

BUILDING A BIOECONOMY ECOSYSTEM: ADDRESSING NATIONAL AND LOCAL CHALLENGES

Jim DeKloe
**Distinguished Professor of Biotechnology
and Biomanufacturing**
Solano College
Vacaville, CA
james.dekloe@solano.edu
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NIMBL The National Institute for
Innovation in Manufacturing
Biopharmaceuticals

 **BioMADE**™

The Biotechnology Century

“...the twentieth century was the century of physics and the twenty-first century will be the century of biology.”

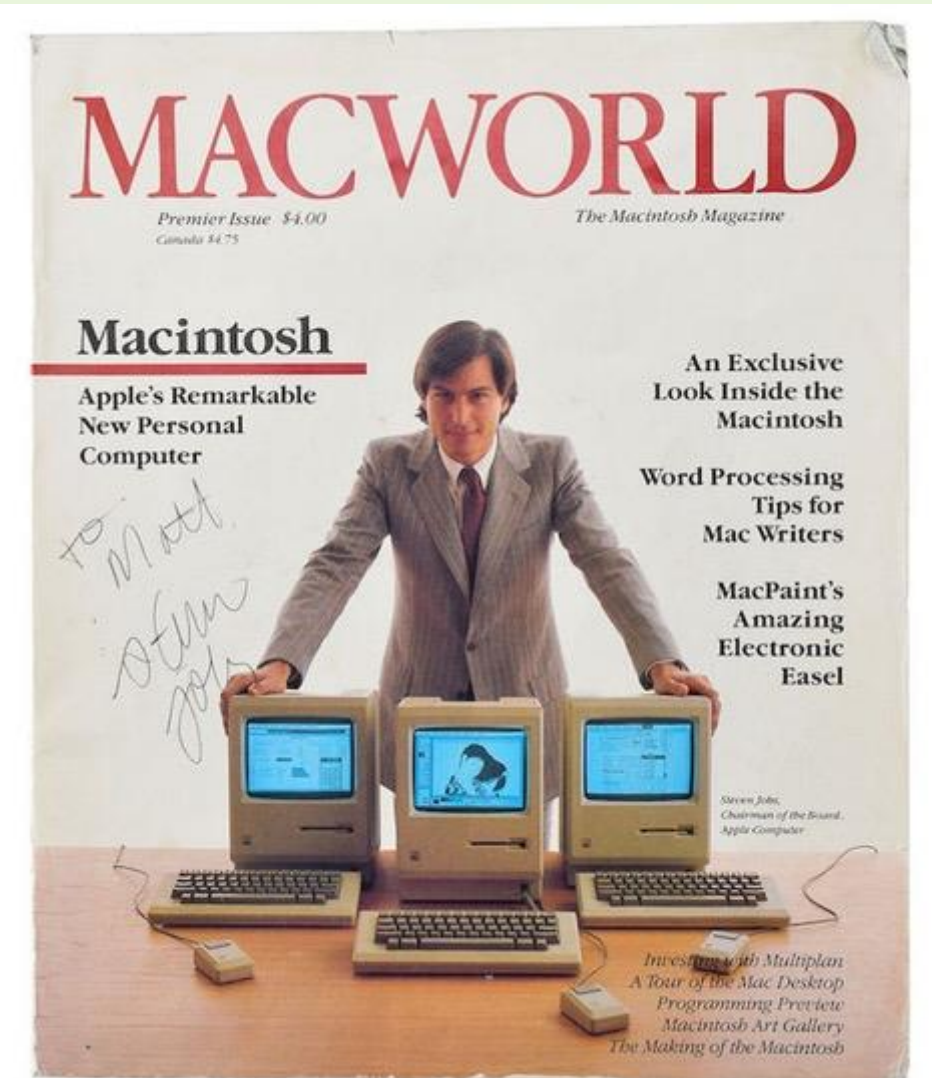
“Biology is now bigger than physics, as measured by the size of the budgets, the size of the workforce, or the output of major discoveries...”;

Freeman Dyson – physicist and futurist - 2007

Freeman Dyson - 2007

“It is likely that biotechnology will dominate our lives and our economic activities in the second half of the twenty-first century, the way that computer technology dominated our lives and our economy in the second half of the twentieth.”

We are at the dawn of a revolution... or is it revolutions?



Two Reports Projection: \$4 - \$30 Trillion Bioeconomy



<https://www.mckinsey.com/industries/life-sciences/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives>

The U.S. Bioeconomy:
Charting a Course for a
Resilient and Competitive Future

A Bioeconomy
Strategy
APRIL 2022

SCHMIDT FUTURES

<https://www.schmidtfutures.com/wp-content/uploads/2022/04/Bioeconomy-Task-Force-Strategy-4.14.22.pdf>

McKinsey Report



Advances in biological science could transform economies and societies, helping to tackle global challenges from climate change to pandemics.

<https://www.mckinsey.com/industries/life-sciences/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives>

“The fourth industrial revolution, categorized as involving the fusion of physical, digital, and biological technologies, will likely be fueled by operationalizing engineering biology research and biomanufacturing.”



- Investments should incorporate accessible workforce opportunities in biotechnology, biomanufacturing, and engineering biology;
- Investments should focus on building up the capability of these rural, midwest, and southeastern regions to cultivate and transform their biomass resources into biobased products;
- Investments should encourage the development of local community spaces that teach synthetic and engineering biology.

<https://ebrc.org/actions-to-enable-an-equitable-and-innovative-us-bioeconomy/>

President's Executive Order on the Bioeconomy White House Summit – September 14, 2022



“We know that the global industry is on the cusp of a revolution powered by biotechnology. Analyses and facts suggest that before the end of the decade, engineering biology holds the potential to be used in manufacturing industries that account for more than one third of global output. That’s equivalent to almost \$30 trillion in terms of value.”

Senior Administration Official

“That’s a really large number and its hard to get your head around. In fact its so large that I asked the team to go back and make sure that it was actually right. To put it into perspective, the entire GDP of the country is about \$21 trillion. So we’re talking about over a decade growing in our industry that’s about 150 percent of the entire US economic output today.”

Brian Deese - Director of the National Economic Council

The Scale of the Upcoming Bioeconomy is Vast



<https://www2.deloitte.com/us/en/pages/energy-and-resources/articles/oil-and-gas-industry-outlook.html>

<https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/ag-and-food-sectors-and-the-economy/>
https://www.fairobserver.com/region/north_america/brian-muller-usa-agriculture-industry-agricultural-farming-american-farmers-38913/

Building Momentum in Regional Ecosystems



October 5, 2022 | AFFOA, AIM Photonics, America Makes, ARM, CESMII, CyManII, IACMI, NextFlex, PowerAmerica | Additive Manufacturing, Education, Fabrics, Flexible Hybrid Electronics, Materials, Photonics, Power Electronics, Robotics, Sustainable Manufacturing, Workforce

Manufacturing evolved in the United States through geographic clusters that produced competitive advantages in expertise, scale of operations, research prowess, and skilled labor. The origin of the automotive sector is an example of a regional cluster, with vehicles assembled in the Detroit area from parts and components manufactured in the upper Midwest. Another would be the evolution of personal computers and microelectronics in the San Jose area, which became known as Silicon Valley.

Viewing a group of companies and institutions as a regional cluster (or what's also often called a regional ecosystem) highlights opportunities for coordination and mutual improvement which benefit the industry, local communities, and national competitiveness. The ecosystem fosters not only incubation of key technologies in the industry but also helps accelerate the scaling and commercialization of the sector. Being part of these regional networks helps firms build and maintain competitive strength in global markets.

Typically, there are three key components that define an advanced manufacturing cluster:

- A cluster of nationally or internationally "traded" private companies, which are the engines of regional economies
- Research organizations, such as major universities, government and private sector labs, and other supporting institutions, such as trade organizations that intersect with manufacturing
- A skilled workforce

Workforce Development is Key in Every Regional Cluster

Workforce is a key component for any regional manufacturing cluster, especially as new technology is developed and changes the nature of job duties. Manufacturing USA network institutes have been at the forefront of advancing workforce initiatives in major regional clusters.



WORKFORCE

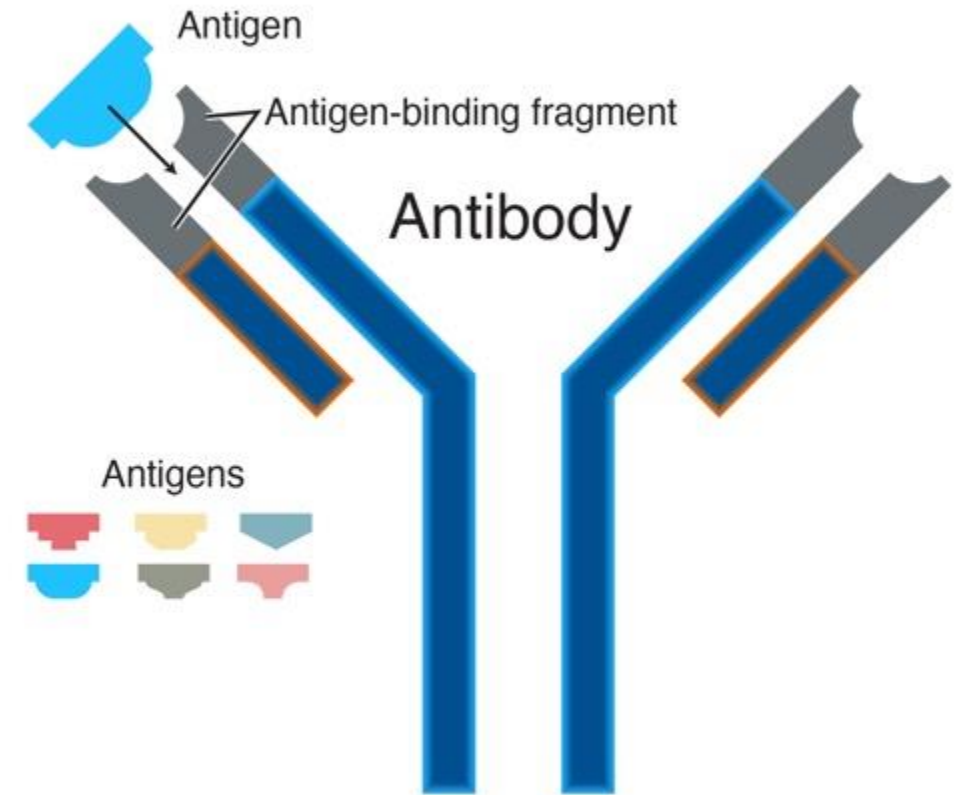
Typically, there are three key components that define an advanced manufacturing center:

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- Research organizations such as major universities, government and private sector labs, and other supporting institutions, such as trade organizations
- A skilled workforce

Pharmaceutical Biotechnology



Monoclonal Antibodies



Solano County Case Study



Vacaville attracts first biotech - 1985

LSBC's GENEWARE® Free-Protein Expression Vectors

The diagram illustrates the structure of the GENEWARE vector and its function. The vector consists of a **Cap structure**, a **Replicase/Transcriptase** gene, a **Movement protein gene**, a **Product gene (eg. GFP)**, and a **Coat protein gene**. The **Product gene** is transcribed and translated into a **Product (eg. GFP)**, which is shown as a green circle. The **Movement protein gene** and **Coat protein gene** are also transcribed and translated into their respective proteins, shown as green bars. The **Product** is then expressed in a plant cell, as shown in the **Normal Light** images.

Normal Light (dpi = days post infection)

2 dpi 4 dpi 7 dpi

UV Light (Fluorescent protein product glowing green)



Alza Pharmaceuticals - 1987



Chiron (Novartis now) - 1992



Genentech Announces Vacaville Expansion - 1994



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Vacaville Unveils California Biomanufacturing Center

October 27, 2020

< Share



Genentech's biomanufacturing facility

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Learn New Tools for Successful Scale-Up from 15mL to 2000L

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[COVID-19 Candidates](#)

Land deals advance Solano County's biomanufacturing hub plans



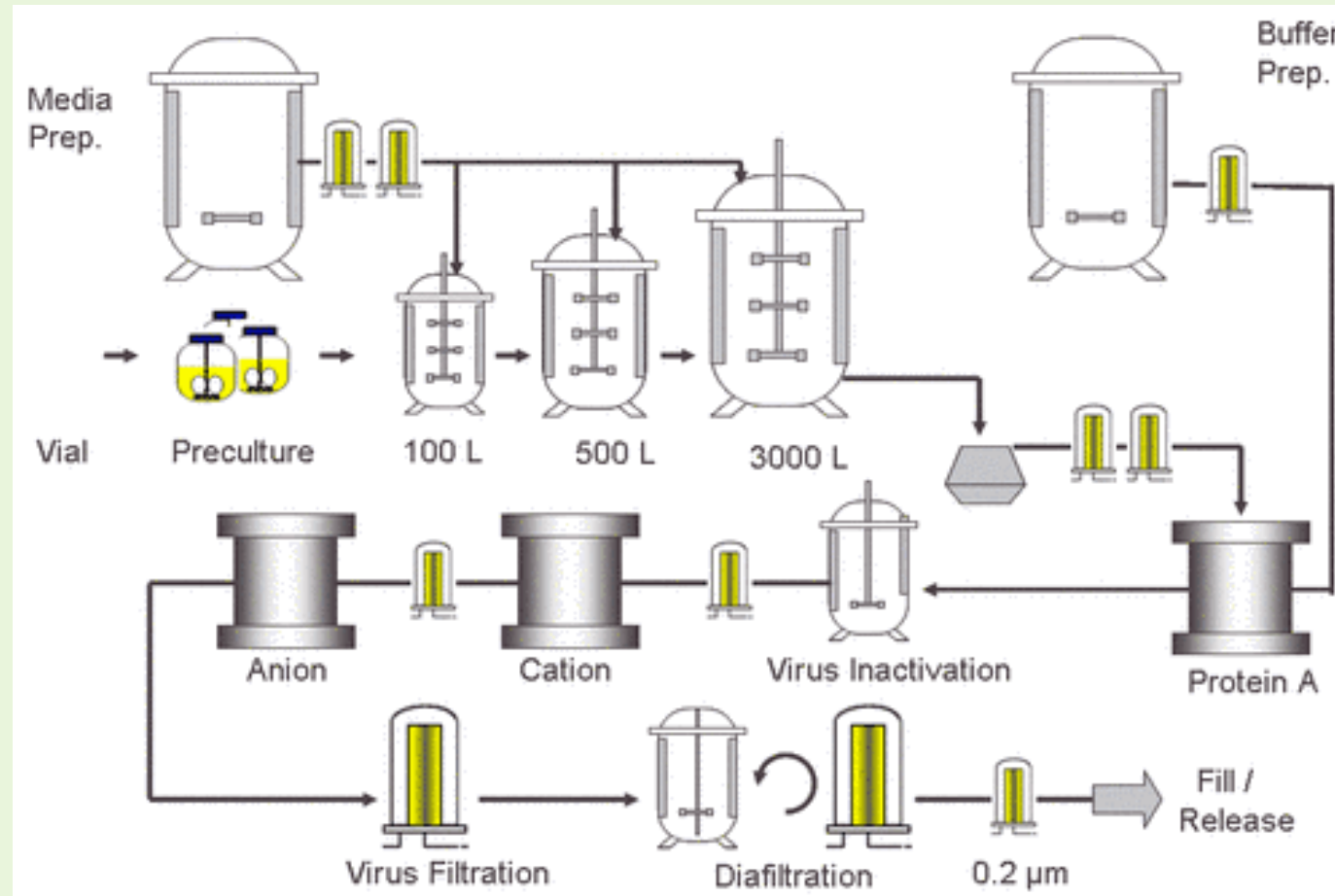
SLIDE 1 OF 4

Architectural rendering of planned Transwestern Ventures biomanufacturing campus at the south end of Vaca Valley Business Park. Transwestern purchased 22.4 acres there in 2022. (courtesy of Transwestern Ventures)

KEN ELLIOTT
FOR THE NORTH BAY BUSINESS JOURNAL
August 3, 2022

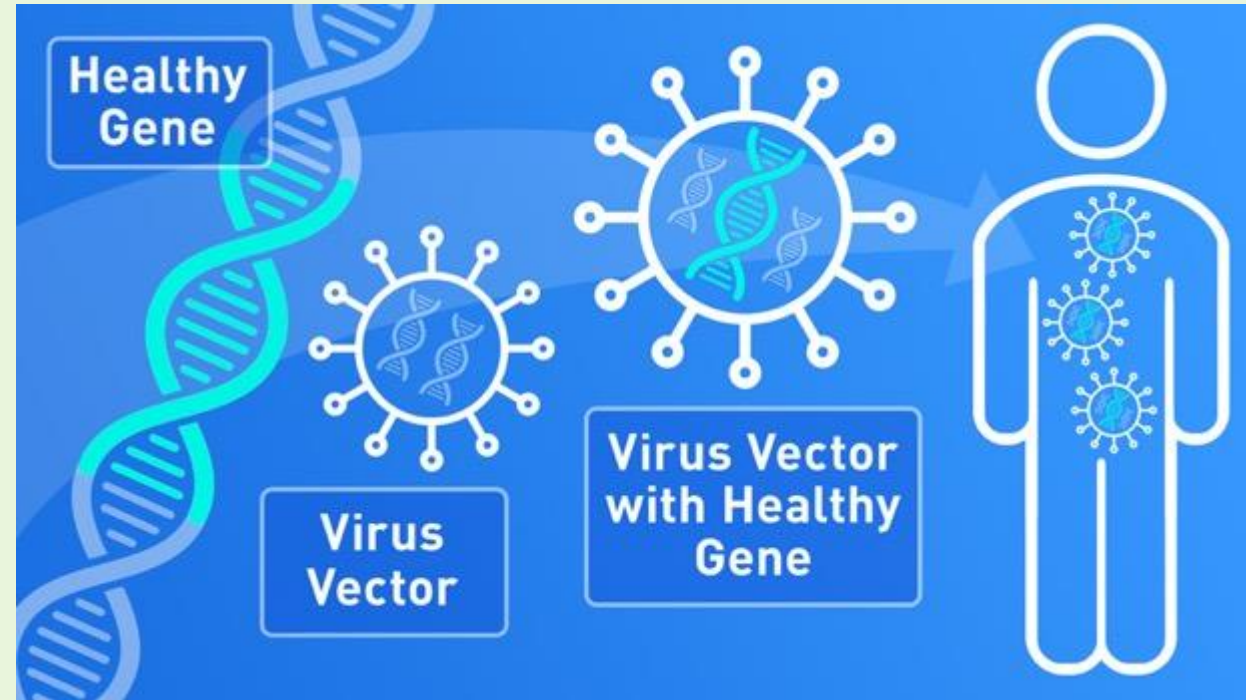


The “traditional” biomanufacturing process



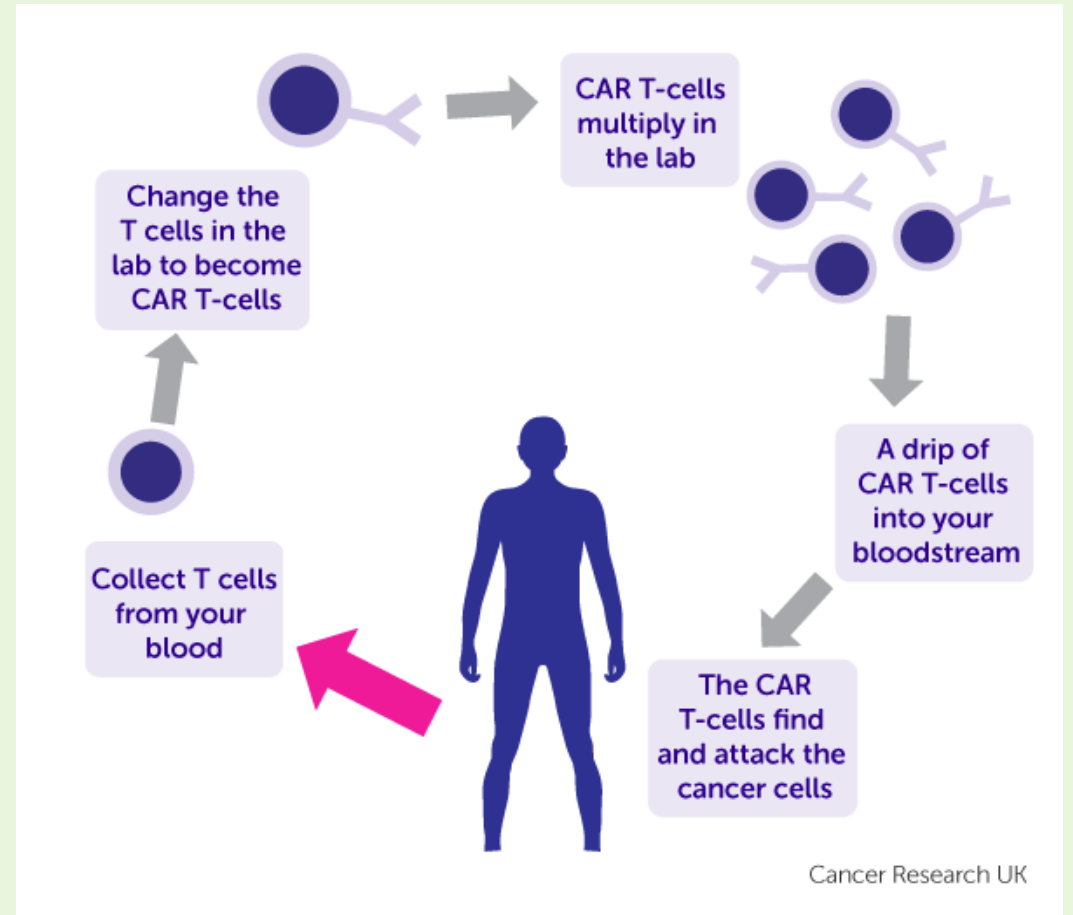
Source: <http://www.invite-research.com/en/contentseite/aktuelle-forschungsprojekte/mobidik.html>

Gene Therapy



<https://www.fda.gov/consumers/consumer-updates/what-gene-therapy-how-does-it-work>

Cell Therapy



<https://www.youtube.com/watch?v=7->

Proposition 14 - Stem Cell Initiative



Genentech Announces Vacaville Expansion - 1994

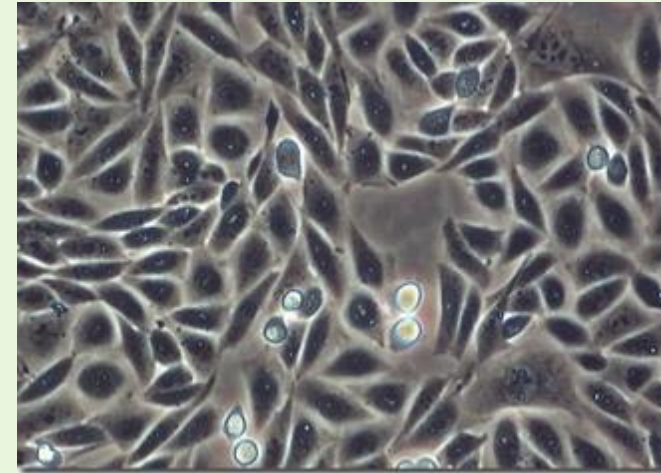
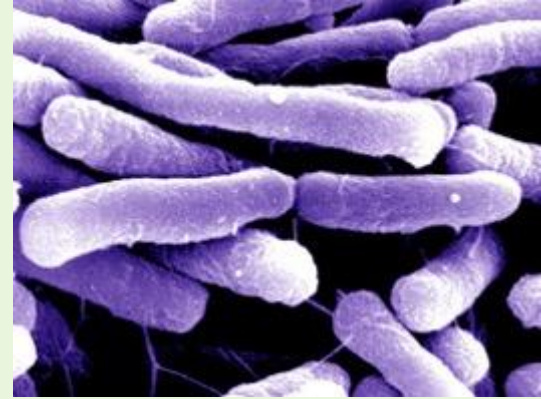


Faculty Development

Genentech
IN BUSINESS FOR LIFE



Emphasis on “Hands-on”





Validating our courses

- Genentech
- Amgen
- Bayer
- Biogen-IDEC
- Eli Lilly
- Roche Diagnostics
- Baxter
Pharmaceuticals
- Dow Agrosiences
- BioMarin



New Approaches and Curriculum

Traditional

Industrial

Education

Training

Lab Atmosphere

Pilot Plant Atmosphere

Set Times

Shifts

Lab Protocols

SOP

Lab Notebook

Batch Records

Individual

Team

Education AND Training

- Most Biotechnology programs in the community college system are formally classified as Career-Technology education (Voc Tech)
- Biotechnology programs offer degrees and certificates
- 25% - 50% of students are post-baccalaureate
- Boot camps and specialty courses
- Reinvent Education

Solano College Biomanufacturing Pathways

SCORE

(Solano College Outreach and Research and Education)

Potential AS and Baccalaureate Students

Articulated High Schools
with Biotechnology
Programs

Bridge to Biosciences

Solano College Science
Students

Solano College AS
Industrial Biotechnology

Graduates of intensive
bootcamps (IBIS)

Incumbent
biomanufacturing workers
seeking a four year
degree

Other Community
Colleges with AS
programs in
Biotechnology (CCSF,
Ohlone, Laney, and
Contra Costa)

Solano College Baccalaureate Degree in Biomanufacturing

Workforce Challenges

Cell Therapy Manufacturing Weak Points



Genentech CCP 2

“I was on the search committee to find a site for expansion of our manufacturing facilities. Everyone was determined we would not expand in California. Our two top candidates were South Carolina and Singapore. Ultimately, we did expand in Vacaville because of Solano College and UC Davis.”

Karen Brockwell Genentech – August 2005

Economic Development

Solano's got it!

Genentech's April 1, 2004 Ground Breaking

**World's Largest
Biotechnology Manufacturing Facility,**
Vacaville, CA



Walter Moore, Genentech; Mayor Augustine; Governor Schwarzenegger;
Susan Hellman-Genentech's President Product Development;
Frank Jackson, Genentech

By 2009...

1200 Jobs, 3/4 Million Sq. Ft., and \$ 1/2 Billion Investment

Solano's Got It! Biotechnology The Best Northern California has to offer

Solano Life Science Companies

Genentech, Inc.
Chiron Corporation
ALZA/Johnson & Johnson
Bio-Rad Laboratories
Large Scale Biology Corp.
HemoStat Lab
DesignRx Pharmaceutical Inc.
Research & Diagnostics Antibodies
Lexrite Labs
AcroMetrix
Biovir Laboratories
Chronix Biomedical



World's Largest Biotech Plant

Genentech has broken ground on three new buildings totaling 380,000 sq. ft. valued at \$577 million in Vacaville, CA which will combine with the existing 427,000 sq. ft. creating the largest cell culture manufacturing process plant with a 340,000 liter production capacity.

Home of UC Davis/Research Park
with largest UC life science graduates and ranked 15th in research funding among U.S. universities with \$426 million in 2002-03

Solano Community College provides an appropriately-trained labor force for growing biotechnology firms through hands-on labs in gel electrophoresis, PCR, fermentation technology, gas chromatography, HPLC, and other molecular biology techniques.

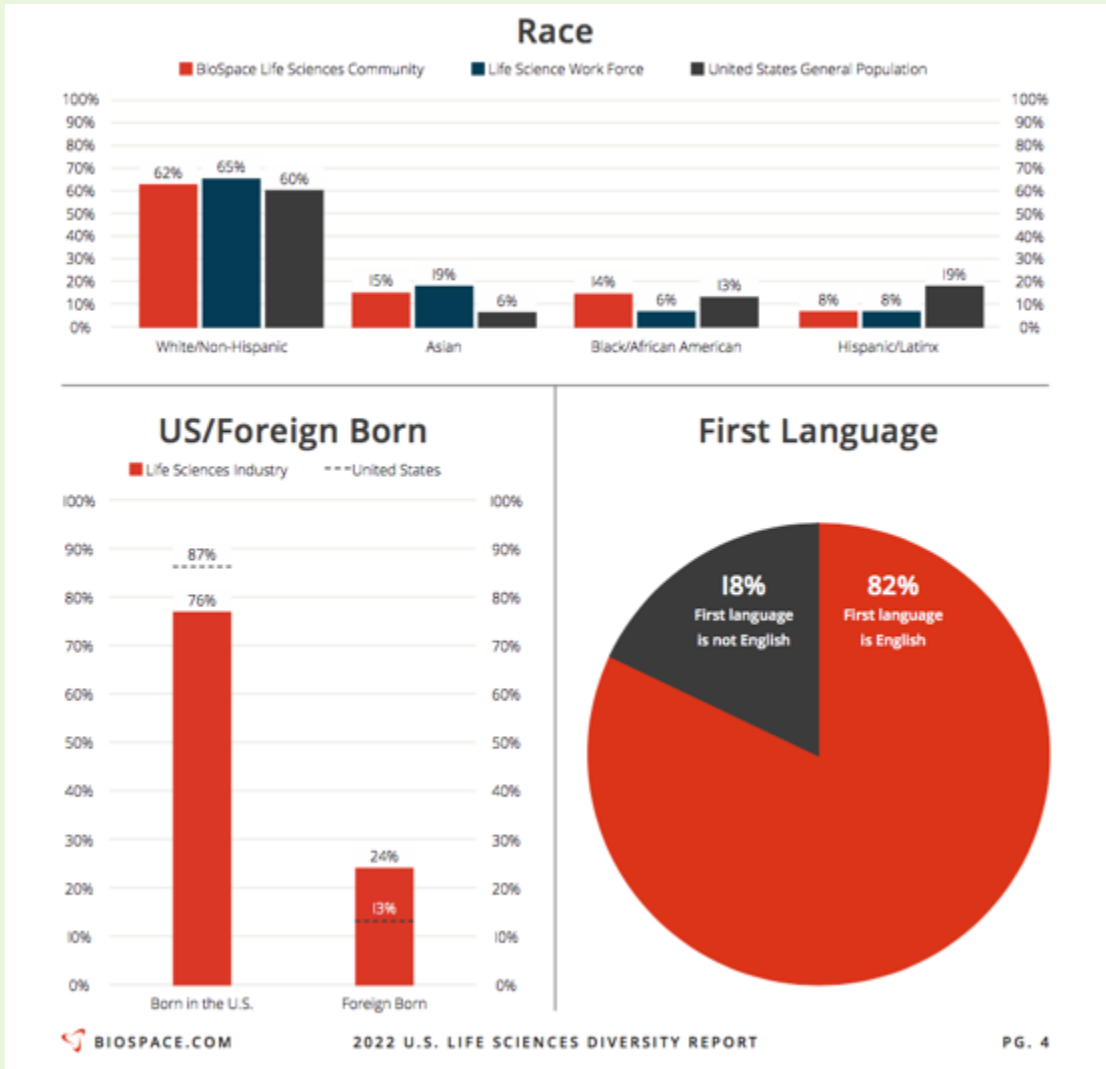
Photos/photo courtesy of The Reporter



Team Solano Toll Free (888) 864-1855

Solano EDC	www.solanoedc.org
City of Benicia	www.ci.benicia.ca.us
City of Dixon	www.ci.dixon.ca.us
City of Fairfield	www.ci.fairfield.ca.us
City of Rio Vista	www.ci.rio-vista.ca.us
City of Suisun City	www.suisun.com
City of Vacaville	www.cityofvacaville.com
City of Vallejo	www.ci.vallejo.ca.us
County of Solano	www.solanocounty.com

Workforce Diversity in the Life Sciences



ALAKA'I: Applied Life-Science Academy: Knowledge Advancing Industry



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Nationwide Challenge



NIIMBL

The National Institute for Innovation in Manufacturing Biopharmaceuticals

Pharmaceutical Biomanufacturing versus Bioindustrial Manufacturing

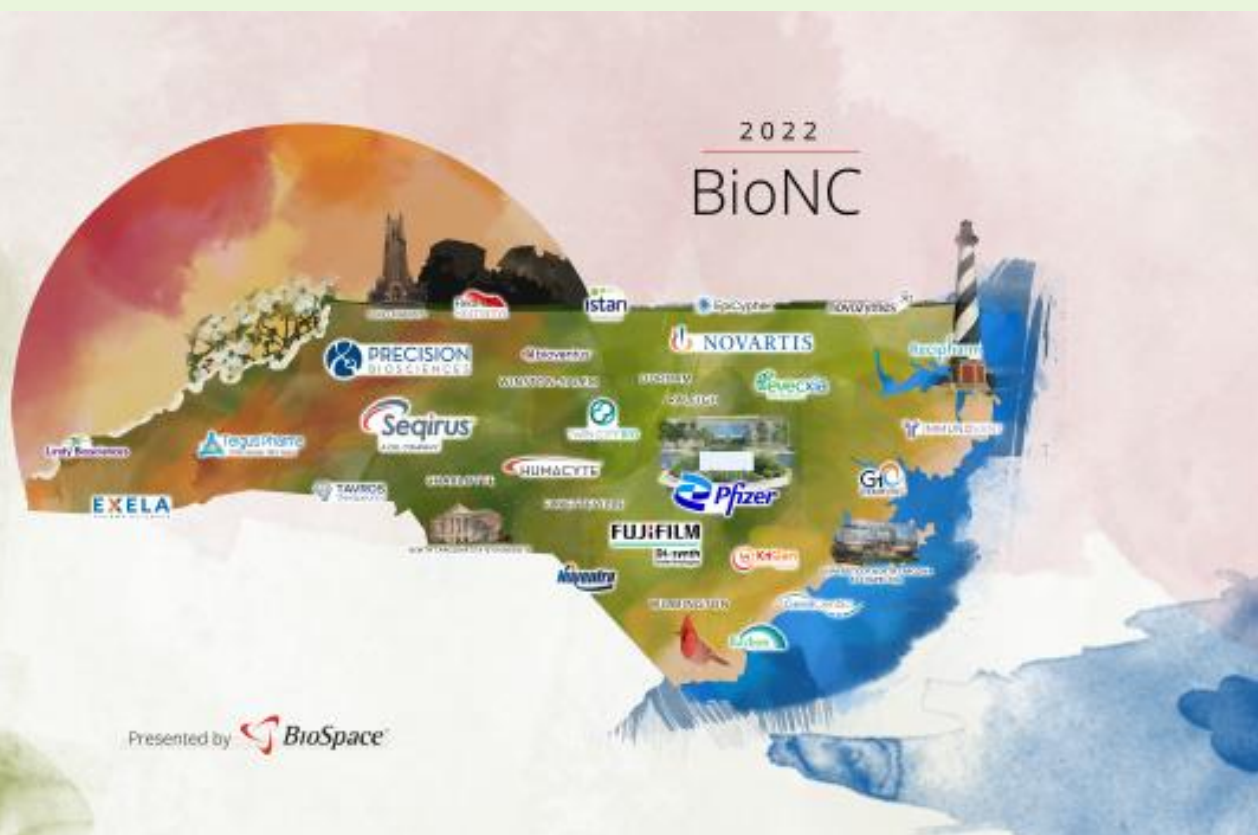
Pharmaceutical Biomanufacturing

- **Primary Consideration: Regulatory Compliance**
- Cell types: Standard (*E. coli*, *Saccharomyces* and *Pichia*, CHO cells)
- **Product Value: Extremely High**
- Volumes: small to large
- Purity: 99.99%
- Facilities: Strictly Controlled
- **Feedstock: Pure pharmaceutical grade chemicals**
- **Upstream: Bioreactors**
- **Commercial Scale decreasing as titers improve**
- Process: aerobic
- Trend toward single use technology
- **Downstream: Chromatography is often part of purification**
- **99.99% purity required**
- Avoid spores
- Cells: certainly genetically engineered
- **Regulatory environment is strict**
- Strict Quality Assurance and Quality Control regulatory requirement
- Training: Process and cGMP training required
- Gowning required

Bioindustrial Manufacturing

- **Primary Consideration: Cost (Cost of the carbon supplied by feedstock; cost of the process)**
- Cell types: varied
- **Product Value: Relatively Low**
- Volumes: Often very large
- Purity: Often Lower Requirements – sometimes crude purification
- Facilities: Not Necessarily Controlled
- **Feedstock: Cost considerations demand less purity**
- **Upstream: Bioreactors**
- **Commercial Scale – large to Massive**
- Process: aerobic (mainly, not exclusively – some anaerobic process) (Mainly) permanent stainless steel
- **Downstream: Cost is a major consideration – older technology like Spray Drying**
- **Less purity tolerated**
- Occasional spore production
- Cells may be genetically engineered (synthetic biology)
- **Regulatory environment is different**
- Quality Assurance for business reasons
- Training: Process
- Gowning may or may not be required?

North Carolina



“For innovative biotech, Massachusetts and California are where the action is, but companies – especially CDMOs – are expanding into the South and Southeast, recognizing opportunities there,” said Patti Seymour, managing director at BDO, in an interview with *BioSpace*.



KATRINA ROGERS (She/Her) • 1st

Founder | Leader | Thinker | Doer | LSWI Board member | BACE Advisory Bo...

3d •

I was recently published in the **Greater Spokane Incorporated Connect Magazine**. I wrote about the **Evergreen Bioscience Innovation Cluster** and Spokane's growing life science ecosystem. ...see more



GROWING LIFE SCIENCES

New Evergreen Bioscience Innovation Cluster Creates Opportunity for Growth

Katrina Rogers, Evergreen Bioscience Innovation



After more than a year of effort, the Washington State Department of Commerce awarded a \$500,000 grant to Greater Spokane Inc. to create the Evergreen Bioscience Innovation Cluster. To secure the grant, we worked with its partners at OSUW and a host of other firms. The funding came through the Innovation Cluster Acceleration Program (ICAP), which identifies the innovation clusters across Washington State.

A modern innovation cluster is an industry-led organization including members from five different economic sectors (i.e. engineers, capital, corporate/industry, government, and academic.) The mission of Evergreen Bioscience focuses on life sciences, cellular therapies, pharmaceutical and medical device innovation and contract services that grow their supply chain to meet manufacturers in a capital-efficient manner. There are gaps and untapped capacity in the supply chain at the region of Spokane, across the market, and around the world. Evergreen Bioscience Innovation will fill an ecosystem-level business development role for contract services in life science discovery, development, and manufacturing. We aim to help our industry fill these gaps and bring economic growth to our region.

In many ways, the Great Bioscience is the culmination of a decade-long effort by the community, much of it led by OSUW (started with Markman-KF which sought to develop an academic hub and bring private development. The initiative identified a "Riverport Campus" (now known as the University District) as its home

and, starting in 2006, brought programs from Eastern Washington University and Washington State University to the campus. Milestones in the following decades include the development of the OSU Health Sciences Building (2006), the creation of the WQAM UW-WSU partnership (2006), WSU College of Nursing (2008), WSU Health Sciences Campus (2009), and the Hahn Research & Education Building (2014).

The growth of the University District, especially in the health and life science sector, opened community leaders to conceive a new initiative in 2015. WSOB 2030, now known as Life Science Spokane, challenged Spokane to move forward creating a world-class center for health and medical sciences and labor, life sciences, research, and innovation. The target of 100 projects aims to leverage the unprecedented growth of the region's health and life science industry to create a positive economic impact across the community. The WSOB 2030 initiative supported the creation of the WSU Great Falls College of Medicine and the new WQAM regional partnership between the University of Washington's School of Medicine and George University but also served as the foundation for Evergreen Bioscience Innovation. The recent relocation of biotechnology companies working through the growth of a local biotech leader in Hybrid and Selek Pharma in West Falls was the latest milestone on the life science growth trajectory.

Initiatives like Evergreen Bioscience don't just happen. They are built over decades of effort and

partnership. The cluster board and I look forward to engaging our industry, academic, capital, entrepreneurial, and government stakeholders to help us clarify our strategy and goals. We open our eyes to a community-wide effort to create sustainable economic development across our state and region.

Want to know more, share your ideas, or get involved? Visit www.growwashington.com.

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