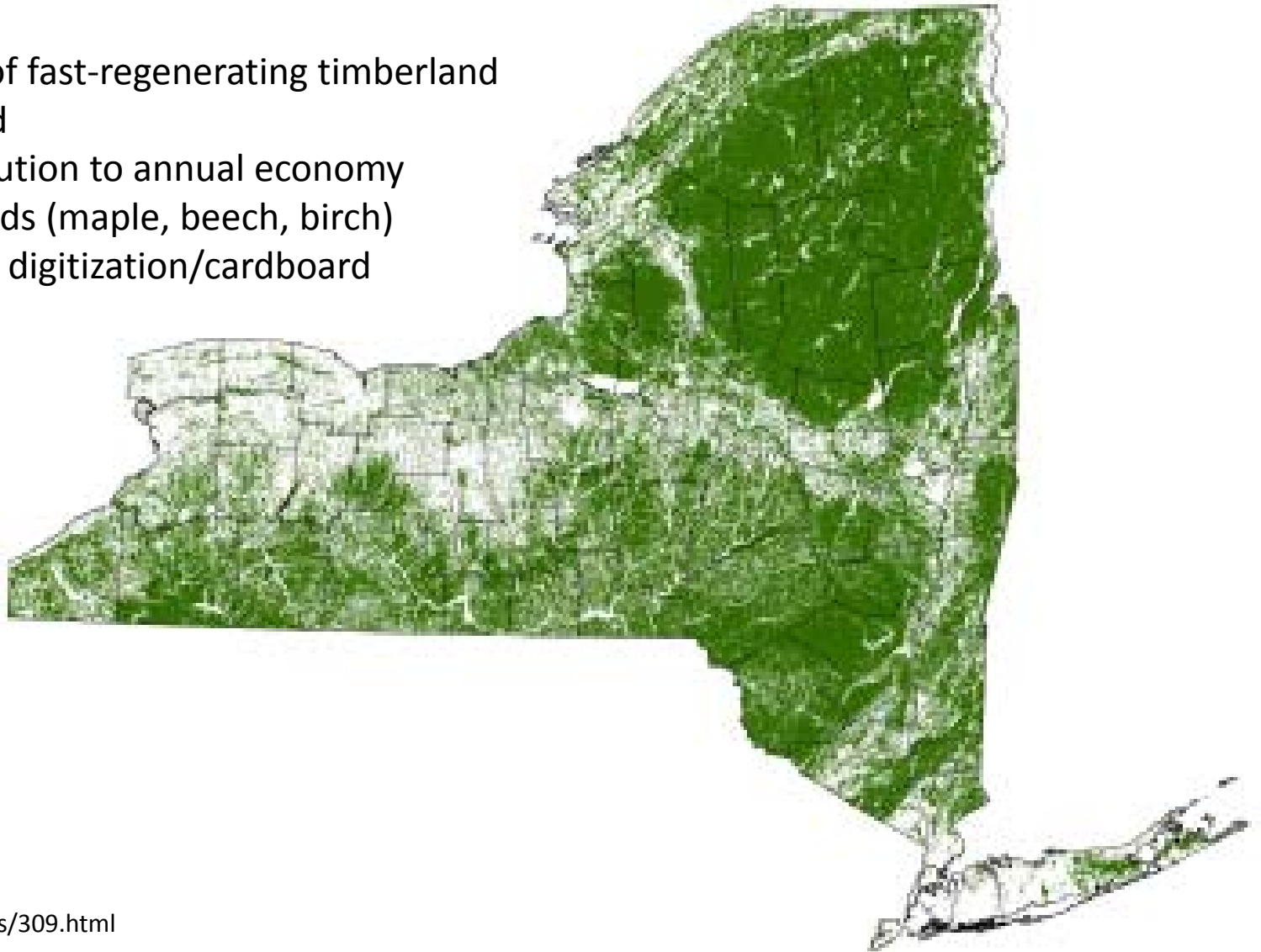


Acrylic acid can be produced via fermentation and represents and \$8B global market.

\$375 billion global market exists for chemical, plastic, and rubber products currently made from petroleum.

NY State as a Sustainable Source of Biomass

- 18.5M acres of fast-regenerating timberland
- 60K employed
- \$4.6B contribution to annual economy
- 53% hardwoods (maple, beech, birch)
- Paper/Pulp -> digitization/cardboard



Chemical and BioEnergy Technology Topics

Course 1: Biomass Processing

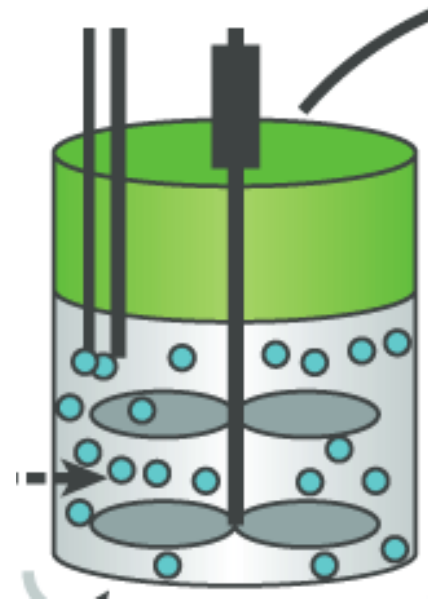
Feedstock pretreatment, fermentation, kinetics, vacuum systems, pump repair, Labview, PLC logic

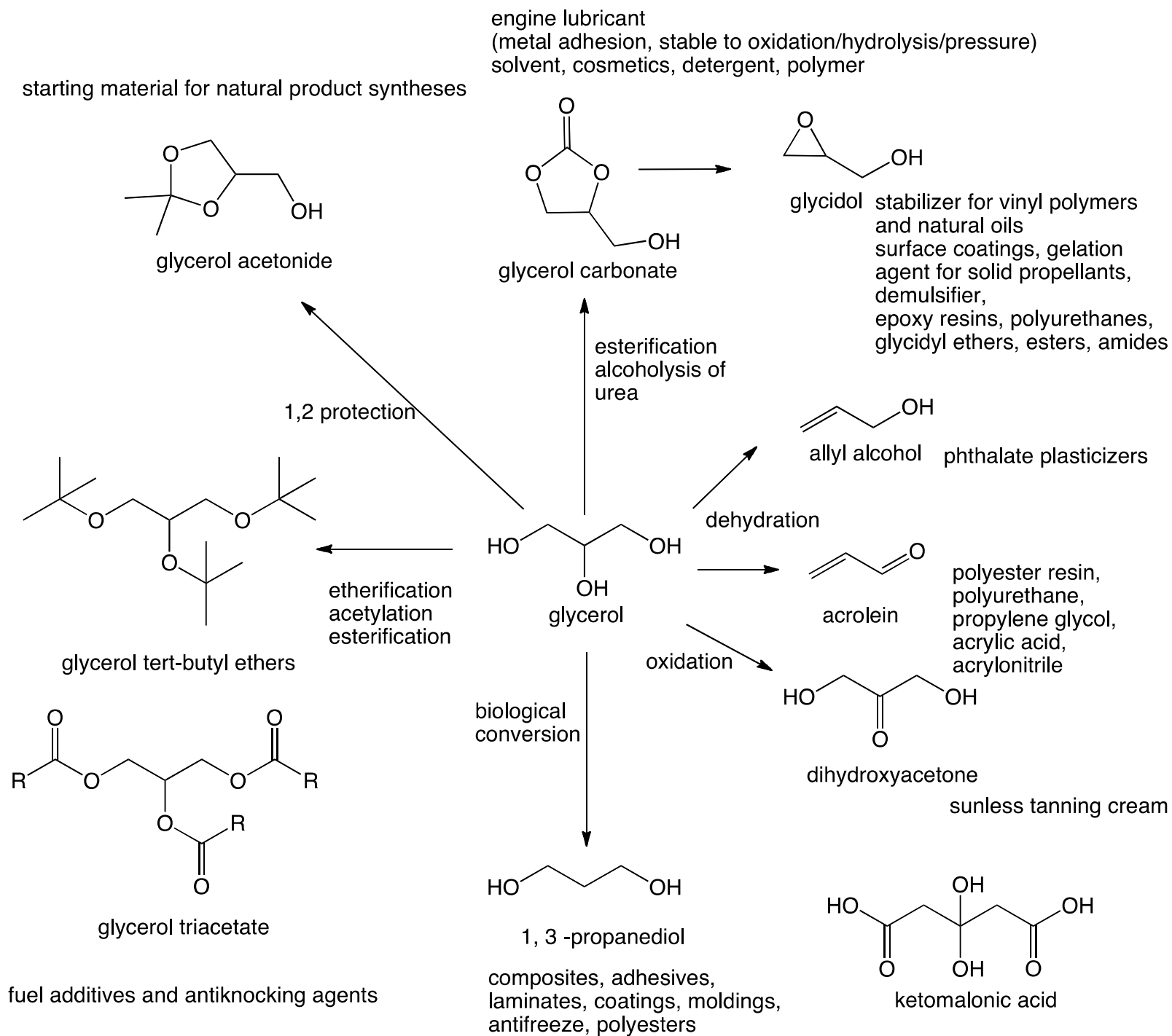
Course 2: Analytical Chemistry

chromatography (HPLC, GC) mass spectrometry, ICP-MS, NMR, ASTM/NREL methods (biodiesel, biomass), product analysis (fuels, organic acids, antibiotics, etc.)

Course 3: Green Chemistry and Waste Valorization

Ionic liquid solvents/catalysis, glycerol/ lignin/hemicellulose separation and conversion





Use of Glycerol and Lignin as Catalysts for Biofuel Production



Contents lists available at ScienceDirect

Fuel Processing Technology

journal homepage: www.elsevier.com/locate/fuproc



Research article

Equilibrium studies of canola oil transesterification using a sodium glyceroxide catalyst prepared from a biodiesel waste stream



Dave Bradley^{a,*}, Erica Levin^a, Christian Rodriguez^b, Paul G. Williard^c, Anina Stanton^d, Aaron M. Socha^{b,d}

^a FYT Fuels, 77 South Street, Dryden, NY 13053, United States

^b Department of Chemistry and Chemical Technology, Bronx Community College – City University of New York, Bronx, NY 10453, United States

^c Department of Chemistry, Brown University, Providence, RI 02912, United States

^d Center for Sustainable Energy – City University of New York, Bronx, NY 10453, United States

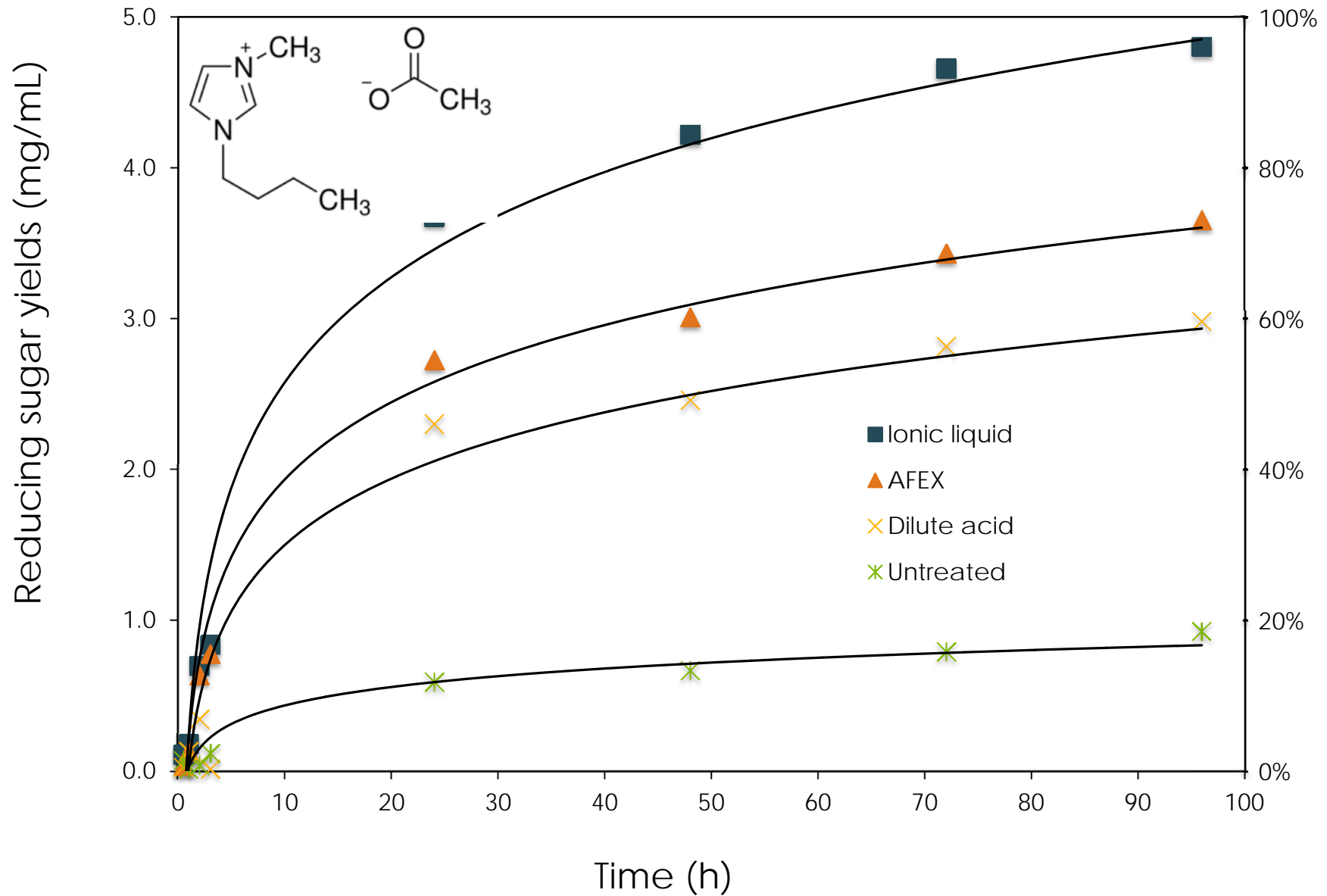
Efficient biomass pretreatment using ionic liquids derived from lignin and hemicellulose

Aaron M. Socha^{a,b,c}, Ramakrishnan Parthasarathi^{a,d}, Jian Shi^{a,d}, Sivakumar Pattathil^{e,f}, Dorian Whyte^{a,b,c}, Maxime Bergeron^a, Anthe George^{a,d}, Kim Tran^{a,d}, Vitalie Stavila^d, Sivasankari Venkatachalam^e, Michael G. Hahn^{e,f}, Blake A. Simmons^{a,d}, and Seema Singh^{a,d,1}

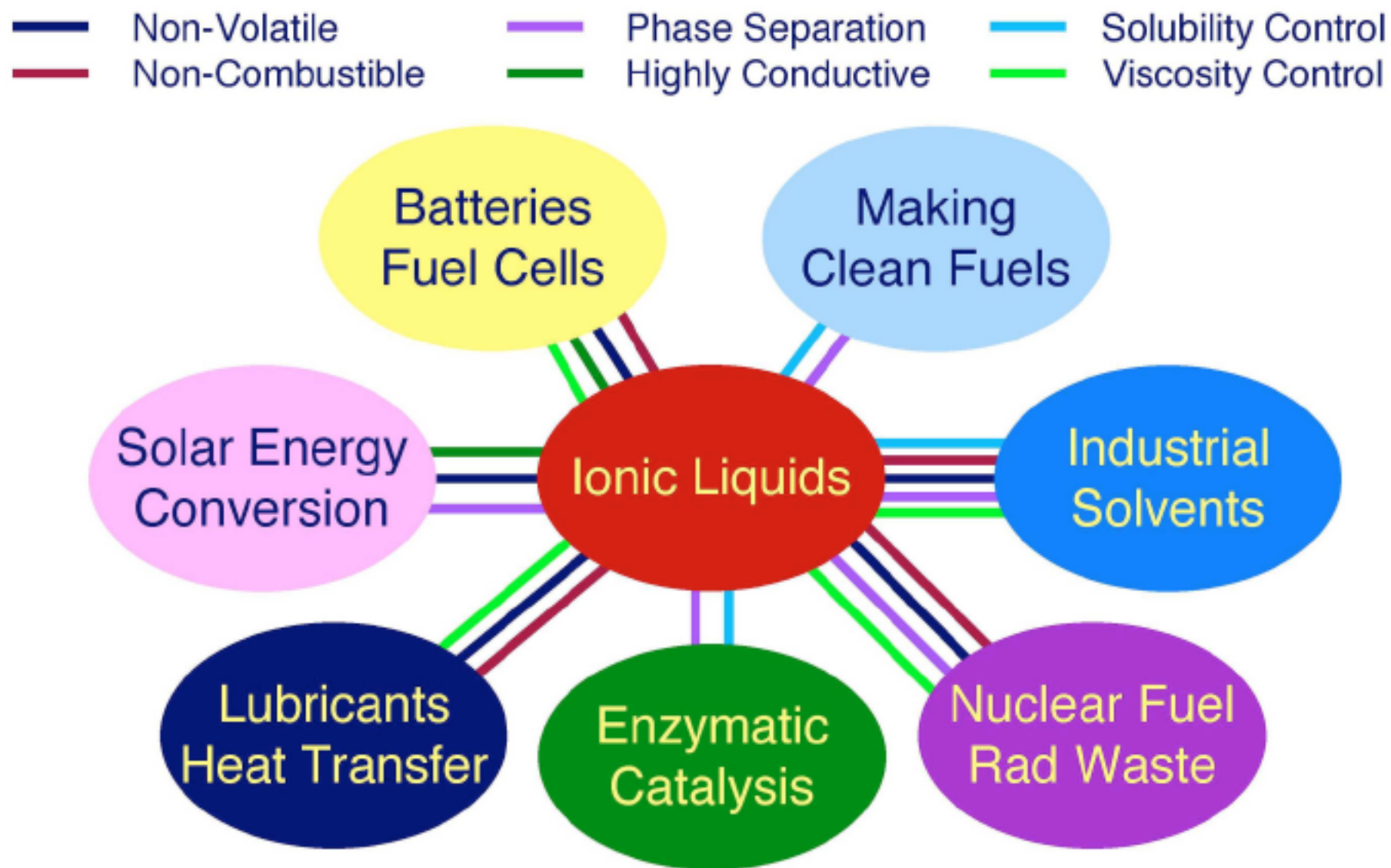
^aDeconstruction Division, Joint BioEnergy Institute, Emeryville, CA 94608; ^bCenter for Sustainable Energy and ^cDepartment of Chemistry and Chemical Technology, Bronx Community College, City University of New York, Bronx, NY 10453; ^dBiological and Materials Science Center, Sandia National Laboratories, Livermore, CA 94551; ^eComplex Carbohydrate Research Center, University of Georgia, Athens, GA 30602; and ^fThe BioEnergy Science Center, Oak Ridge National Laboratory, Oak Ridge, TN 37831

Edited by Alexis T. Bell, University of California, Berkeley, CA, and approved July 9, 2014 (received for review March 27, 2014)

Comparison of Biomass Pretreatment Methods



Additional Uses of Ionic Liquids



Industrial Advisory Board

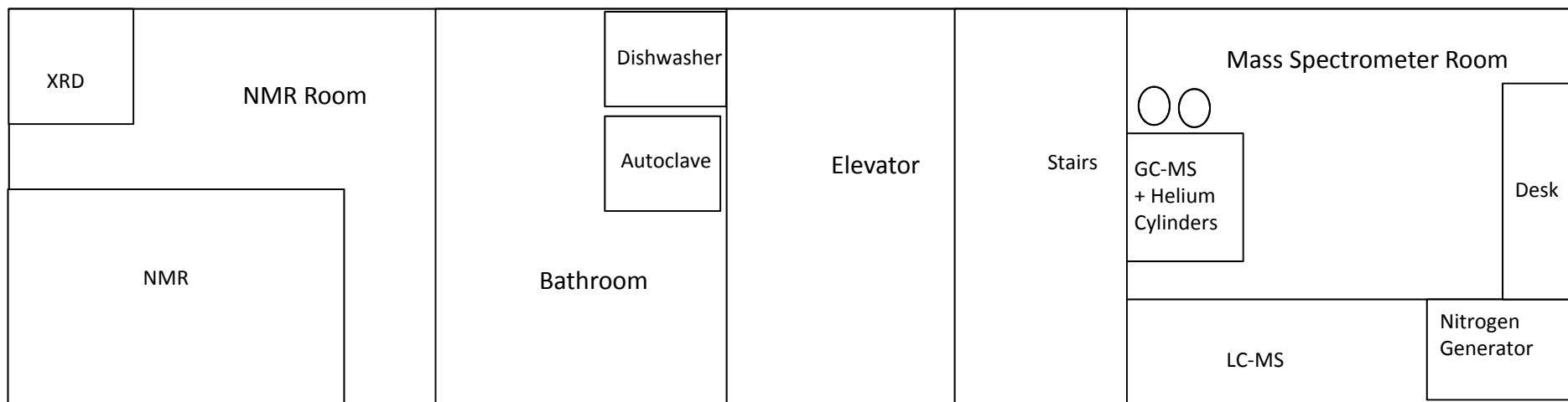
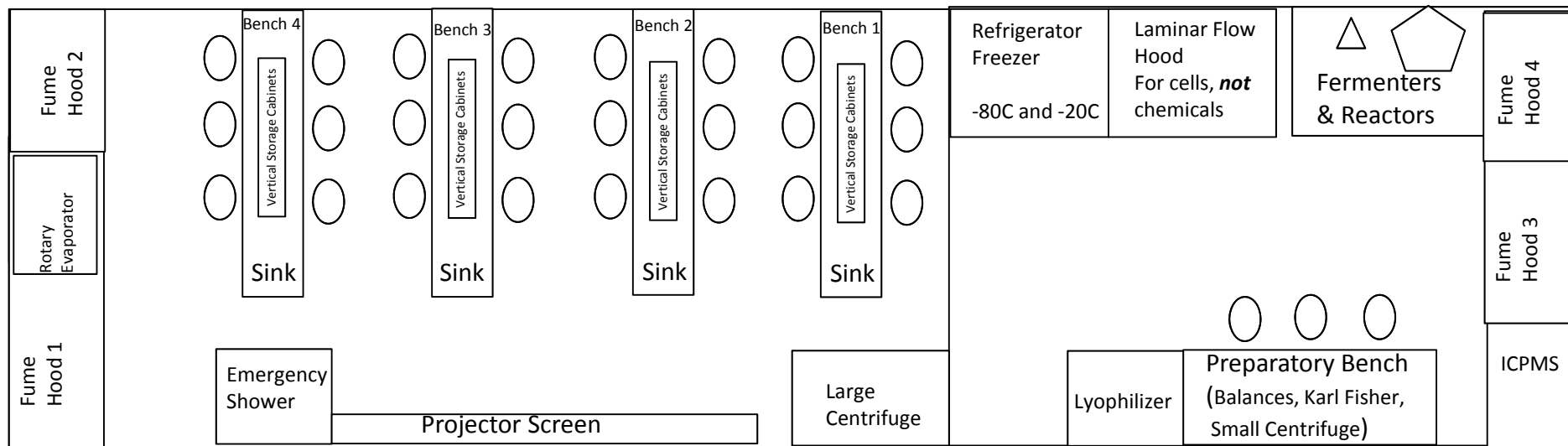
- NC State Department of Forest Biomaterials
- Proionic GmbH, JBEI
 - Ionic Liquid Synthesis and Characterization
 - Biofuel Strain “crowd sourcing”



Anellotech



Sustainable Fuel and Product Development Lab



Conclusions

- Goal is to design an interdisciplinary curriculum between chemistry, biology and engineering focused on petroleum replacement products and processes
- Analytical chemistry and problem solving skills can be applied to a wide range of careers
- By using principals of green chemistry (waste re-purposing, alternative reaction solvents), we intend to build scientific entrepreneurship and a workforce comfortable with these critical concepts and emerging technologies



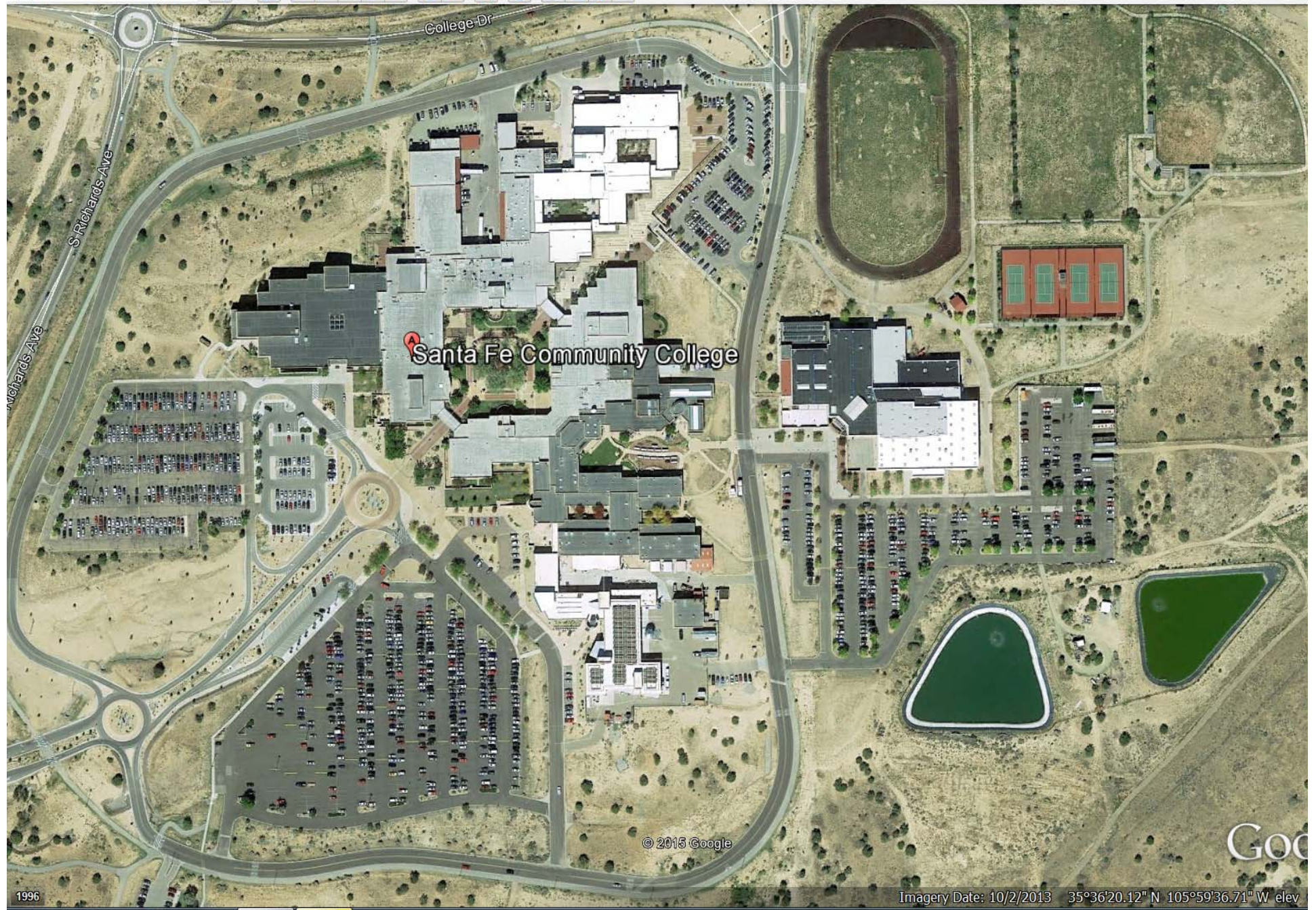
SFCC

SANTA FE COMMUNITY COLLEGE

- ~ 6,500 credit students
- 70% > 25 years old
- 50% have children
- Public school drop-out rate near SFCC – 40-50%

- 75% Part time
- 62% Female
- 45% Hispanic
- 5% Native American
- 2015-2016 Best for Vets:
Career and Technical Colleges





© 2015 Google

Go

Still Dragon and Santa Fe Brewing:
Ethanol production

Sapphire Energy and NSE:
Algae Test Bed

Fluid Imaging:
Algae Analysis

Culinary Gardening:
Campus food

Biomass Boiler:
Campus heating

GEK:
Pyrolysis of
woodchips

Springboard Biodiesel:
Biodiesel production

National Center for Genome
Resources
& Girl Scouts:
Metagenomic and water analysis

Spirulina Micro Farming

Spartina:
Prairie Cord Grass cultivation

Solar Array:
campus power

Anaerobic Digestion:
Methane Gas

Campus Wastewater Treatment

Campus power and water
Rooftop solar power and
water harvesting

Ecoponex:
Greenhouse, Aquaponics and
Algae integrated systems

85%
Energy
Sovereign



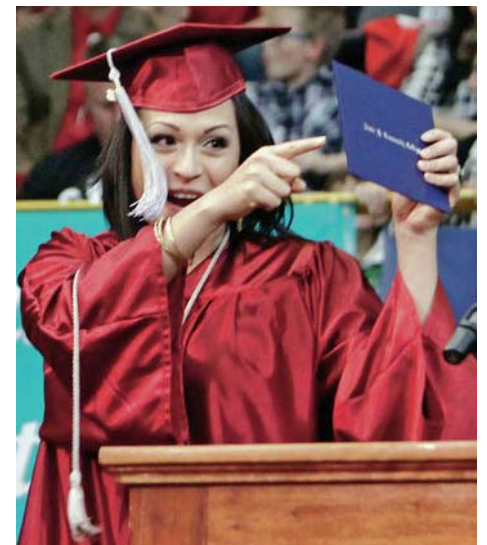


- 1 in 5 SFCC students has food insecurity
- Campus Cupboard open T & W
- Students - current ID
- Adult Ed – receipt
- Retention up ~10%
- Anderson Charitable Foundation
- Santa Maria de la Paz Catholic Community
- SFCC's Clay Club
- SFCC employees

YouthBuild



- Out-of-school at-risk youth (16-24)
- a 9-m commitment for weekdays (9-4).
 1. GED certificate and Certificate in Construction Technologies.
 2. placement in post-secondary education or employment.
- May 18 – 7 GED's





Since opening: only one electric bill - \$23.87





Empower Students, Strengthen Community
Empoderar los Estudiantes, Fortalecer la Comunidad.



ENERGY EFFICIENCY



**SOLAR
ENERGY**

WELDING

BIOGAS

PLUMBING

**WATER
CONSERVATION**

**WATER/WASTEWATER
OPERATIONS**

AQUAPONICS

**GREENHOUSE
MANAGEMENT**

**ALGAE
CULTIVATION**

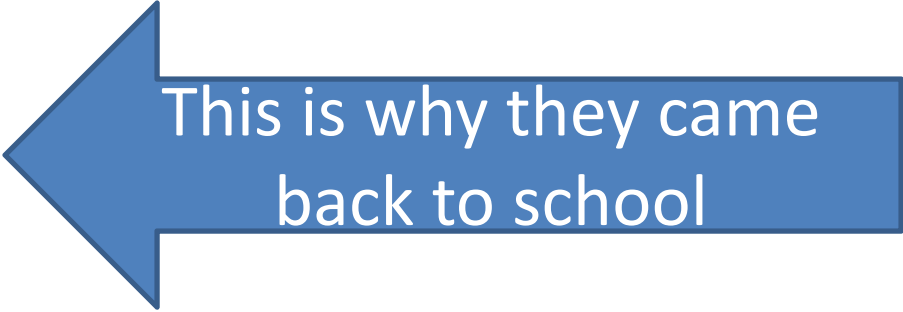
**BIOMASS
ENERGY**

**GREEN
BUILDING**



Stealth STEM

- Students re-entering the community college system DO NOT want an “education”
- They want a good-paying stable JOB!!!!
- The traditional academic system does not serve their needs:
 - General education courses
 - Core courses
 - Specialized courses
 - Degree



This is why they came
back to school

Sustainability Studies



BA



Course	Prerequisite
SUS 300, Foundations of Sustainability	College composition and reading
SUS 325, Energy Systems and Sustainability	SUS 300 or 301; C- or better
SUS 340, Environmental Chemistry	CHE 112; C- or better
SUS 341, Sustainable Agriculture	College composition and reading; SUS 300 or 301
SUS 440, Watershed Science and Land Use Impacts	SUS 300 or 301; C- or better
SUS 350, Permaculture Design I	AS/BS degree ,or junior standing ,or permission
SUS 351, Permaculture Design II	SUS 350, C- or better

Course	Prerequisite
ENVR 111 Introduction to Sustainability	NONE
ALTF 111 Introduction to Alternative Fuels	NONE
WATR 160 Applied Chemistry for Water Operators	NONE
GRHS 121 Greenhouse Operation and Management	NONE
WATR 216 Watershed Management	NONE
GRHS 123 Introduction to Hydroponic Systems	NONE
GRHS 127 Hydroponic Vegetable Production	GRHS 121, 123, 125

In order to be fully admitted to the Sustainability Studies program, you are required to earn an Associate of Arts, Associate of General Studies, or Associate of Science degree.

Stealth STEM


































1st Semester

- New students
 - “I don’t need biology to learn how to make biodiesel”
 - “I can’t do math”
 - “Why do I need chemistry? I just want to grow plants.”
- Put the students in the lab
- Let them work on the topics they came back to school to learn
- Give them enough rope to hang themselves

2nd Semester

- Continuing students
 - “Dr. Gómez, the chemistry class is full. What do I do?”
- Students who “discover” they need STEM courses do much better than students who are “told” they need STEM courses
- Paid internships are the best retention tool
 - “You mean I can get paid to do this?”

ALTF 111

-  admin.ppt
 -  Lecture 01 - Quick Overview.ppt
 -  Lecture 02 - Intro to electricity.ppt
 -  Lecture 03a - Hazard Communication.pptx
 -  Lecture 03b - Coal.ppt
 -  Lecture 04 - Carbon Dioxide and Global Warming.ppt
 -  Lecture 05a (pH Water - Chemistry).ppt
 -  Lecture 05b - Ocean Acidification.ppt
 -  Lecture 06a (cell types).ppt
 -  Lecture 06b - Conservation.ppt
 -  Lecture 07a (Metric system-error-sci not).pptx
 -  Lecture 07b - Geothermal.ppt
 -  Lecture 08a (Photosynthesis).ppt
 -  Lecture 08b - Introduction to Bioenergy.ppt
 -  Lecture 09a - Algae.ppt
 -  Lecture 09b - Wind.pptx
 -  Lecture 10a (Biomolecules).pptx
 -  Lecture 10b - Biogas.pptx
 -  Lecture 11 Biodigesters with Nick Chambers.docx
 -  Lecture 12 Gassification with Nick Chambers.docx
 -  Lecture 13 - Hydro power.pptx
 -  Lecture 13proj (electricity project).ppt
 -  Lecture 14 - Solar.ppt
 -  Lecture 15 - Nuclear Energy.ppt
 -  Lecture 16 - Radiation and Risk.pptx
 -  Lecture 17a Microscopes.pptx
 -  Lecture 17b - Hemocytometer - FlowCAM.docx
 -  Lecture 18 (Our Mr Sun).pdf
 -  Lecture 19 - Intro to transportation fuel.ppt
 -  Lecture 20 - Engines.ppt
 -  Lecture 21a (Calvin Cycle).ppt
 -  Lecture 21b - Fuels (Alcohol).ppt
 -  Lecture 22 Biodiesel Intro.ppt
-

Stealth STEM

- The Sustainable Technologies/Biofuels and Water treatment programs at SFCC have enrolled in the last 5 years;
 - 247 students of various backgrounds (ages 13-61).
 - 76 students received
 - 21 AAS
 - 69 Certificates.
 - 9 students have transferred to 4-year universities in STEM fields,
 - 3 in graduate school.
 - 5 are employed in the biofuel/algae industry,
 - 15 are employed in Water/Wastewater Treatment (several by the City of Santa Fe)
 - 10 have created businesses employing 37 people from the Santa Fe region.

Training Center Corporation

The TCC (owned by SFCC) operates under the University Research Park Act whose mission is to;

- promote the public welfare and prosperity of the people of New Mexico;
- foster economic development within New Mexico;
- forge links between New Mexico's educational institutions, business and industrial communities and government through the development of research parks on university real property;
- engage in other cooperative ventures of innovative technological significance that will advance education, science, research, conservation, health care and economic development within New Mexico.

SANTA FE COMMUNITY COLLEGE



TRAINING CENTER CORPORATION



Training Center Corporation

2015-2016 the Training Center Corporation created

- six private-sector ventures at the Santa Fe Community College
 - linked with academic programs to provide hands-on internships and on-the-job training for new workers.
- TCC houses entrepreneurs in the fields of
 - advanced biotechnology,
 - bio-manufacturing,
 - Neuroscience,
 - sustainable agriculture.
- By 2018 the TCC will be providing
 - 12 new hands-on, paid internship opportunities
 - 12 new full and part-time jobs
- By 2020 the TCC will have added 70 or more paid positions to the Santa Fe economy.

TCC partnership	Number of jobs/ internships	Start date	Funding
NTXBio LLC	2 FTE 2014; 5 FTE 2016 ; 4 internships	Spring 2015	HD3 Investor Community
Rio Grande Neurosciences	3 FTE 2015 ; 4 internships	Fall 2015	HD3 Investor Community
Apogee Spirulina	1.5 FTE 2016 ; 2 internships	Spring 2016	Private
Spartina Biotechnologies, LLC	2 internships	Fall 2015	NMSBA leveraged grant-funded research project
Pending			
Ecoponex	14 FTE jobs and 34 FTE indirect construction jobs ; 4 internships, SFCC classes	Summer 2016	City & County of Santa Fe. Investor support.
Eldorado Biofuels	2 FTE/ 6 PT 2016 for 4 years; 4 internships annually	Summer 2016	LANL Collaboration: Dept. of Energy Grant

SFCC takes no IP ownership, SFCC gets a small piece of the company

California's Biomanufacturing Baccalaureate

Novelty and Workforce Needs

Mike Fino

Interim Dean, Math and Sciences & Professor, Biotechnology



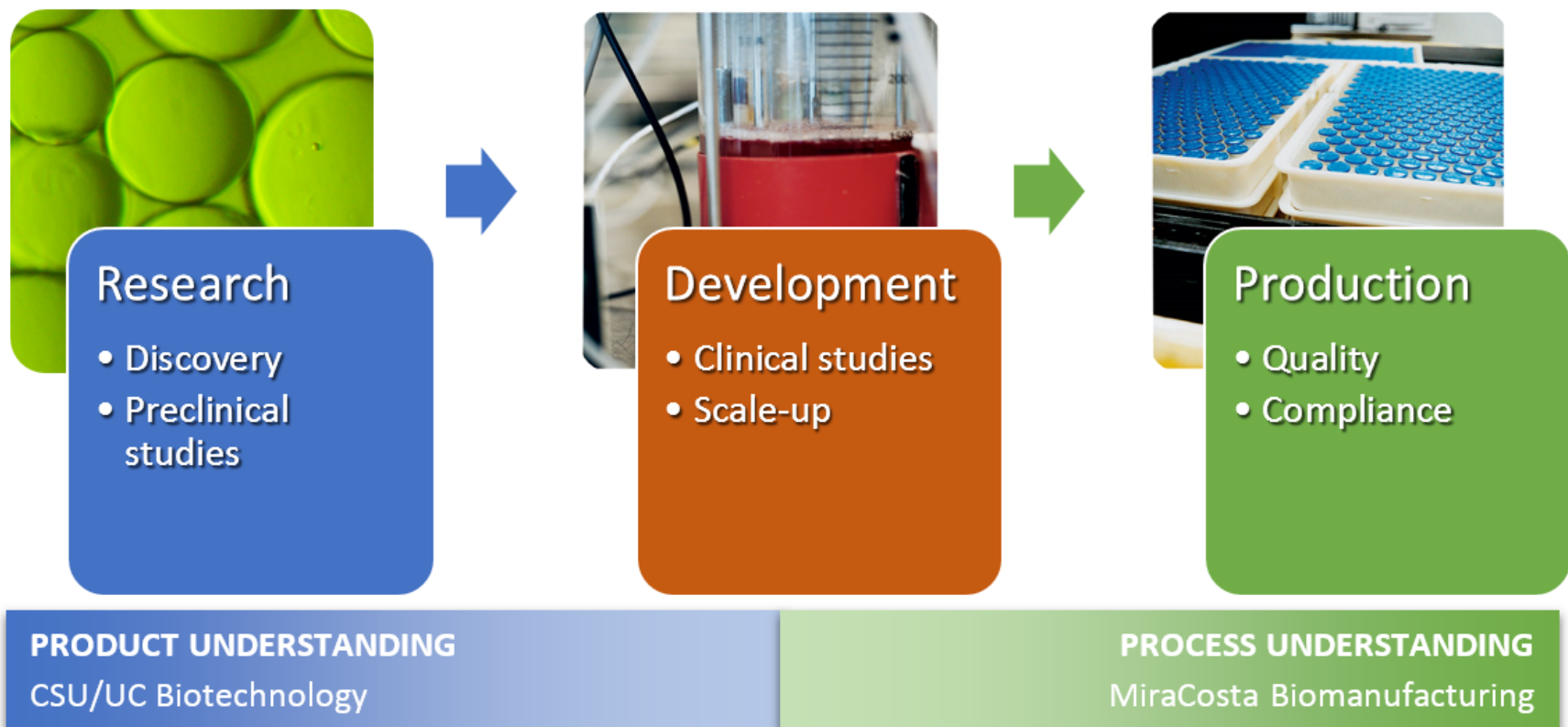
Need for a biomanufacturing baccalaureate

- 2008: the first profitable year
- Anecdotal information from local companies
- Published reports at regional and state level for biotechnology and, specifically, manufacturing
- Broad support from industry, workforce groups, local government, state, and national organizations



Non-duplication of CSU/UC degrees

Biotechnology Product Lifecycle



Upper Division Biomanufacturing Coursework

Biomanufacturing Science and Technology

- Process Sciences
- Design of Experiments for Biomanufacturing
- Design of Biomanufacturing Facilities, Critical Utilities, Processes, and Equipment
- Bioprocess Monitoring and Control
- Capstone Seminar in Biomanufacturing Technologies (Capstone)

Biomanufacturing Quality

- Supply Chain and Enterprise Resource Planning
- Advanced Topics in Quality Assurance and Regulatory Affairs
- Six Sigma and Lean Manufacturing
- Methods in Quality Improvements, Investigations, and Audits
- Capstone Seminar in Biomanufacturing Quality

**Upper
Division GE**

Bioethics

**Molecular Mechanisms
of Disease**

**Leadership and Personal
Development**

Targeted Occupations

Manufacturing

- Technician/Associate/Specialist/Operator
 - (Bio)manufacturing
 - Bioprocess
 - Biological
 - Upstream
 - Downstream

Quality

- Technician/Associate/Specialist/Coordinator/Inspector/Analyst
 - Quality
 - Quality Assurance
 - Quality Control

Questions?

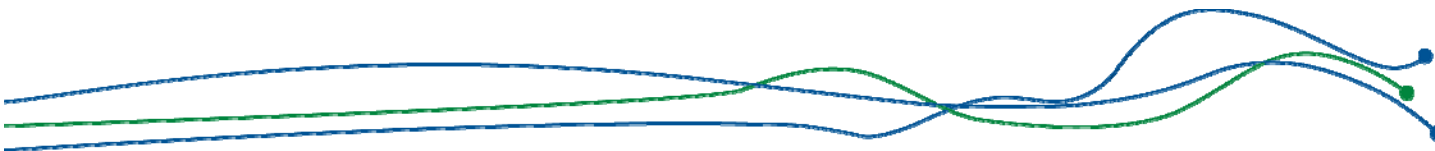
COMING
FALL 2017



**BACHELOR'S
DEGREE**
— IN —
BIOMANUFACTURING

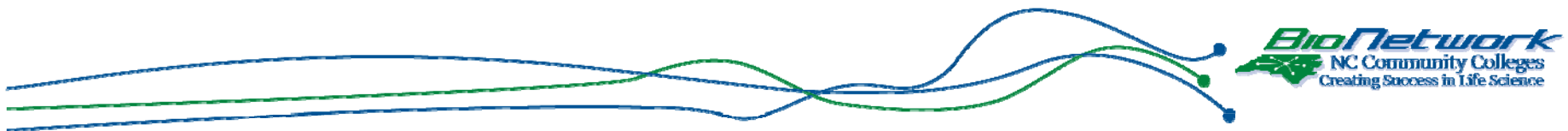
Food For Thought: NCCCS's Response to

CCP@ BIO 2016
San Francisco Marriott Marquis
June 2016



Overview

- Overview of BioNetwork
- Overview of FSMA
- Impact of FSMA
- BioNetwork FSMA related training programs and lab resources

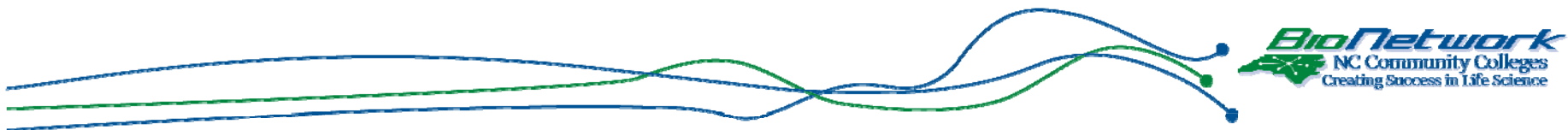


Workforce Development Partnership



The *NCCCS* provides a comprehensive training approach for the bioscience industry through two partner programs:

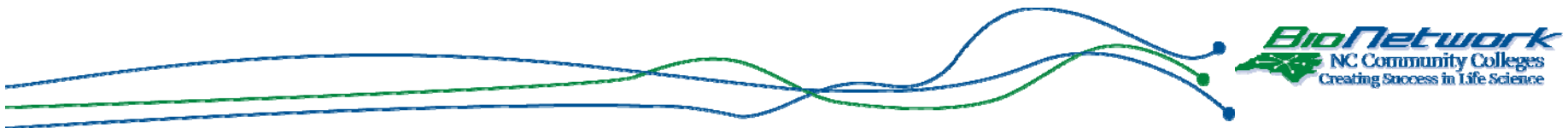
NCWorks
customized training



NCCCS Workforce Development Approach

In 1958, the NCCCS developed a training program designed to support North Carolina's new and expanding industries. It has evolved to become the [NCWorks Customized Training Program](#).

In 2004, [BioNetwork](#) was created through Golden LEAF funding to support the growing bioscience industry in North Carolina.



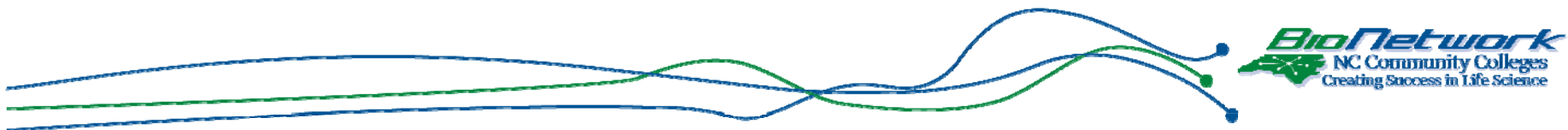
NCCCS Workforce Development Approach

NCWorks customized training

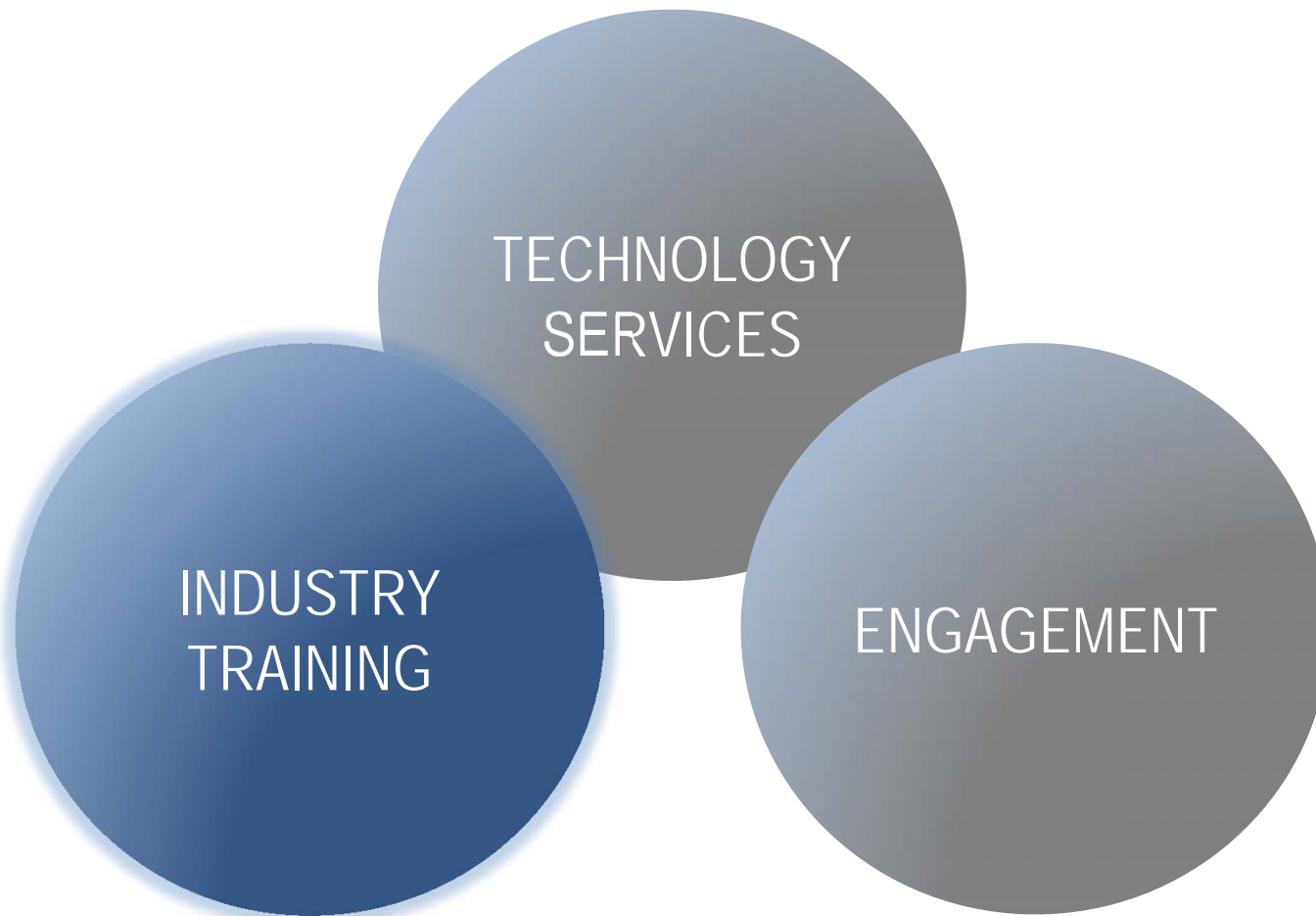
- Comprehensive training utilizing state-funds
- Job growth, technology investment, productivity enhancement
- BioNetwork functions as technical component of training project



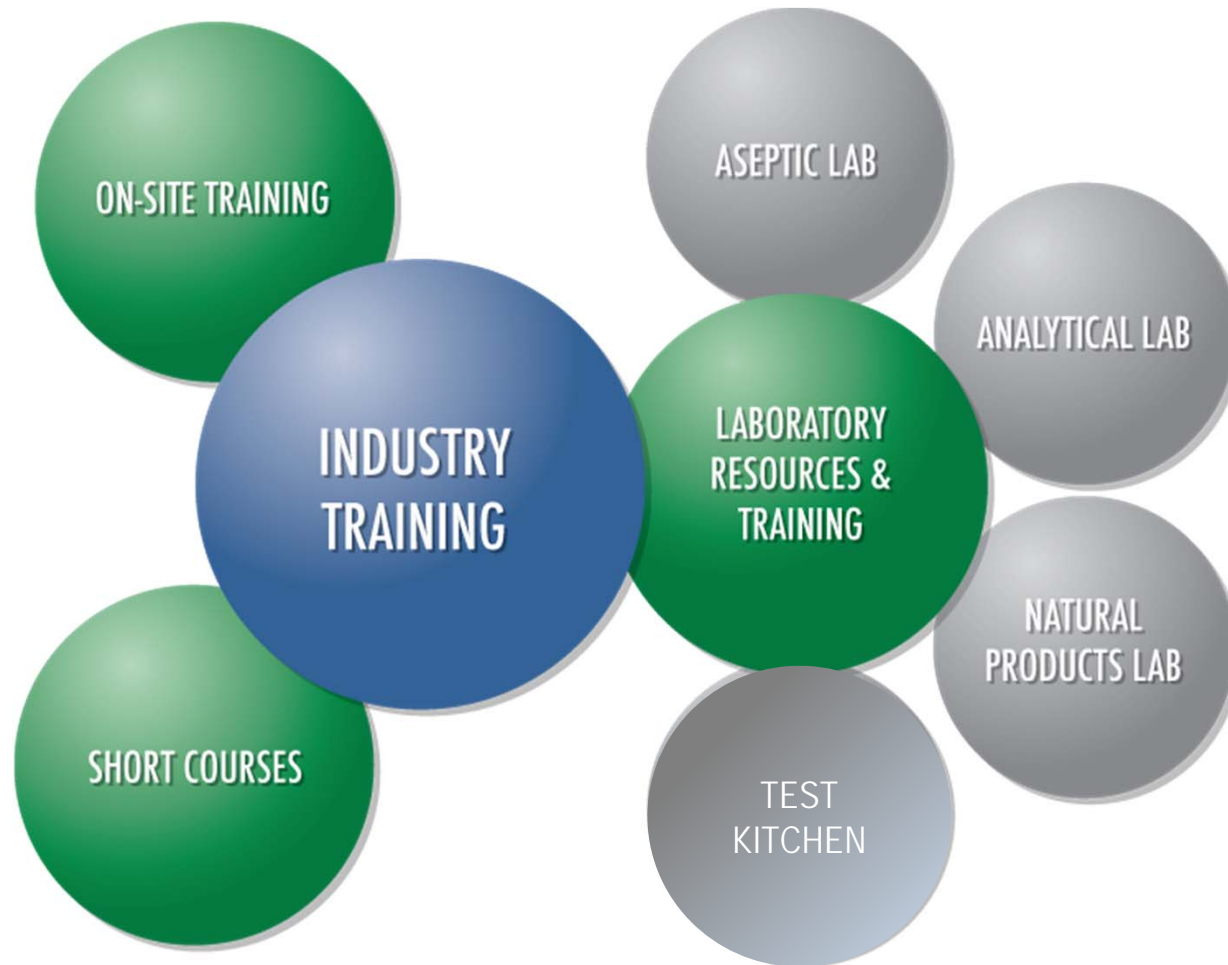
- Technical training
 - Delivered as part of an NCWorks CTP
 - Delivered at low, self-support fees if not part of NCWorks CTP
- Laboratory resources
- Video and eLearning resources



Service Areas



Industry Training



BioNetwork Metrics

In 2014-15, BioNetwork provided education and training to the growing life science workforce:

- 77 Unique companies served by BioNetwork
- 256 Laboratory services and 338 hours of laboratory use provided to businesses and entrepreneurs
- 2,361 Individuals received industry training
- 78 Continuing education courses held



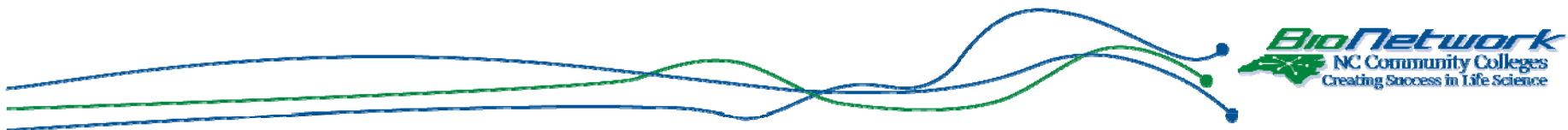
FDA Food Safety Modernization Act (FSMA)

- The most sweeping reform of our food safety laws in more than 70 years



FDA FOOD SAFETY
MODERNIZATION ACT

- Signed into law January 4, 2011
- It aims to ensure the U.S. food supply is safe
- Shifts the focus from responding to contamination to preventing it

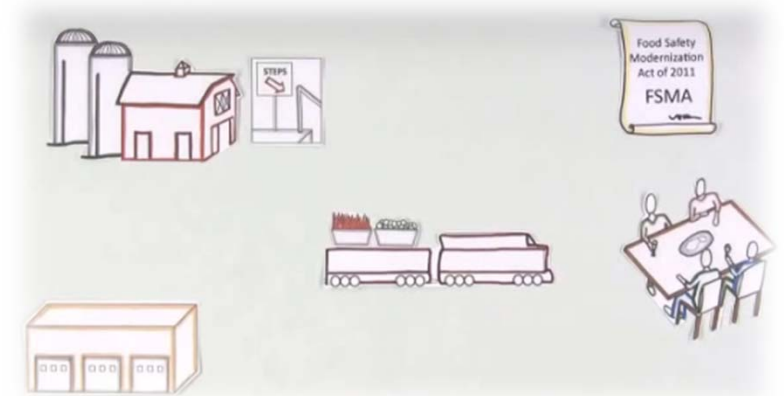
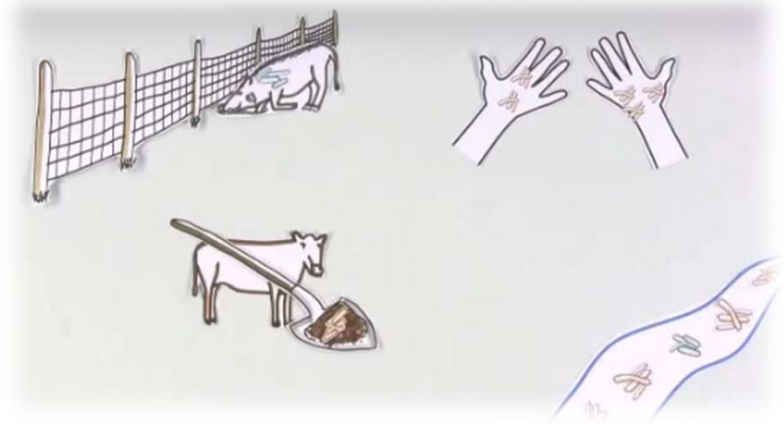


Why is FSMA needed?

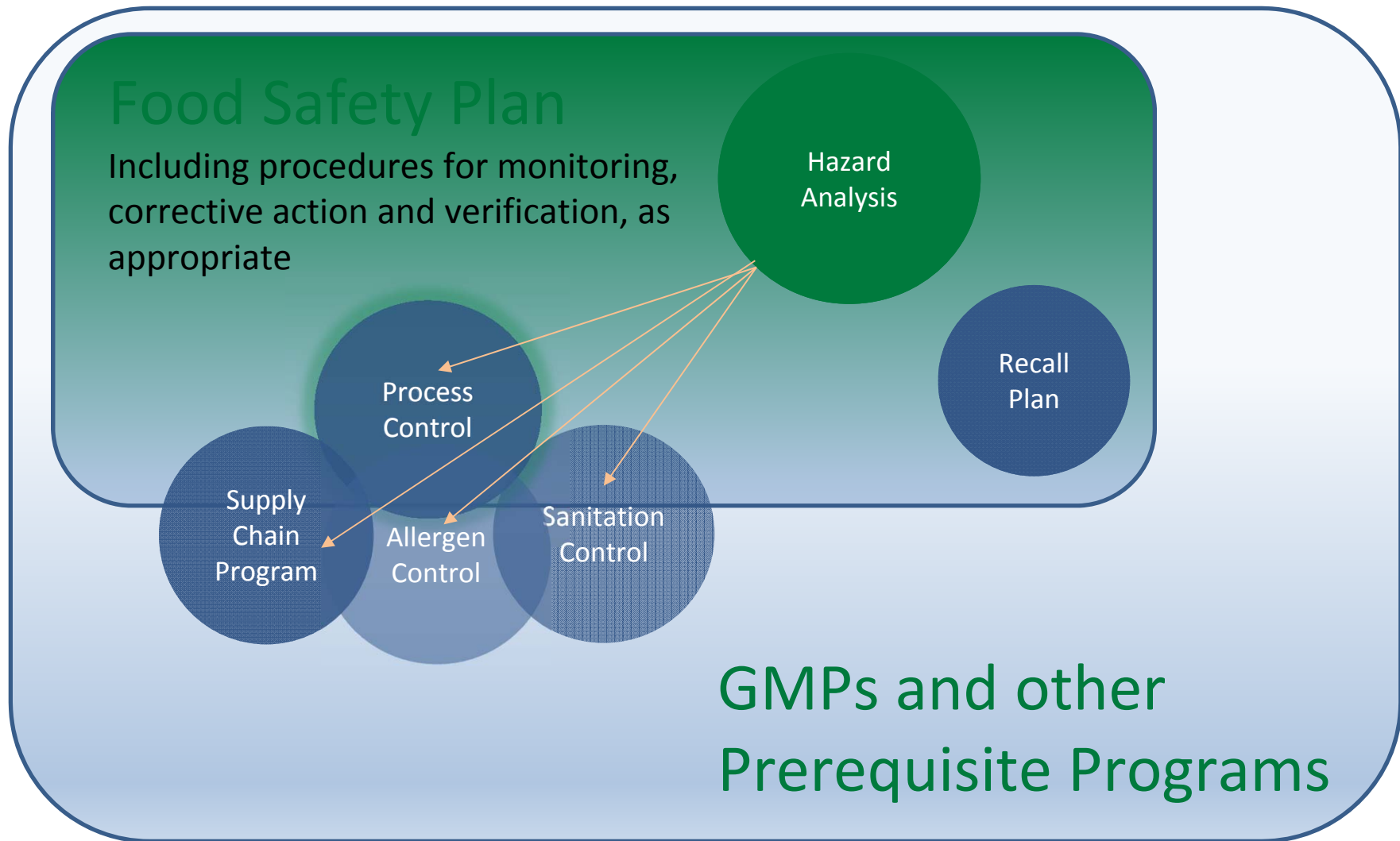
- Food supply more **high-tech and complex**
 - **New hazards** in foods not previously seen
- **Globalization** of the food supply
 - Currently, the FDA inspects less than one pound in a million of imported foods
- Shifting **demographics**
 - Growing population (~ 30%) of individuals are “at risk” for foodborne illness

Impact of FSMA

- Hazard focused and specific to product and processes
- “New” to Produce and Animal food industries
- Sanitary Transport of foods
- Import/Foreign Supplier verification
- Responsible parties must have FDA approved qualified individuals training

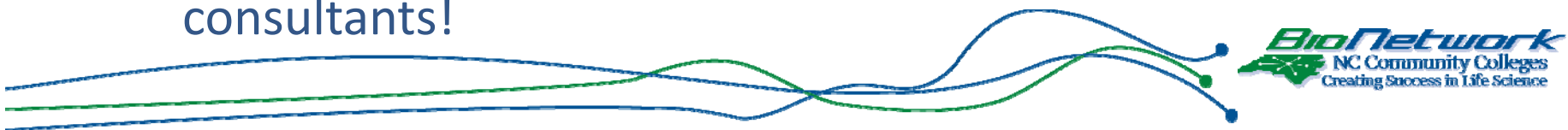


New Food Safety System



Some Challenges

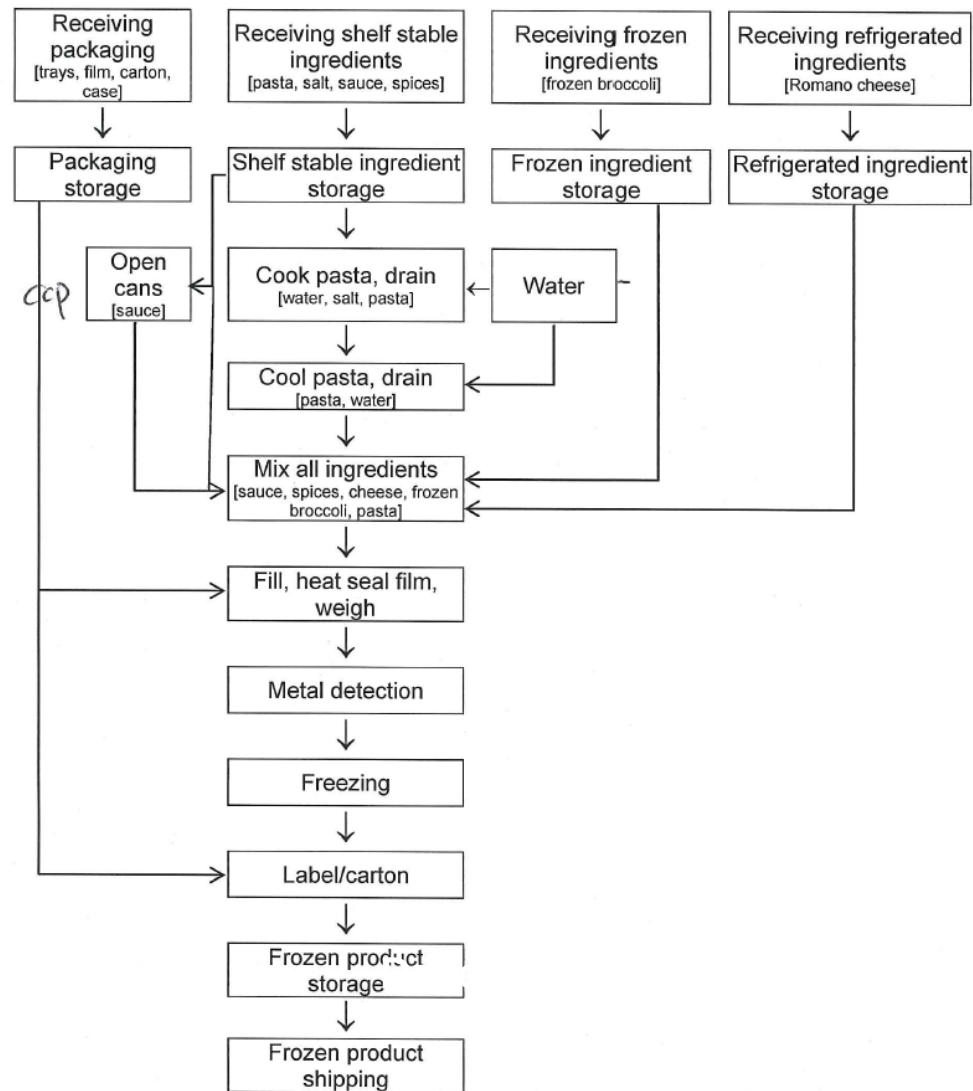
- Some industries are new to Food Safety
- Inadequate number of trainers
 - 3 out of 404 approved Food Safety Preventive Controls Alliance (FSPCA) instructors for the nation are based out of NC
- Compliance dates are confusing
 - based on size of business/profits
- Inadequate Guidance documents from regulators/academia for specific product types
- Inadequate validations exist for many products
- Hazard Analysis is very complicated and we aren't consultants!



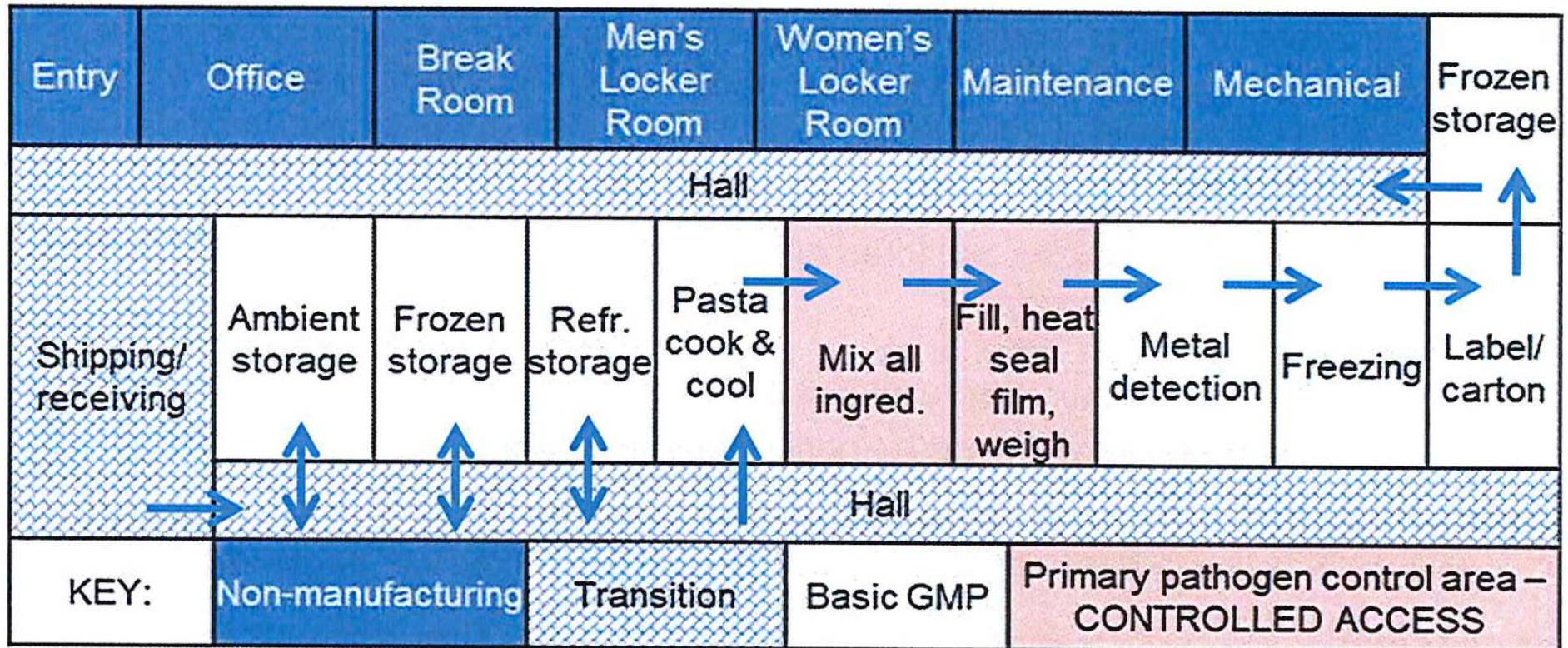
An example: Fettuccini Marinara with Broccoli



Manufacturing Fettuccini Marinara with Broccoli



Product Movement



Hazard Analysis

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Receiving packaging	B None						
	C Undeclared allergens	X		Labels on cartons must declare allergens present in the product and print errors have occurred	Allergen Control for label review by qualified individual	X	
	P None						
Receiving shelf stable ingredients – pasta	B Sporeforming pathogens such as <i>B. cereus</i>	X		<i>B. cereus</i> spores may be present in dry pasta and outbreaks due to growth after hydration have occurred. Levels present at receiving are not hazardous and will not change as long as the pasta is dry.	Subsequent cooling step prevents <i>B. cereus</i> growth and toxin formation in rehydrated pasta.		X
	Vegetative pathogens such as <i>Salmonella</i>		X	<i>Salmonella</i> may be present in pasta at a very low frequency and subsequent cooking is more than adequate to destroy it			
	<i>Staphylococcus aureus</i> enterotoxin	X		<i>S. aureus</i> can form heat stable toxin during pasta production at the supplier without preventive control.	Supply-chain Control is essential to prevent <i>S. aureus</i> enterotoxin prior to receipt.		X
	C Allergen – wheat	X		Wheat is an allergen and could contribute to cross-contact for other products that do not contain wheat.	Allergen Control for cross-contact prevention and allergen labeling at a later step		X
	P None						
Receiving shelf stable ingredients – salt	B None						
	C None						
	P None						
Receiving shelf stable ingredients – tomato sauce	B None			Low pH, shelf-stable product is not likely to have biological hazards			
	C None						
	P None						

Food Manufacturing Courses

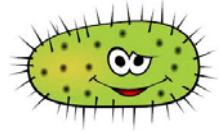
- **Fundamental Food Safety**
 - Code of Federal Regulations
 - Current Good Manufacturing Practices (CGMP)
 - Personal Hygiene
 - Hazards
 - Sanitation
 - Allergens
 - Documentation
 - FSMA
- **FSMA Overview series**
- Hazard Analysis and Critical Control Points (**HACCP**)
- **Food Defense**
- **Certifications**
 - SQF, BRC, AIB, other
- **Writing Effective SOPs/Reports**
- **Auditing and Investigation Skills**
- **Food Laboratory Skills**
- **Maintenance Practices**

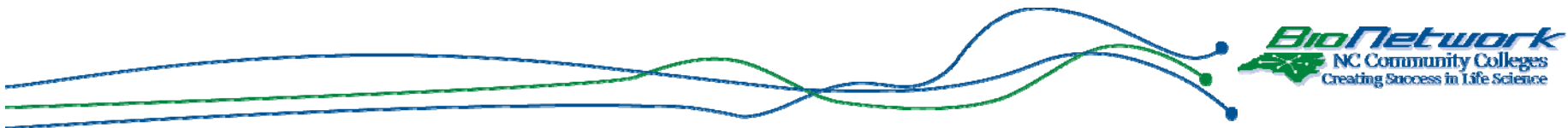


Courses in development

- FSPCA Qualified Individuals Training
- Association of Food and Drug Officials (AFDO) Approved Seafood HACCP course

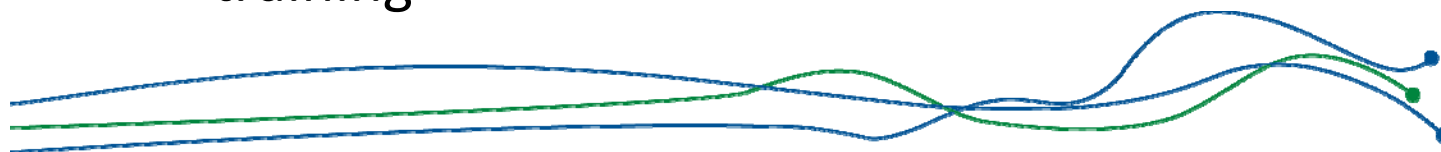
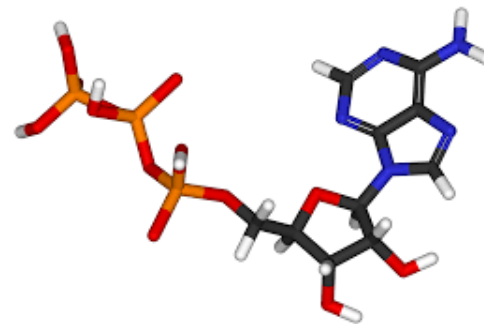


- Re-vamped Microbiology laboratory courses
 - Fundamental Microbiology 
 - Advanced Methods
- Polymerase Chain Reaction (PCR) courses
- Next Generation Sequencing (NGS) courses



Test Kitchen

- Hybrid laboratory/kitchen
- Equipment and rental space for small scale entrepreneurs
- Cannot retail produced products
- 100 units or less
- Foundational Food Safety coursework required before rental
- Hazard Analysis plan required before rental
- Advanced equipment training



Test Kitchen



The background of the slide is a light gray field filled with a complex pattern of overlapping geometric shapes. These shapes include circles of various sizes and squares, some of which are partially obscured by others, creating a layered, abstract effect. The lines are thin and black, contrasting with the light gray background.

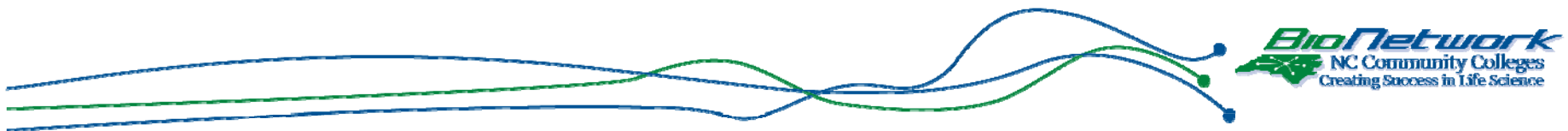
Questions?

Work With Us



Andrew Capps | Coordinator | Industry Training

828.782.2317 | acapps@ncbionetwork.org | ncbionetwork.org





Algal-based Education K-14 and Beyond

Ira "Ike" Levine, Ph.D.
Foundation President & Board Chair
ATEC P.I.

OUR FOCUS

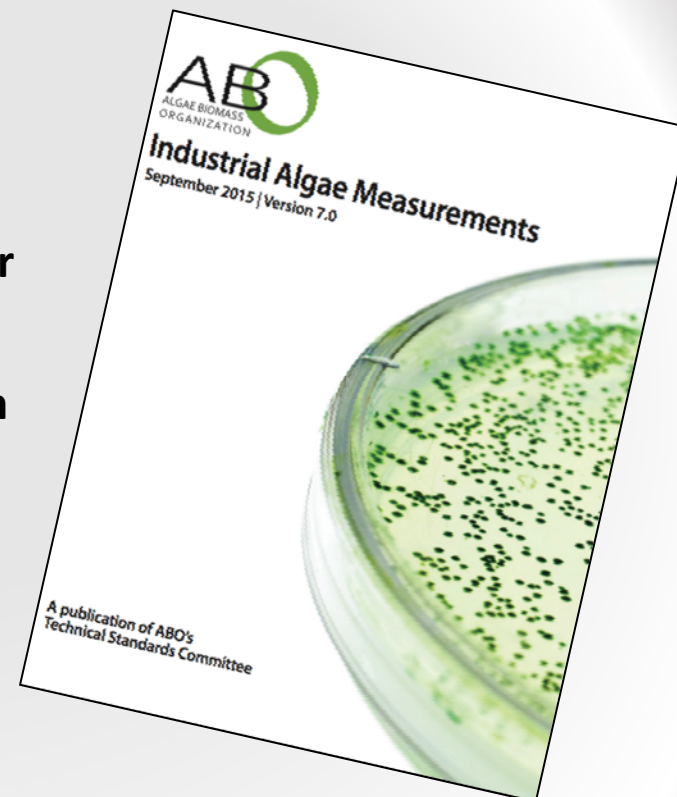
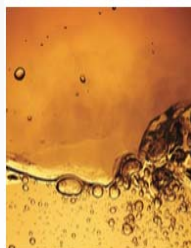


Founded in early 2013 as a 501(c)(3) non-profit Educational Foundation

Industrial Algae Measurements v. 7.0

7 Chapters:

1. State of the art algal product and operations measurements
2. Techno-Economic and life cycle analysis for unified descriptions of algae operations
3. Regulations and policy on algal production operations (*NEW*)
4. Use of wastewater in algal cultivation (*NEW*)
5. Regulatory and process considerations for marketing algal-based food, feed, and supplements
6. Regulatory considerations and standards for algal biofuels
7. Open and closed algal cultivation systems (*NEW*)



Provide a common language for information to flow to industrial stakeholders to aid with commercialization of algal biofuels and bioproducts



K-12 STEM Initiative

PURPOSE: To educate & excite students on the power of ALGAE to:

1. Significantly reduce Greenhouse Gases
2. Provide a sustainable source of biomass for Food & Bioproducts
3. Lead the path to Commercial Biofuels

*K-12 Initiative pilot completed
April 2016*

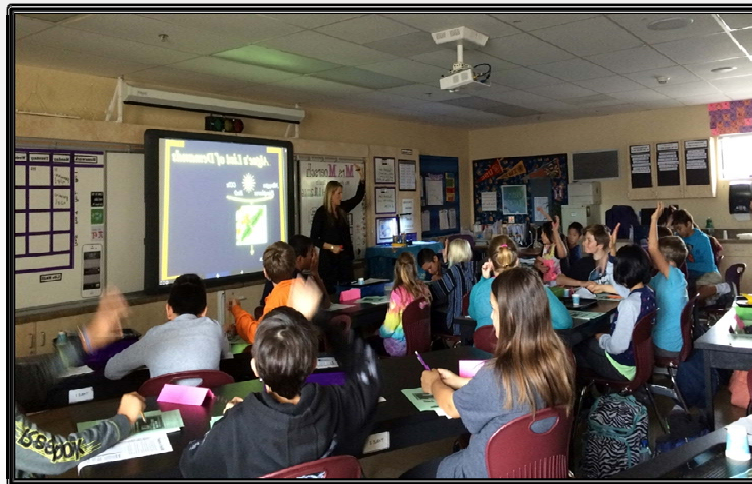
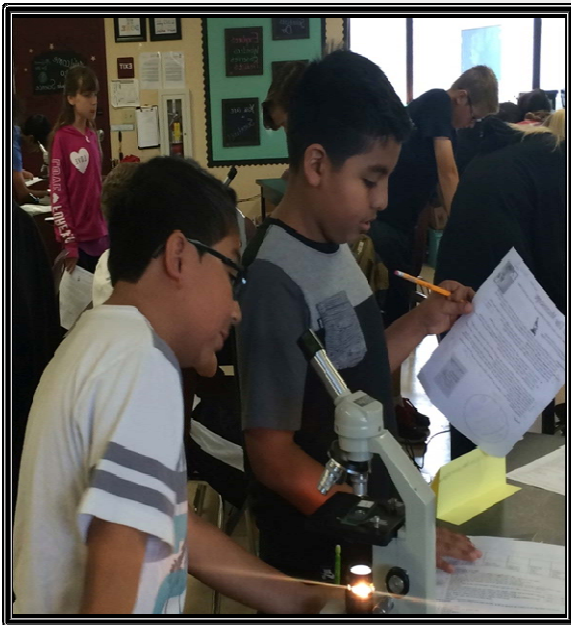
*300 6th/7th grade students
in San Diego, California*





1. Developing Algae STEM Kits to distribute free of charge to schools across the nation.
2. Fundraising through private funds & grants to fund 50 kits in the 2016/2017 academic year.
3. Partnering with educators to develop curricula & training tools for teachers.
4. Networking with school districts to spread the word!
5. Educating and inspiring students on how algae will meet global needs in our lifetime.

Students will join The Algae Nation!





U.S. DEPARTMENT OF
ENERGY | Energy Efficiency &
Renewable Energy
BIOMASS TECHNOLOGIES OFFICE



Objectives:

1. Develop and Implement a two year community and/or technical college degree in *Algae Biology, Cultivation, and Technology*.
2. Establishment of an aquaculture extension training program in *Algal Farming*.



Corporate
Partners



ABO/ASU/UCSD/ATP³

Social Media

Website

Federal/State/Local Governments

Online Traffic Generator
MOOC

BETO/USDA/EPA/DOL

Online Courses

Biotech
Micro/Macro
ACC
Internships
Externships

Regional, Intensive
Lab/Field Experiences

Cultivation
Micro/Macro
SFCC
Internships
Externships

Degree or Certificate

Transfer to
Advanced Degree

Degree or Certificate

Entrepreneur

Lab/biotech

JOBS

Cultivation/operations

Entrepreneur

- ~ 6,500 credit students
- 70% > 25 years old
- 50% have children
- Public school drop-out rate near SFCC – 40-50%

- 75% Part time
- 62% Female
- 45% Hispanic
- 5% Native American
- 2015-16 Best for Vets: Career and Technical Colleges





PROPOSED ASSOCIATE IN APPLIED SCIENCE IN ALGACULTURE – Algae Biology, Technology & Cultivation

- **New Courses**
- **ALGE 111 – Introduction to Algaculture**
- **ALGE 211 – Advanced Algaculture**
- **ALGE 221 – Algae Harvesting**
- **ALGE 298 – Algaculture Capstone**
- **BIOL 252 – Algae Biotechnology 1**
- **BIOL 250 – Introduction to the Biology of Algae (Phycology)**
- **BIOL 253 – Algae Bioprospecting Informatics (Algae Biotechnology 2)**
- **PLMB 141 – Pumps and Motors**

Certificate in Algaculture (32 hrs min)

Associate in Applied Science - Algaculture Technologies (61 hrs min)

Fall 1	Spring 1	Summer 1
ALGE 111 Introduction to Algaculture (3-proposed)	ALGE 211 Advanced Algaculture (3 – proposed)	ALGE 221 Algae Harvesting (3 – proposed)
STEM 111 Introduction to Science, Technology, Engineering and Mathematics (3)	PLMB 141 – Pumps and Motors (2 – proposed)	ENGL 111 Composition and Rhetoric (3)
BLDG 111 Construction Safety (3)	BSAD 119 Entrepreneurial – Planning and Introduction (3)	HPER – any (1)
ALTF 111 Introduction to Alternative Fuels and Vehicle Technologies (3) [or] ENVR 111 Introduction to Sustainability (3)	CHEM 111 Introduction to Chemistry [and] (3) CHEM 111L Introduction to Chemistry Lab (1)	
BIOL 111P Introduction to Biology [and] (3) BIOL 111PL Introduction to Biology Lab (1)	ELEC 111 Electronic Fundamentals (4)	
TOTAL (16)	TOTAL (16)	TOTAL (3)
TOTAL (16)	TOTAL (16)	TOTAL (7)

Fall 2	Spring 2	Summer 2
BIOL 250 – Introduction to the Biology of Algae (3 – proposed)	ALGE 298 – <u>Algaculture</u> Capstone (3 – proposed)	
ENVR 113 Instrumentation and Control Labs (3)	HIST 260 History of New Mexico *** (3)	
PHIL 258 Environmental Ethics and Sustainability (3)	Approved Social/Behavioral Sciences [or] Humanities and Fine Arts (3)	
BLDG 115 Trades Math [or] (3) WATR 112 Applied math for Water Operators (4) [or] MATH 111 or higher (3)	ENGL 119 Professional Communication [or] (3) ENGL 216 Technical Writing (3)	
Approved elective (1-4)	Approved elective (1-4)	
TOTAL (13-17)	TOTAL (13-16)	



Biotechnology Program Integrating Algae Training



Small changes in the lab module selections of existing courses can easily adjust the biotechnician training program to serve the algae technician workforce.

Support from the online phycology courses can assist in the flexibility of the biotechnology program in rapidly meeting the changing needs of industry.

Biotechnology Program Integrating algae training

First-year

Introduction to Biotechnology I. Including a lab module on culturing algae, framed by a research question, such as the effect of light intensity, color of phycobiliprotein production in cultured microalgae.

Introduction to Biotechnology II. Including a lab module on purification of phycobiliproteins from cultured microalgae.

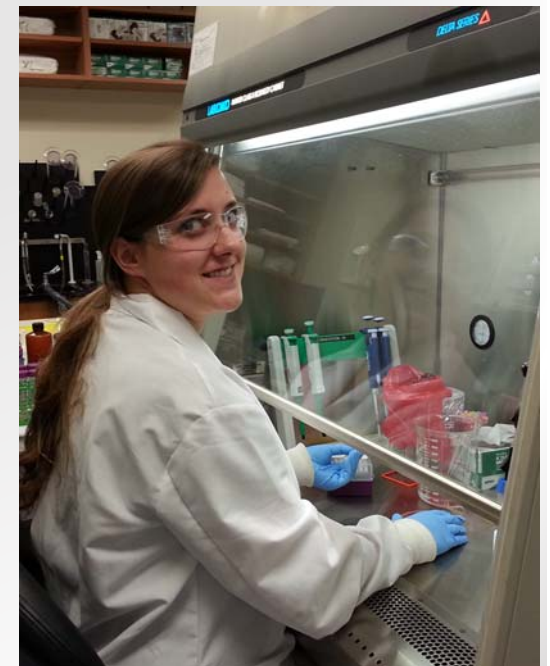
Second-year

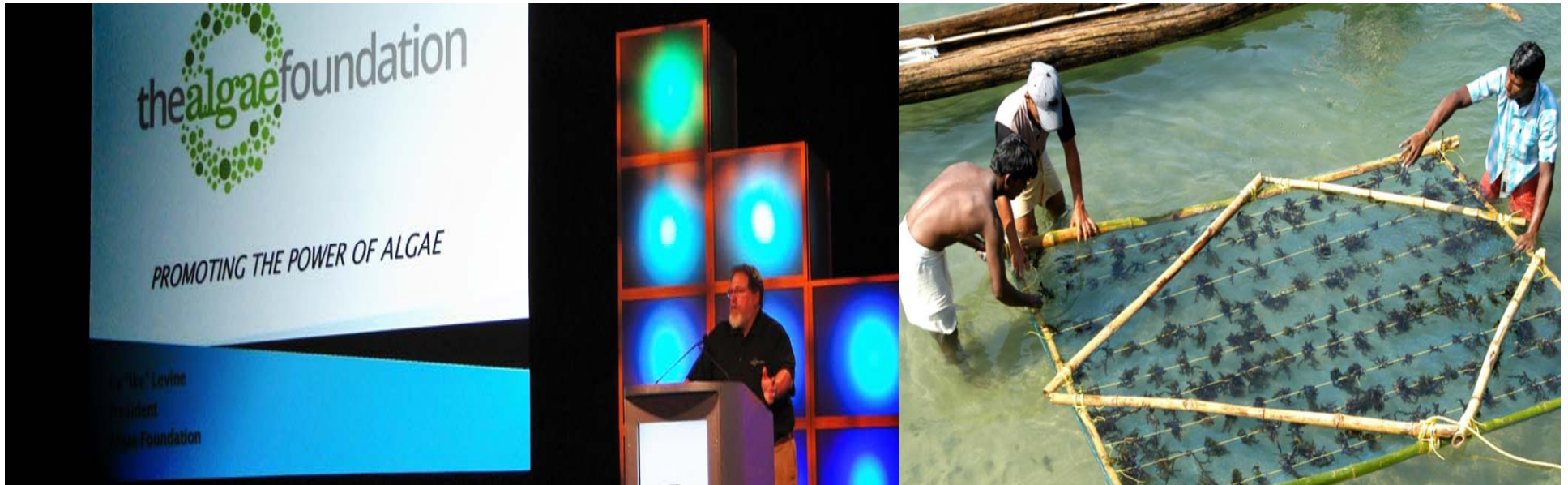
Bioinformatics. Including a comparison of phycobiliprotein gene sequences and identification of binding sites of phycobilins in proteins.

Biotechnology Instrumentation. Including a lab module on the isolation of astaxanthins and purification by HPLC.

Cell Culture Techniques. Comparison of photobioreactor performance in scale-up. (for the biomanufacture-focused course, when offered) Isolation, culturing, and cryopreservation of environmental isolates (for the lab technician- focused course)

Molecular Biology Techniques. Include a DNA barcoding module for identification of microalgae in environmental isolates.



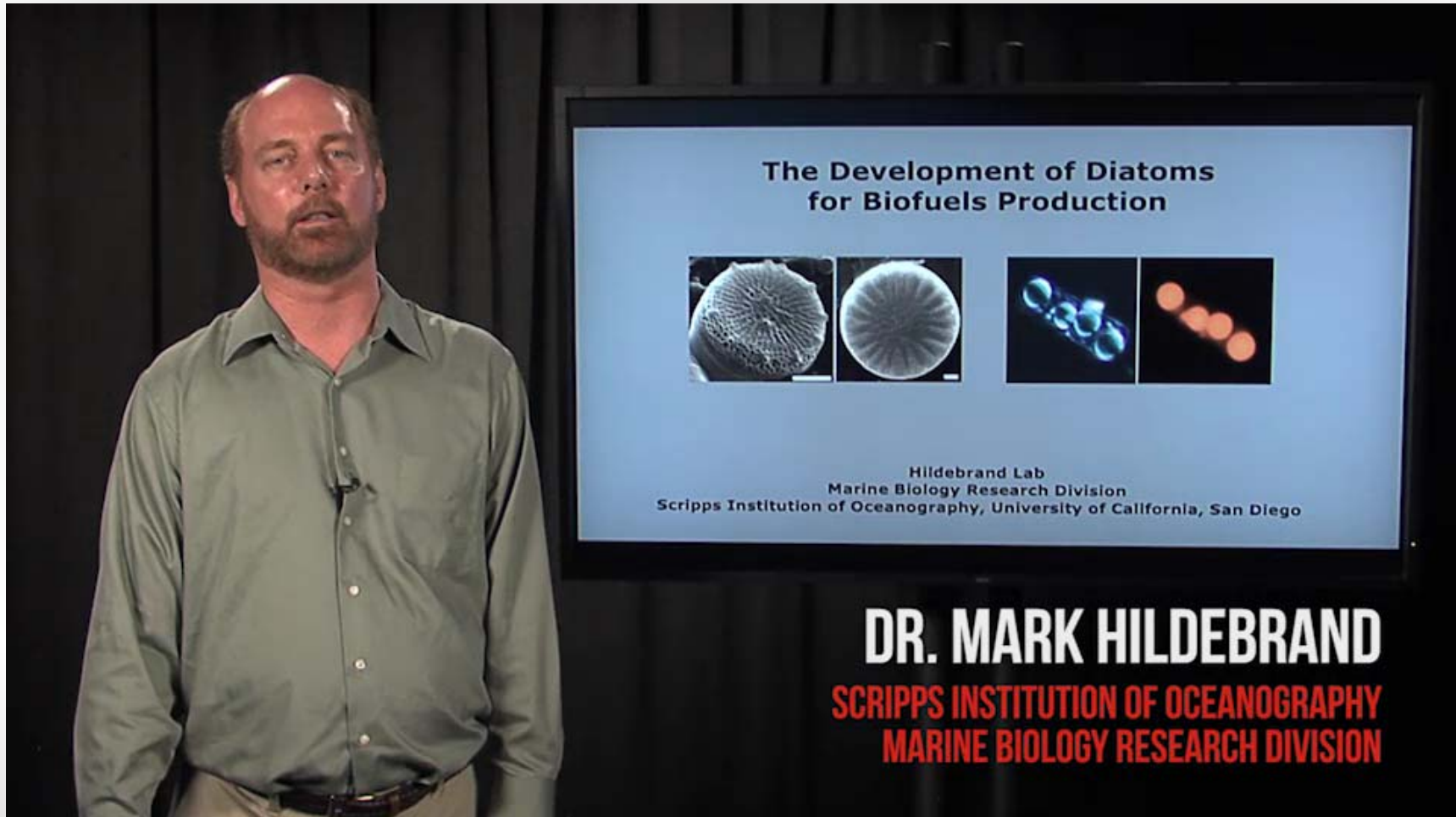


Arizona State University Online Curriculum Development

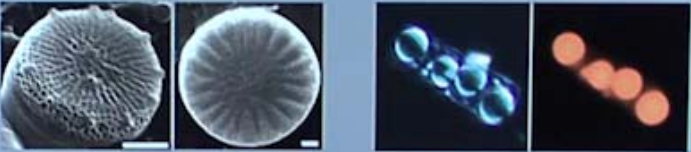
1. ASU curriculum developers and instructional designers work with subject matter experts to develop course(s).
2. Content is assembled into the continuing education platform, Blackboard.
3. Courses are hosted on ASU-CE and can be accessed by any ATEC degree seeking students.

University of California, San Diego

Biofuel MOOC - Algae



The Development of Diatoms
for Biofuels Production



Hildebrand Lab
Marine Biology Research Division
Scripps Institution of Oceanography, University of California, San Diego

DR. MARK HILDEBRAND
SCRIPPS INSTITUTION OF OCEANOGRAPHY
MARINE BIOLOGY RESEARCH DIVISION

- AzCATI has supplied content from ATP³ workshops to build curriculum for 7 new SFC Courses for new A.A.S. degree program
- Efforts are designed to create well-educated individuals suited for entry level positions at algae companies or as algal-based entrepreneurs.
- Additional goal is to send successful students onto universities to complete their Bachelor's degrees



ATEC Collaboration
Thomas Dempster, PhD
Director of ATP³ Education & Training

ATP³ Developed Hands-On Laboratory Activities

- Laboratory Safety Procedures
- Sample Collection & Storage
- Measuring Culture Density
- Spectrophotometer Utilization
- Hemocytometer Cell Counting
- Light & Fluorescence Microscopy
- Microalgal Computational Identification
- Large Scale Culture Transfers
- Harvesting and Dewatering Technologies
- Sample Preparation and Freeze Drying
- Total Lipid Extraction & Characterization
- Carbohydrates, Proteins & Starch Analyses



ATEC Extension Program

The extension program will be available throughout the country via online platform

Short Course, 1-2 weeks

Initial courses to be offered in Arizona, California, Florida, Hawaii, Maine and New Mexico, the states with existing algae biomass efforts



Acknowledgements

Funding for this project was provided by the U.S. Department of Energy's Bioenergy Technologies Office and supported by the National Renewable Energy Laboratory.



Photos, Slides, and Input Assistance Provided by:

Algae Biomass Organization: Tiffany Canliss

Arizona State University Online: Bill Brandt

ATP³ : Thomas Dempster

Austin Community College: Linnea Fletcher, Patricia Phelps

MiraCosta Community College: Mike Fino

NREL: Cindy Gerk, Philip Pienkos

Rutgers University Extension Program: Gef Flimlin

Santa Fe Community College: Luke Spangenburg, Stephen Gomez, Ondine Frauenglass

University of California, San Diego: Steve Mayfield, Wendy Stegman

Thank You

