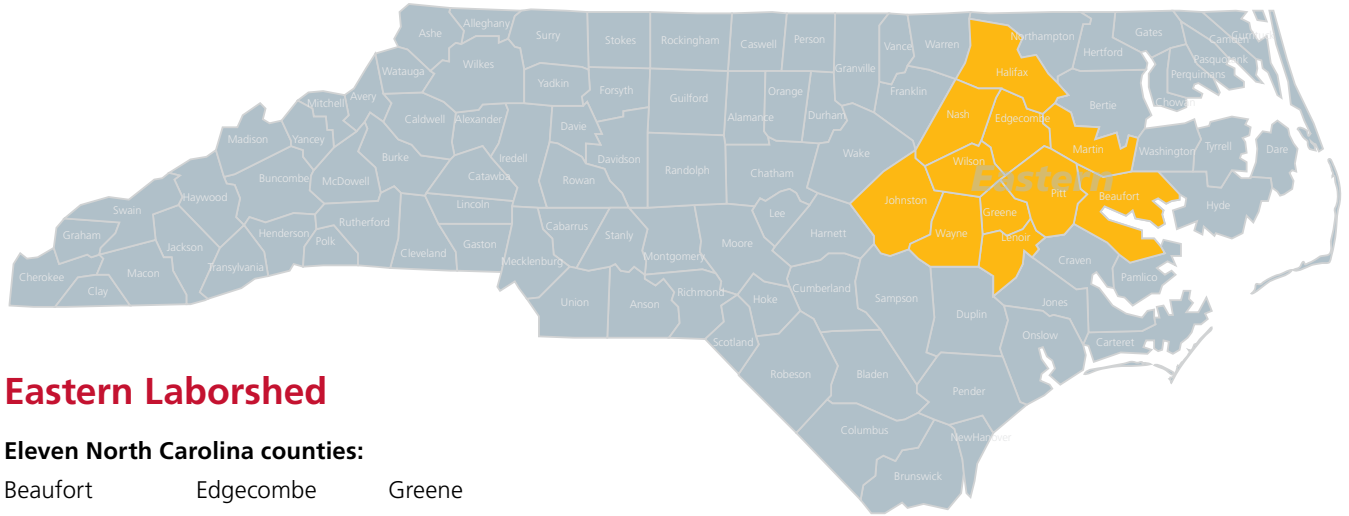




NORTH CAROLINA BIOPHARMA MANUFACTURING LABOR MARKET ANALYSIS — *Eastern Region*

NORTH CAROLINA BIOTECHNOLOGY CENTER | NORTH CAROLINA'S EASTERN REGION



Eastern Laborshed

Eleven North Carolina counties:

Beaufort	Edgecombe	Greene
Halifax	Johnston	Lenoir
Martin	Nash	Pitt
Wayne	Wilson	

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**NORTH CAROLINA'S
EASTERN REGION**

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1. EXECUTIVE SUMMARY

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Biggins Lacy Shapiro & Co, (BLS & Co), a New Jersey-based site selection and economic development consultancy, was engaged by the North Carolina Biotechnology Center and North Carolina's Eastern Region (the regional economic development partnership in Eastern North Carolina) to gauge the capability of the region's labor force to sustain additional biomanufacturing plant investments. Upon completing this assignment it is our conclusion that the regional labor market is sufficiently large and adequately skilled to support one, and perhaps more, large biopharmaceutical manufacturing plants provided that area workforce developers are able to address shortages of skilled plant maintenance personnel.

Our analysis adopts a site selector's perspective and was designed around the types of information that clients typically try to understand before making an important location decision. Our methodology borrows from site selection engagements and labor market assessments performed on behalf of corporate clients and refined over years of practice. This approach included:

1. Creating a "proxy" project and associated labor requirements. The basis for this analysis was a fully integrated, GMP compliant, biologics manufacturing plant producing an existing, approved, cell-based drug. The plant will ramp-up staffing over a 2-year period. Our hiring standard is based on 15 potential applicants for each available position (15:1 hiring ratio).
2. Defining the geographic boundaries of the labor market (the "laborshed"). This constituted an 11-county region in Eastern North Carolina centered around the cities where biopharmaceutical manufacturing has tended to cluster: Greenville, Rocky Mount and Wilson.
3. Quantifying and assessing the availability of experienced manufacturing talent in the laborshed and new workforce entrants who will replenish this pool. To do so we identified the most relevant occupations in key functional areas of a biologics plant: 1] Manufacturing/Production; 2] Quality Assurance/Quality Control; 3] Process Development and 4] Plant Operations & Support. We also attempted to align these functions with the various degree programs at North Carolina's community colleges and universities. Data was gathered via interviews with human resources officials and managers at local biomanufacturing plants, instructors at community colleges and universities and economic developers. We also accessed federal and state occupational and academic data bases, among other secondary information sources.

4. Inferring from these data the depth and breadth of the regional labor market and its ability to sustain our project.

Our findings address each of the plant's most important functions:

Manufacturing/Production

Local employers generally reported little difficulty hiring and retaining qualified production staff when the economy was strong. Annual turnover was (and remains) quite low (less than 5%) somewhat atypical in a manufacturing operation and particularly in a GMP environment. Several, though not a majority, of Eastern employers required lower-skilled or inexperienced applicants to possess a certificate of completion from BioWork, the entry-level training course for the life sciences manufacturing industry developed by the North Carolina Biotechnology Center and the North Carolina Community College System. Many employers also hire (or would hire) graduates of, or students enrolled in, Associates degree programs such as Industrial Pharmaceutical Technology and Bioprocess Manufacturing Technology.

The project requires 200 operators of which 140 (or 70 hired per year) must have prior industry experience or directly transferable skills. BLS & Co estimates that the Eastern North Carolina regional laborshed will yield a pool of approximately 2,400, far outstripping the demand for experienced employees in any given year. BLS & Co also concludes that our project's share of inexperienced operators can be met by the 156 BioWork "graduates" produced annually in the region and by the 32 students enrolled in the Industrial Pharmaceutical Technology and Bioprocess Manufacturing Technology degree programs in the area's community colleges.

Quality Assurance/Quality Control

Validation specialists are a challenge to recruit; many employers try to manage this requirement by using contractors. Employers report that hiring experienced talent for other QA/QC positions is not particularly difficult.

The project requires 100 QA/QC analysts and technicians of which 90 (or 45 per year) must have prior experience. BLS & Co estimates that the regional labor market will provide approximately 600 qualified potential applicants to meet our project's needs (an ample, though not abundant supply). We also estimate that the relatively few inexperienced QA/QC technicians can be hired from approximately 85 community college students who are enrolled in Associates degree programs in Biotechnology every year, or the 263 university graduates from Eastern NC, or receiving their

education in Eastern NC, who've majored in Chemistry, Biology, Biochemistry, etc.

Process Development

Eastern region employers report an available base of engineering talent to staff process development positions and also the ability to attract professionals from the Raleigh-Durham area when the economy softens. Employers also say they are able to tap local colleges and universities for recent engineering graduates to fill any positions that do not require experience.

The project will hire 14 experienced process development staffers per year. BLS & Co estimates that the Eastern NC labor market can supply approximately 380 persons with the required skills or experience. We also estimate that every year 22 students from Eastern North Carolina or attending school in the East will graduate with degrees in Chemical Engineering or Industrial Engineering; enough to address the need for approximately six inexperienced process development employees.

Plant Operation

Experienced instrumentation technicians/mechanics and electronics technicians are among the most difficult positions to hire according to employers interviewed in Eastern North Carolina. Very few, if any were content to hire and train inexperienced personnel.

BLS & Co projects a potential supply of 171 experienced technicians in the East; an applicant-to-hire ratio of just 8:1 which is less than sufficient to meet our projected need (approximately 20 per year). Setting compensation levels above the region's median wage for plant operations employees (\$50,401) could help employers to increase the size of this labor pool. Alternative strategies include hiring less experienced maintenance personnel and providing suitable in-house training and career development opportunities. BLS & Co notes that the approximately 113 students enrolled annually in Industrial Engineering Technology, Industrial Maintenance Technology and Facility Maintenance Associates degree programs at community colleges in Eastern North Carolina could represent one source of new supply. However, employers remain reluctant to hire these students even as they exhort the community college system to step-up efforts to train for these critical skills.

Summary

The table below provides a synopsis of our project's talent requirements and sources of qualified workers or labor market entrants that have the potential to satisfy this demand.

Summary of all Sources of Labor: Eastern NC

Function	Total Hires	Annual Hires	Target Yield @ 15:1 Ratio	Projected Annual Supply	Source of Supply
Existing Biopharma Manufacturing Labor					
Manufacturing/Production	140	70	1,050	2,424	Labor Force
QA/QC	90	45	675	609	Labor Force
Process Development	28	14	210	376	Labor Force
Plant Ops/Manufacturing Support	40	20	300	171	Labor Force
Emerging Biopharma Manufacturing Labor					
Manufacturing/Production	60	30	—	188	BioWork and Community Colleges
QA/QC	10	5	—	406	Community Colleges & Universities
Process Development	12	6	—	22	Universities
Plant Ops/Manufacturing Support	0	0	—	243	Community Colleges & Universities

2. INTRODUCTION

2.1 Background

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This report constitutes Biggins Lacy Shapiro & Company's (BLS & Co's) analysis of the market for biopharma manufacturing labor in Eastern North Carolina; an assessment made from the perspective of a site selector. As practiced by a site selection firm, labor market analyses typically attempt to quantify the availability and quality of the workforce for an established skill set(s) and at a given price point, or wage. Clients use this information to choose between competing destinations for a new project (e.g., a new distribution center or manufacturing plant), and/or to help them understand how large they might grow in an existing market without jeopardizing their continued access to qualified labor at affordable wages.

This analysis was inspired by the desires of those at the North Carolina Biotechnology Center and its economic development partners in North Carolina's Eastern Region to understand if the local biomanufacturing industry and North Carolina's extensive post-secondary educational infrastructure have developed a sufficient number of experienced employees and prospective workforce entrants to attract additional biopharma manufacturing operations to the region. This report focuses primarily on the workforce metrics that a new employer would want to understand before making a location decision.

Why this concern about labor markets? In a 2001 survey by Site Selection Magazine 74% of corporate executives said finding available, skilled labor was their biggest challenge and that "labor, whether in a growing or declining economy, still plays a crucial role in corporate location decisions."¹ However, labor markets in many areas of the United States are at risk due to slowing growth and troubling skill shortages. According to recent studies by the US Bureau of Labor Statistics, the nation's labor force is projected to grow by only 1% per year, compared with 2.6% during the periods of peak growth in the 1970's. Over the longer term the Bureau envisions that growth of the nation's labor force will come to a standstill. Such trends signal that employers will have to learn to do more with less. However, a 2006 survey by the Conference Board and the Society for Human Resources Management warned that the workforce of the future is wanting: fully 70% of recent US high school graduates had substandard skills and college gradu-

ates were thought to be just adequately prepared to enter the modern workforce.²

It is clear that employers cannot, and do not, take the availability of a skilled workforce for granted when making a location decision. It should be equally apparent that any area or region that can boast of an abundance of experienced and skilled workers and the infrastructure to grow and resupply this valuable resource will have an advantage in the global competition to attract good jobs and investment.

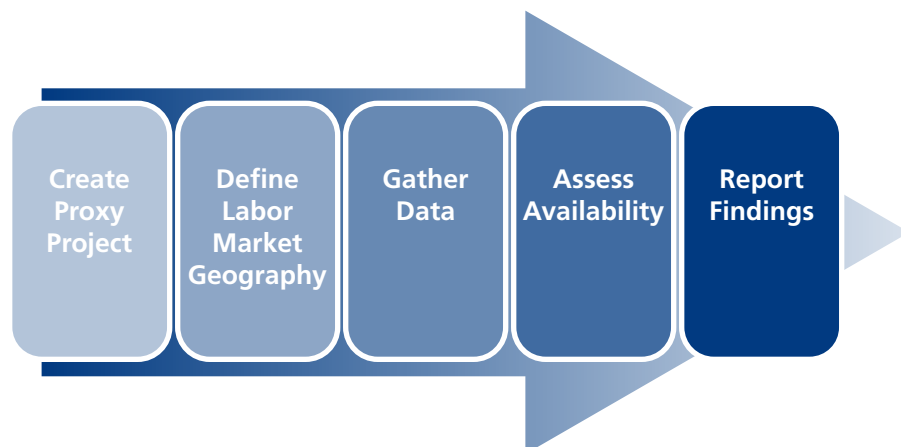
2.2 Organization

This report is organized around the labor requirements of a 400-employee biopharma manufacturing plant, as described in more detail below. For each key function in such a plant (e.g., manufacturing, quality control), we have attempted to quantify the available pool of experienced, skilled workers and the "pipeline" of new talent being produced annually by North Carolina's community colleges and universities.

2.3 Methodology

Our approach to this engagement included the following key activities:

- Creating a "proxy" project and labor requirements
- Defining the spatial dimensions of the labor market (the "laborshed")
- Assessing the availability of experienced biomanufacturing labor and new workforce entrants
- Reporting findings and making conclusions as to the ability of a new biomanufacturer to compete for its fair share of labor; e.g., to achieve a sustainable labor pool.



2.4 Defining the “Proxy” Project and Labor Requirements

This engagement is somewhat unique from labor market analyses that BLS & Co undertakes on behalf of its corporate clients. Without a predefined project requirement including numbers and types of positions, skills, attributes, etc., there can be no context for an assessment of the Eastern NC region. The solution was to create our own “proxy” project, a realistically-drawn fictional entity that will enable us to perform a market-based assessment of the area.

Our fictional project was designed with the active input of a panel of industry, economic development and academic experts assembled for this study by the North Carolina Biotechnology Center. A fully-integrated plant (fermentation thru fill/finish) was deemed well-suited to our purposes. Project employment was pegged at the high end of the spectrum, reflecting the prospect demographic that has been encountered most frequently by local economic developers. The distribution of the workforce is typical of the life science manufacturing operations known to our panelists (and later verified by BLS & Co during field interviews with local employers). This profile is summarized below:

Type of Facility	<ul style="list-style-type: none"> Fully integrated biologics plant Manufactures approved, cell-based drug
Employment	<ul style="list-style-type: none"> Approximately 400 at full buildout 2-year ramp-up
Workforce	<ul style="list-style-type: none"> 50% Manufacturing/Production 25% QA/AC 10% Process Development 10% Plant Operations 5% Other [management, etc.]

Following are brief position descriptions for key functions within our project:³

- Manufacturing/Production:** Combines technical knowledge with procedural accuracy in diverse areas from cell development (for biomanufacturing) to sterilization and chemical mixing (for traditional drug making); also focus on product finishing and packaging tasks. Representative positions include:

- Process Technician:** High School Diploma and relevant experience/training
- Formulation/Fill Technician:** High School Diploma and relevant experience/training
- Packaging Technician:** High School Diploma and relevant experience/training
- QA/QC:** Plays a central role by ensuring products and production processes meet stringent federal manufacturing standards. Representative positions include:
 - Quality Control/Assurance Technician:** 2-year Associates degree
 - Quality Control Associate:** B.S. degree
- Process Development:** On hand R&D staff to make improvements and modifications to existing production processes and identify possibilities for extending production technologies and applications.
 - Process Development Associate:** 2-year Associates degree & experience
 - Process Development Scientist:** MS & experience or Ph.D
- Plant Operations:** Maintenance workers to ensure the smooth and continuous functioning of highly complex machinery.
 - Maintenance Technician:** High School Diploma and trade certification
 - Instrumentation Technician:** 2-year Associates degree

Based on our conversations with area employers and BLS & Co’s previous project experiences, compensation and benefits at our proxy plant have been pegged at the market median (50th percentile) in Eastern NC. We also assume a 15:1 hiring ratio, meaning that employers will make one hire for every 15 applicants, this too is based on project experience and our local interviews. Finally, our manufacturing clients have always voiced a preference for a non-union labor environment whenever attainable. As North Carolina’s workforce has among the lowest rates of unionization in the country (2.0% of the private-sector workforce vs. 7.5% nationally), this is not expected to present any serious hiring challenges.

2.5 Defining the Geographic Scope

It is important at the beginning of this analysis that we determine the boundaries of the geographic area to be investigated. How are we to physically define the Eastern NC labor market? Our answer is based in part on the needs of this study and on the limitations of the data that

are available for this type of analysis.⁴

For the purposes of this study we defined the Eastern NC biomanufacturing laborshed as that area comprising a 45-minute driving distance from the East's three major pharmaceutical employment nodes:

- Wilson: home to Merck, Sandoz, Purdue and soon Becton Dickinson
- Greenville: site of DSM and Metrics
- Rocky Mount: home of Hospira, the first pharmaceutical manufacturer to locate in Eastern North Carolina.

It has been our experience that a 45-minute ride by automobile is often the maximum distance that a nonexempt (hourly) worker will travel for a desirable job paying the median wage in an area. This general radius was confirmed via our interviews with local employers.

We had planned to define the outermost boundaries of this laborshed by aggregating the three commute zones, thereby creating a customized polygon within which we would then collect and analyze various labor data. However, in doing so we ran into data scope and coverage issues – particularly the lack of good occupational data at the highly specific 6-digit SOC code level needed to define the types of jobs that would exist inside this biomanufacturing facility. The

Projected Laborshed:



solution was to base our analysis on aggregated county-level data for the area that most nearly approximates the laborshed defined by our custom polygon.

The result is an 11-county area comprising the counties of:

- Beaufort
- Greene
- Johnston
- Martin
- Pitt
- Wilson
- Edgecombe
- Halifax
- Lenoir
- Nash
- Wayne

Both Johnston and Nash counties are close enough to the Raleigh-Durham metropolitan area to be considered part of that laborshed as well. We chose not to include Franklin or Wake counties because only a small and relatively scarcely-populated section of these counties falls within our polygon. Doing so would have led to an undue influence on Eastern North Carolina from the biopharmaceutical activity in and around the Triangle Region. The map below shows this laborshed (lightly shaded) and our customized polygon as an overlay:

2.6 Gathering the Data

For this analysis our data gathering included:

- Primary research, including field interviews with employers, recruiters, academics and economic development officials in Eastern NC; and
- Secondary research, including data describing occupations and academic curricula characteristic of the biopharma manufacturing sector in the Eastern NC laborshed. Much of the labor market data needed for this assignment are available from the major federal data sources (e.g., the Census Bureau, the Bureau of Labor Statistics) as well as the North Carolina Department of Labor, the University of North Carolina system, the North Carolina Community College System and others.

Using these resources BLS & Co began assessing the Eastern NC regional labor market.

2.7 Challenges

The data sources created a number of challenges for our analysts:

- We conducted interviews with seven major biopharma employers in Eastern NC and also with area educators, recruiters and economic development officials. A staple of labor market analyses as practiced by BLS & Co, these conversations were very fruitful and yielded good information regarding current employment, hiring experiences, turnover, job training, etc. However these discussions cannot substitute for scientifically-controlled “surveys” as the sample size is too small and not every respondent was prepared, or willing to answer all of our questions.
- We encountered issues with scope and coverage, as noted in our laborshed discussion above. For example, to quantify the specific occupations involved in biomanufacturing we resorted to 6-digit SOC codes (explained in more detail in section 3.2). Doing so required that we collect data from the North Carolina Department of Labor for each county in the Eastern region because our customary data provider was unable to provide the detail needed.
- We faced challenges gathering university enrollment and graduation data. The data bases of the University of North Carolina system are very comprehensive but do not report the county of residence of graduating students at the curriculum level. To approximate these data BLS & Co used the distribution of student residences at the individual university level.
- Government privacy laws dictate that labor agencies not publish detailed local data if doing so would disclose information pertaining to only one or two companies. In such situations agencies are required to suppress the data which can frustrate labor market research. For our study these disclosure thresholds were not met for several occupational titles and consequently no data were reported. In such instances BLS & Co and its consulting partner, WDG Consulting, derived the estimated employment and wage by trending known reported variables from prior years.

3. THE SUPPLY OF EXISTING BIOPHARMA MANUFACTURING LABOR

3.1 Biopharma Industry Profile

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At the core of the Eastern North Carolina region are five counties that have formed the NC BioEast Alliance: Edgecombe, Nash, Pitt, Wayne and Wilson. These counties are home to a well-established pharmaceutical manufacturing cluster that presently includes:

- Hospira;
- Merck;
- DSM Pharmaceuticals;
- Purdue Pharmaceuticals; and
- Sandoz

These employers are joined by other life science companies and contractors in the area including Carolina Medical Products, Craft Technologies, CTMG, Inc., Metrics, Goldsboro Laboratories, PhytoMyco Research Corporation, and Pioneer Surgical Orthobiologics.^{5 6}

The area's balance sheet reveals both cutbacks and expansion. The job losses include those at DSM Pharmaceuticals (Pitt County's largest manufacturing employer) which announced additional layoffs of 10% to 15% of its workforce in mid-October 2008. These cuts follow earlier reductions that saw the number involved in pharmaceutical manufacturing fall from 1,100 to 900 in the last several years. Also, Merck in Wilson has been undergoing staff reductions for a number of years with the potential for additional layoffs always present. In the "plus" column, Metrics, a contract drug developer located just down the road from DSM, recently announced that it will add 50 more jobs, doubling the size of its production plant. Metrics expects to benefit from the layoffs at DSM. Another gain for the area includes Becton Dickinson's March 2008 announcement that it will locate a new plant, and 92 jobs, in Wilson.

The North Carolina Biotechnology Center surveyed biopharmaceutical companies as part of its 2003 and 2007 "Windows on the Workplace" training needs assessments. It's most recent effort found that biopharma manufacturing and related activity increased in Eastern NC at about the same rate as the entire state (14.6% vs. 13.1%). The data also reinforce the perception of the area as a center for traditional pharmaceutical manufacturing (where growth outpaced the state by 19.8% vs. 7%) while biologics registered relatively little growth (5.1%).

Table 1
Employment from "Windows on the Workplace," 2007: Eastern NC

	2002	2007	% Change '02 - '07	Projected 2010	% Change '07 - '10
Biomanufacturing Total					
Statewide	4,415	5,933	34.4%	6,442	8.58%
Eastern NC	214	225	5.1%	225	0.00%
Traditional Pharmaceutical Manufacturing					
Statewide	8,808	9,424	7.0%	—	—
Eastern NC	3,175	3,803	19.8%	—	—
Pharma Manufacturing Service Provider					
Statewide	2,374	2,286	-3.7%	—	—
Eastern NC	1,166	1,193	2.3%	—	—
Total Statewide	15,597	17,643	13.1%	—	—
Total Eastern NC	4,555	5,221	14.6%	—	—

Source: North Carolina Biotechnology Center, 2008

3.2 Biopharma Manufacturing Occupations

A key objective of this study is to quantify the supply of existing, experienced biopharma manufacturing talent in Eastern North Carolina. BLS & Co's chosen methodology is based on occupational data rather than industry or sectoral data. The sector approach would have required using North American Industry Classification System (NAICS) codes, the standard system of classifying industry adopted by the federal government. The limitations of NAICS codes are two-fold: 1] the System does not recognize "Biotechnology" or "Biomufacturing" as industrial sectors; and 2] the System does not discriminate between scientific, manufacturing, administrative jobs, etc.

To address these omissions we resorted to the US Bureau of Labor Statistics' Standard Occupational Classification (SOC) system, and SOC codes for occupational employment and wage data. The SOC system is the occupational classification system used by all federal statistical agencies. It consists of 801 detailed civilian occupations, organized

into 22 major groups. Excluded are military occupations which are not covered in the Bureau of Labor Statistics survey. Because the SOC system does not distinguish biomanufacturing jobs from other technical and scientific occupations we turned to the work performed in 2006 by the San Diego Workforce Partnership, and in particular, its "crosswalk" between SOC codes and another, well-regarded occupational classification system developed by the Radford Biotechnology Survey. In cooperation with North Carolina Biotechnology Center staff this crosswalk allowed us to narrow our focus considerably by eliminating occupations that had little or no relevancy to biopharma manufacturing and by enabling us to "drill down" to very specific 6-digit occupational codes for those jobs that were deemed appropriate to our proxy project. This approach has resulted in the identification of the following SOC codes and occupations as those most frequently found in a biopharma manufacturing plant. Please notice that the functions have been aligned with those used to characterize the distribution of the workforce in our proxy project in Section 2.4:

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Biopharma Manufacturing Occupations

Function	SOC Code	SOC Description
Manufacturing/Production	19-4021	Biological Technicians
	19-4031	Chemical Technicians
	51-1011	Supervisor/Managers of Production/Operating Workers
	51-4011	Computer Controlled Machine Tool Operators
	51-8031	Waste Treatment Plant/System Operators
	51-8091	Chemical Plant/System Operators
	51-9011	Chemical Equipment Operators/Tenders
	51-9012	Separating, Filtering, Clarifying, etc. Machine Operators
	51-9111	Packaging and Filling Machine Operators/Tenders
Quality Assurance/ Quality Control	13-1041	Compliance Officers, Except Agriculture, Construct.
	17-2199	Engineers, All Other
	19-1021	Biochemists and Biophysicists
	19-1022	Microbiologists
	19-1029	Biological Scientists, All Others
	19-1099	Life Scientist, All Others
	19-2031	Chemists
	19-4099	Life, Physical, Social Science Technicians, All Others
29-2012	Medical and Clinical Laboratory Technicians	

Function	SOC Code	SOC Description
Process Development	11-3051	Industrial Production Managers
	17-2031	Biomedical Engineers
	17-2041	Chemical Engineers
	17-2112	Industrial Engineers
	17-2131	Materials Engineers
Plant Ops/Manufacturing Support	17-3023	Electrical and Electronic Engineering Technicians
	17-3026	Industrial Engineering Technicians
	51-4012	Numerical Tool and Process Control Programmers

3.3 Existing Biopharma Manufacturing Skill Base

The BLS & Co approach yields approximately 10,500 persons in Eastern North Carolina

employed in occupations that are transferable to a biopharma manufacturing plant (see Table 2). To this group we also might add a certain percentage of those who are presently unemployed in Eastern North Carolina. We cannot know the precise number of unemployed presently possessing the skills to work in a biopharmaceutical manufacturing plant, but it is reasonable to expect that the proportion could be similar to the unemployment rate of the workforce as a whole: 6.8% or another 900+ potential employees.

The data indicate an overall drop of 10% in this biomanufacturing labor pool in Eastern North Carolina between 2000 and 2008. This is not altogether surprising given the falloff in manufacturing employment across the nation as

a whole over the past four decades, and the impact of the previous recession which hit hard many of North Carolina's traditional industries such as furniture, textiles, tobacco and more recently, electronics. This decline is not shared uniformly by all work disciplines however. Areas such as Quality Control and Quality Assurance, which are arguably the most relevant to a biomanufacturing operation, actually grew by almost 5% since the beginning of the decade. Employers with whom we spoke during our visits to the East were generally quite positive regarding the supply of experienced labor in and around the major employment centers. Even during times of impressive economic growth and relatively low unemployment these employers reported that voluntary turnover rates were low and their ratios of qualified applicants per hire were at or above their expectations.

In the following section we will address how much of this labor force is available for each functional area of our proxy plant. With the assistance of our consulting partner,

Table 2: Employment by Biomanufacturing Occupation, 2000 – 2008: Eastern NC

SOC Description	Year 2000			Year 2008			Change 2000 – 2008		
	Eastern Region	State of NC	U.S.	Eastern Region	State of NC	U.S.	Eastern Region	State of NC	U.S.
Manufacturing/ Production	8,170	65,550	1,664,580	7,090	64,670	1,562,360	-13.2%	-1.3%	-6.1%
QA/QC	1,670	22,460	739,120	1,750	20,860	761,160	4.8%	-7.1%	3.0%
Process Development	1,210	14,590	439,740	1,100	13,650	423,170	-9.1%	-6.4%	-3.8%
Plant Ops/ Manufacturing Support	600	10,380	332,250	500	5,900	254,670	-16.7%	-43.2%	-23.3%
Total	11,650	112,980	3,175,690	10,440	105,080	3,001,360	-10.4%	-7.0%	-5.5%

Source: North Carolina Department of Labor - Occupational Employment Statistics (OES), and Equal Opportunity Employment Commission (EEO) 2000 Data.

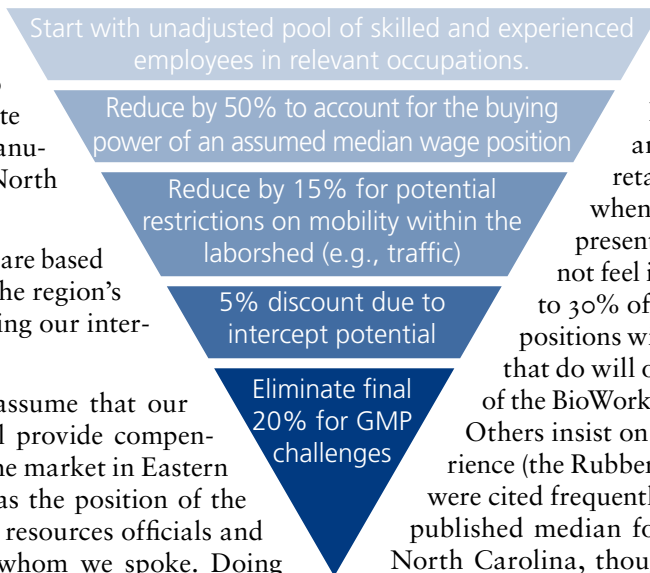
* Derived using multiple data sources - Claritas, EEO and OES.

Wadley Donovan Gutshaw Consulting, we've derived the following methodology to yield a market-driven estimate of the availability of biomanufacturing worksite skills in North Carolina's Eastern Region:

These sequential adjustments are based on what we learned about the region's labor market dynamics during our interviews with area employers:

1. As a starting point we assume that our proxy manufacturer will provide compensation at the median of the market in Eastern North Carolina. This was the position of the majority of plant human resources officials and general managers with whom we spoke. Doing so effectively prices 50% of the market out of our reach – if wages were the sole decision-making criterion during a prospective employee's job search.
2. Employers cited few concerns regarding congestion and the transportation infrastructure that could otherwise limit a prospective employee's willingness to commute. We conservatively estimated that 10% of potential applicants would be disinclined to accept a particular job due to the adverse impact on their commute.
3. We eliminated another 5% based on the likelihood that they would pass-up a job at our proxy plant for another, equally attractive opportunity closer to home.
4. We made our final adjustment (20%) based on the perceived attractiveness of a job in the biopharmaceutical manufacturing industry. Employers cited the challenges of working in a GMP environment as one of the most significant disincentives to employment at their plant.

This methodology results in an accessible pool of almost 3,600 experienced and skilled employees. The results for each function in our proxy plant follow.



3.4 Manufacturing/Production

Few local employers reported any sustained difficulty hiring and retaining production staff (operators) when the economy was strong. In the present softening labor market many do not feel it necessary to fill more than 20% to 30% of their manufacturing/production positions with inexperienced workers. Those that do will often require proof of completion of the BioWork program (described in Section 4). Others insist on some prior manufacturing experience (the Rubbermaid and Bridgestone tire plants were cited frequently). Wages generally reflected the published median for these occupations in Eastern North Carolina, though some employers with whom we spoke will pay considerably more (almost \$70,000 per year) for highly specialized skills.

BLS & Co projects approximately 2,400 potential applicants for the 140 manufacturing/production positions requiring experience. As these jobs would be filled at the rate of 70 per year, the potential labor supply would far outstrip the desired 15:1 hiring ratio. The table below summarizes the requirement and the derivation of labor supply:

Manufacturing/Production Labor Supply Derivation			
Number Required:	100 per year		
Number with Experience:	70 per year (70%)		
Number without Experience	30 per year		
Median Wage and Differentials:	East NC:	vs. State:	vs. US:
	\$40,300	108.6%	99.8%
Total Experienced Pool:	7,090		
Wage Adjustment:	- 3,545		
Commute Adjustment:	- 355		
Intercept Adjustment	- 160		
Attractiveness Adjustment:	- 606		
Final Yield:	2,424 prospective experienced applicants		
Target Yield at 15:1 hiring ratio	1,050 per year		

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3.5 Quality Assurance/Quality Control

Other than the challenges involved with recruiting and retaining validation specialists, local employers reported few difficulties hiring for their QA/QC positions. Almost all insisted on prior experience and degrees in Chemistry or Biology (for analyst positions) or Associates degrees (for tech positions). Most report they have only an occasional need for validation skills and address these requirements via contractors. The preferred QA/QC experience is at another biopharma company (one employer with whom we spoke insists on hiring only those with oral solid dose or vaccine experience). Some have been able to take advantage of the downsizings at DSM and GSK to fill their QA/QC vacancies. When not hiring directly from the biopharma industry local employers say they can recruit experienced chemists from outside testing labs and consulting firms. Some have reported success recruiting from food and cosmetics companies. Reported wages were generally at or slightly below the published area median.

BLS & Co anticipates a potential 609-person applicant pool for the 45 experienced staffers to be hired into the QA/QC organization during the two year ramp up period. This essentially satisfies our 15:1 target hiring ratio.

QA/QC Labor Supply Derivation			
Number Required:	50 per year		
Number with Experience	45 per year (90%)		
Number without Experience	5 per year		
Median Wage and Differentials:	East NC: \$56,936	vs. State: 102.1%	vs. US: 93.4%
Total Experienced Pool:	1,780		
Wage Adjustment:	- 890		
Commute Adjustment:	- 89		
Intercept Adjustment	- 40		
Attractiveness Adjustment:	- 152		
Final Yield:	609 prospective experienced applicants		
Target Yield at 15:1 hiring ratio	675 per year		

3.6 Process Development

Eastern North Carolina biopharma employers commend the area for its availability of engineering talent. One plant official observed that he had been receiving significant applicant flow from persons living in and around the Research Triangle, including those recently let go at Wyeth, Catalent and GSK, (the improvements to Route 540 and Route 264 facilitate a relatively easy “reverse commute”).

BLS & Co. projects a potential supply of 376 experienced process development employees within the Eastern North Carolina laborshed. This exceeds the desired hiring ratio for 14 such experienced hires per year during the 2-year ramp-up period.

Process Development Labor Supply Derivation			
Number Required:	20 per year		
Number with Experience	14 per year (70%)		
Number without Experience	6 per year		
Median Wage and Differentials:	East NC: \$79,872	vs. State: 110.2%	vs. US: 99.9%
Total Experienced Pool:	1,100		
Wage Adjustment:	- 550		
Commute Adjustment:	- 55		
Intercept Adjustment	- 25		
Attractiveness Adjustment:	- 94		
Final Yield:	376 prospective experienced applicants		
Target Yield at 15:1 hiring ratio	210 per year		

3.7 Plant Operations

Experienced instrumentation technicians/mechanics and electronics technicians were among the greatest hiring challenges cited by employers interviewed in Eastern North Carolina and were subject to the highest levels of voluntary turnover. It was also said to be especially difficult hiring mechanics with GMP experience. Many blame the present skill shortages on the de-emphasis of shop in high school and the poor impression of maintenance careers among high school students. Almost every person with whom we met insisted that these jobs were becoming more skilled and sophisticated; one employer pays as much as \$90,000 per year to their lead maintenance personnel.

A number of employers did report success recruiting electronics technicians, electricians and nuclear power technicians from the Navy, though not in large enough numbers to meet total demand. A recruiter with whom we spoke said the most complicated industrial processes in the armed services (and particularly the Navy) are typically similar to those in a GMP environment. These techs typically have a great deal of experience and are willing to relocate to North Carolina for a good job (many will come from Virginia, Florida or the West Coast – the military provides free relocation from their last duty station).

BLS & Co. projects a potential supply of 171 experienced manufacturing support employees within the Eastern North Carolina laborshed. As our needs are 20 such employees per year our hiring ratio is only 8:1 which does not meet our desired standard. Increasing the target wage above the market median could grow the size of this pool. An alternative strategy involves hiring less qualified maintenance personnel and providing suitable in-house training and career development opportunities.

Plant Operations Labor Supply Derivation			
Number Required:	20 per year		
Number with Experience:	20 per year (100%)		
Number without Experience	0		
Median Wage and Differentials:	East NC: \$50,401	vs. State: 109.2%	vs. US: 102.8%
Total Experienced Pool:	500		
Wage Adjustment:	-250		
Commute Adjustment:	- 25		
Intercept Adjustment	- 11		
Attractiveness Adjustment:	- 43		
Final Yield:	171 prospective experienced applicants		
Target Yield at 15:1 hiring ratio	300 per year		

4. THE SUPPLY OF EMERGING BIOPHARMA MANUFACTURING TALENT

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4.1 Emerging Biopharma Manufacturing Skill Base

The emerging skill base is represented by enrollees and recent graduates from the community colleges and university systems (both public and private). In Eastern North Carolina each county has a community college; the region's only major university and medical school (East Carolina University) is located in Greenville. Three private colleges in the Eastern labor shed are Mt. Olive College, Barton College and North Carolina Wesleyan.

4.2 BioWork Enrollment and Course Completions

Three community colleges in the region (Johnston CC, Pitt CC and Wilson CC), offer BioWork, a 128-hour course providing entry-level training for the life sciences manufacturing industry and designed by the North Carolina Biotechnology Center. Because BioWork has only limited barriers to entry it is available to job seekers with lower levels of education. Not surprisingly, the majority of BioWork students come from low-paying industries such as retail sales, food service and healthcare support. Many also have been displaced from traditional manufacturing sectors.⁷ Graduates of the BioWork program will not be the sole source of inexperienced manufacturing/production workers available to biopharma manufacturing employers in Eastern North Carolina, but the program can be a valuable contributor. Several, though not a majority, of the Eastern NC employers with whom we spoke said they require proof that new production employees have completed their BioWork coursework.

Earlier we projected that 70% of the 200 manufacturing/production positions require experience. The remaining 30%, or 60 employees could be satisfied by the approximately 400 BioWork course completers produced annually by community colleges in the Eastern region as detailed in Table 3 below.

Table 3: BioWork Enrollees and Graduates, 2004 – 2008: Eastern NC

Community College	2004-2008 Average Enrollment	2004-2008 Average Annual Completions*
Johnston CC	327	307
Pitt CC	37	35
Wilson CC	50	47
Total	414	389

Source: North Carolina Community College System Data Warehouse

*Note: Completions based on average 94% reported at Wake Tech and Wilson CC

However, our interviews revealed that on average only 40% to 50% of course completers take jobs within the biopharmaceutical industry. Thus we discounted the estimated annual supply of BioWork completers in Eastern NC to 156 per year. Despite this, the number of BioWork graduates in Eastern NC will exceed the anticipated demand generated by our project. Also, employers in the East are not limited to these three colleges; the potential BioWork pool, which averages approximately 840 enrollees per year system-wide, can be considerably larger. Finally, officials at the North Carolina Biotechnology Center's Eastern office observed that biopharma job announcements often prompt a jump in BioWork enrollment as local residents respond to each new opportunity.

4.3 Biopharma Manufacturing Curricula

Neither is the emerging labor pool limited to BioWork graduates. To quantify the potential supply of Associates degree candidates and new undergraduate, graduate and doctoral degree holders BLS & Co and the staff of the Biotechnology Center identified the academic curricula most relevant to biopharma manufacturing.

We used the US Department of Education's Classification of Instructional Program (CIP) coding system, the Radford Biotechnology Study and the work performed by the San Diego Workforce Partnership to develop our inventory of education programs. This list includes only those codes for which North Carolina's community colleges and universities reported enrollment between 2005 and 2008:

Biopharma Curricula

Function	CIP Code	CIP Description
Manufacturing/Production	A21080	Industrial Pharmaceutical Technology (AS)
	A50440	Bioprocess Manufacturing Technology (AS)
Quality Assurance/Quality Control	A20100	Biotechnology (AS)
	A20140	Environmental Science Technology (AS)
	A20180	Industrial Laboratory Technology (AS)
	260101	Biology/Biological Sciences
	260202	Biochemistry
	260204	Molecular Biology
	260502	Microbiology
	261102	Biostatistics
	261201	Biotechnology
	400501	Chemistry
Process Development	140701	Chemical Engineering
	143501	Industrial Engineering
Plant Ops & Manufacturing Support	A40240	Industrial Engineering Technology (AS)
	A50240	Industrial Maintenance Technology (AS)
Plant Ops & Manufacturing Support	D50170	Facility Maintenance Worker (AS)
	150612	Industrial Technology/Technician
	150613	Manufacturing Technology/Technician
	150699	Industrial Production Technologies/Technician

4.4 Community College Enrollment and Degrees

BioNetwork is a statewide initiative of the North Carolina Community College System that provides specialized training and equipment to develop the state's workforce for the biotechnology and pharmaceutical industries. Eastern North Carolina biopharma employers complemented the System on the solid foundation it provides workers via its bioprocessing and scientific curricula. Employers particularly appreciated access to the community colleges' industrial arts programs which are seen as critical for the training of maintenance and manufacturing support employees now that the high schools have de-emphasized the industrial arts.

The community colleges serving the 11-county Eastern North Carolina region enroll an average of 230 students per year in biopharma manufacturing disciplines and graduate an average of 43 per year in all areas except Process Development. A significant number of these enrollees will not complete their degrees in a timely manner, if at all. Among this group are those who will leave college for a new job and fail to complete their degree requirements. Others work full-time while in school and thus may take many years to achieve their degrees. Employers interviewed by BLS & Co report relatively high levels of satisfaction with these non-degree "dropouts," thus the number of students potentially available to industry should not be limited to those who have completed their degree requirements. Below we have chosen to reflect Associates degree enrollees in the pool that can satisfy our project's allowance of inexperienced labor.

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Based on these data BLS & Co estimates the community colleges will be able to produce the following annual supply of inexperienced new hires:

- 188 prospective production employees (when BioWorks completers are included) to satisfy our project's appetite for 30 inexperienced new hires per year
- 85 prospective QA/QC employees to meet a need for just 5 inexperienced new hires per year; and
- 113 prospective Plant Operations personnel, all of whom will require additional experience to be considered qualified for positions.

4.5 Undergraduate Degrees

Although some employers fill manufacturing jobs with candidates possessing 4-year degrees, this is not the norm. Generally, the undergraduates receiving biopharmaceutical-related degrees find themselves in process development and quality control positions, depending on the types and amount of industry experience they also have been able to attain. For these jobs the annual output of North Carolina's public and private universities is more than ample to fill our project's requirements.

As employment outcome data was hard to come by BLS & Co defined the potential labor pool as those graduating students whose permanent address

is in Eastern North Carolina as well as those graduating from colleges in Eastern North Carolina but residing elsewhere in the state or beyond. Table 5 below indicates that the sixteen schools of the University of North Carolina system (including East Carolina University), plus the three private colleges in the Eastern region (Barton, Mount Olive and North Carolina Wesleyan) produce an average of almost 500 biomanufacturing-related graduates per year⁸.

Based on conversations with the chairs of several university departments BLS & Co assumes that 75% of these graduates – approximately 375 – will enter the labor force, the remainder will continue their education or pursue other activities.

Eastern North Carolina biopharma employers report that they extensively tap the region's university assets. East Carolina University (ECU) is the dominant institution of higher education in the region and is well-regarded, particularly for its Chemistry program (it is the only university in North Carolina with a GMP training facility) and its new Engineering program and concentrations in Bioprocess Engineering, BioMedical Engineering and Engineering Management. However local employers also rely on the area's smaller, private schools for specialized expertise. For example, a liquid generic drug manufacturer staffs its quality control organization with Chemistry and Biology graduates from Barton Col-

Table 4: Selected Associates Degrees: Students from Eastern NC

Function	CIP Code	Curriculum	2004-2008 Average Enrollment	2004-2008 Average Annual Degrees
Manufacturing/ Production	A21080	Industrial Pharmaceutical Tech	9	
	A50440	Bioprocess Manufacturing Tech	23	2
Subtotal			32	2
QA/QC	A20100	Biotechnology	84	25
	A20140	Environmental Sci & Tech	1	0
Subtotal			85	25
Plant Ops & Mfg Support	A40240	Industrial Engineering Tech	17	0
	A50240	Industrial Maintenance Tech	85	16
	D50170	Facility Maintenance Worker	11	0
Subtotal			113	16
Total			230	43

Source: North Carolina Community College System, BioNetwork

lege as well as ECU, and another local pharmaceutical manufacturer partners with Barton to provide management development programs. Several manufacturers seek to fill analytical chemistry positions with graduates of Campbell University's Pharmaceutical Sciences program (in the Triangle), along with ECU.

Discounting these graduation rates by 25% to account for graduates who will pursue additional education, BLS & Co projects that North Carolina's colleges and universities can supply an annual allotment of at least:

- 263 graduates who've majored in Chemistry, Biology, Biochemistry, Molecular Biology, etc. to satisfy the small annual need for relatively inexperienced QA/QC staffers;
- 12 graduates from Eastern NC who've majored in Chemical or Industrial Engineering to satisfy the need for approximately six inexperienced Process Development staffers; and
- 99 graduates from Eastern NC who've majored in Industrial Technology, Manufacturing Technology, etc. and could step into professional and managerial positions in Plant Operations and Manufacturing Support.

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Table 5: Selected Undergrad Degrees: Eastern NC

Function	CIP Code	Curriculum	Average Annual Degrees: 1999 – 2007	
			Grads From Eastern NC*	Grads at Univ's In Eastern NC
Process Development	140701	Chemical Engineering	9	0
	143501	Industrial Engineering	7	0
Subtotal			16	0
Plant Ops & Mfg Support	150612	Industrial Technology	32	61
	150613	Manufacturing Technology	6	11
	150699	Industrial Production Tech	7	15
Subtotal			45	87
QA/QC	260101	Biology/Biological Sciences	125	141
	260202	Biochemistry	11	8
	260204	Molecular Biology	0	0
	260502	Microbiology, General	4	0
	261102	Biostatistics	0	0
	261201	Biotechnology	0	0
	400501	Chemistry, General	34	27
Subtotal			174	176
Total			235	263

Source: University of North Carolina, Academic Planning Inventory, (<http://fred.northcarolina.edu/enrindex.html>)

*Note: Grads from Eastern NC are based on share (%) of students at each univ reporting Eastern NC as residence

4.6 Graduate & PhD. Enrollment and Degrees

Lastly, we considered the potential pool of students graduating with advanced degrees in the biopharmaceutical disciplines. Even more so than their undergraduate counterparts, these persons would likely assume either process

development or quality control positions, either at a higher level, or at the same level but with less actual on-the-job experience. The average number of annual, UNC system-wide graduates (99 total) while not large, still constitutes a significant addition to the labor pool. BLS & Co projects the private universities would produce few, if any, additional advanced degrees.

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Table 6: Selected Graduate & Ph.D Degrees: Eastern NC

Function	CIP Code	Curriculum	Average Annual Degrees: 1999 – 2007	
			Grads From Eastern NC*	Grads at Univ's in Eastern NC
Process Development	140701	Chemical Engineering	8	0
	143501	Industrial Engineering	2	0
	143601	Manufacturing Engineering	0	0
Subtotal			10	0
Plant Ops & Mfg Support	150612	Industrial Technology	2	29
QA/QC	260101	Biology/Biological Sciences	8	16
	260202	Biochemistry	0	3
	260204	Molecular Biology	0	5
	260401	Cell/Cellular Biology	0	1
	260502	Microbiology, General	3	0
	260503	Medical Microbiology	0	3
	260801	Genetics, General	1	0
	261001	Pharmacology	0	0
	261004	Toxicology	0	0
	261101	Biometry/Biometrics	2	0
	261102	Biostatistics	3	0
	261201	Biotechnology	1	0
	269999	Biological and Biomedical Sci	0	2
400501	Chemistry, General	5	5	
Subtotal			23	35
Total			35	64

Source: University of North Carolina, Academic Planning Inventory (<http://fred.northcarolina.edu/enrindex.html>)

*Note: Grads from Eastern NC are based on share (%) of students at each univ reporting Eastern NC as residence

5. CONCLUSIONS

Table 7 below provides a synopsis of our project's talent requirements and potential sources of qualified workers or labor market entrants that have the potential to satisfy this demand. Biggins Lacy Shapiro & Co concludes that the pipelines of existing and emerging biomanufacturing talent in Eastern North Carolina can likely sustain at least one additional large biopharma manufacturing plant of the scale of the proxy project, and perhaps more, without taxing the regional labor market or the state's community college and university systems.

Our biggest concern is for the potential supply of skilled maintenance technicians in the East, which is less than sufficient to meet our projected need. A possible source is the 100+ students enrolled annually in Industrial Engineering Technology, Industrial Maintenance Technology and Facility Maintenance Associates degree programs at community colleges in Eastern North Carolina. However, employers remain reluctant to hire these students even as they exhort the community college system to step-up efforts to train for these critical skills.

Table 7: Summary of all Sources of Labor: Eastern NC

Function	Total Hires	Annual Hires	Target Yield @ 15:1 Ratio	Projected Annual Supply	Source of Supply
Existing Biopharma Manufacturing Labor					
Manufacturing/Production	140	70	1,050	2,424	Labor Force
QA/QC	90	45	675	609	Labor Force
Process Development	28	14	210	376	Labor Force
Plant Ops/Manufacturing Support	40	20	300	171	Labor Force
Emerging Biopharma Manufacturing Labor					
Manufacturing/Production	60	30	—	188	BioWork and Community Colleges
QA/QC	10	5	—	406	Community Colleges & Universities
Process Development	12	6	—	22	Universities
Plant Ops/Manufacturing Support	0	0	—	243	Community Colleges & Universities

REFERENCES

Endnotes

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- ⁴ “Conducting a Community Audit,” US Department of Labor, Employment and Training Administration. August 2000.
- ⁵ “Building the Life Sciences Community in the NC BioEast Alliance Region,” BioAbility, LLC. 2008
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- ⁷ “Job Creation and the Knowledge Economy: Lessons from North Carolina’s Life Science Manufacturing Initiative.” Nichola Lowe, *Economic Development Quarterly*, November 2007
- ⁸ This estimate was derived by multiplying the average number of students graduating annually from relevant degree programs at each state university by the overall percentage of state university students reported as living in the Eastern Region.



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