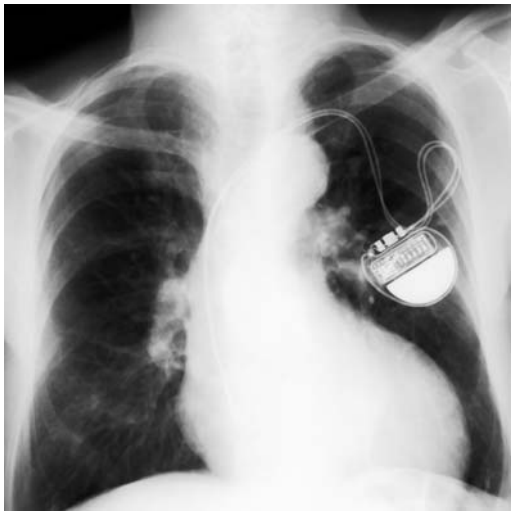
ECONOMIC & WORKFORCE DEVELOPMENT
through the CALIFORNIA COMMUNITY COLLEGES

BUSINESS AND WORKFORCE PERFORMANCE IMPROVEMENT INITIATIVE

Medical Device Industry

Los Angeles County

March 2008



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BASED ON A 2007 SURVEY OF MEDICAL DEVICE EMPLOYERS IN LOS ANGELES COUNTY, IT IS ESTIMATED THAT THE INDUSTRY WILL REQUIRE NEARLY 2,500 ADDITIONAL WORKERS OVER THE NEXT 12 MONTHS. EMPLOYERS SURVEYED ANTICIPATE EMPLOYMENT GROWTH OF 12.45% OVER THE NEXT YEAR FOR THE OCCUPATIONS IN GREATEST DEMAND. SOURCE: BW RESEARCH PARTNERSHIP

Executive Summary

The medical device industry is a high-growth industry in Los Angeles County. With increasing employment opportunities, above-average wages and a defined career path for advancement, the industry's growth presents an opportunity for community colleges to expand their programs.

Medical devices cover a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of diseases or abnormal conditions.[1] Product examples include:

- stents, pacemakers and other implantable devices
- bioimaging and advanced imaging equipment
- orthopedic and prosthetic implants and devices
- dental instruments and orthodontics
- laser eye surgery equipment and ophthalmic goods

The Centers of Excellence studied the medical device industry statewide because of the following factors:

- industry concentration in California.
- industry growth – mainly due to the changing health care needs of an increasingly aging population.
- advances in manufacturing technologies that enable smaller, more sophisticated devices to be produced, are also fueling industry growth.

A central feature of this report is the release of primary research on the medical device industry conducted for the Centers of Excellence by BW Research Partnership[2], a recognized leader in labor market research. The results of this study suggest an opportunity for regional community colleges to play a role in the development of the workforce needed by the medical device industry. Over 72% of employers surveyed for this report indicated difficulty in recruiting employees with appropriate education and training. More than half of employers surveyed expressed interest in on-site customized training for current employees.

[1] U. S. Food and Drug Administration, definition of medical devices, www.fda.gov/cdrh
[2] BW Research Partnership, www.bwresearch.com

The following eight occupations were identified through executive interviews with industry leaders as key jobs needed within the industry and as being most relevant to community college students:

- Assemblers and/or Electrical & Electronic Assemblers
- Engineering & Operations Technicians
- Quality Control Technicians
- Research & Development Technicians
- Supervisors/Managers of Technicians and Maintenance Workers
- Clinical Trials & Regulatory Assistants and/or Technicians
- Inspectors, Testers and Graders
- Safety, Hazmat, and Environmental Controls Technicians

All eight occupations are technician-level jobs, and can be filled with students with an Associate Degree. Currently, none of the community colleges in Los Angeles County have programs specific to the medical device manufacturing industry. However, colleges that have biotechnology, biomedical technology, and biomedical instrumentation/electronics related programs can adapt these programs to prepare workers for the occupations described in this report.

Colleges who can establish partnerships with local medical device businesses and public workforce agencies will be well positioned to meet the growing workforce demand. Technical assistance with program and curriculum development is available from the regional Economic and Workforce Development (EWD) Centers: the California Applied Biotechnology Center (CalABC), the Centers for Applied Competitive Technologies (CACTs) and the Regional Health Occupation Resource Centers (RHORCs). A list of centers and partners is available on p. 13-14.

Introduction

The California Community Colleges System has charged the Economic & Workforce Development (EWD) Network with identifying industries and occupations that have unmet employee development needs. These industries will provide opportunities for colleges to partner with businesses to address their workforce development needs.

The medical device industry has been presented recently as a growing sector of the bioscience field in various publications (see reference list). These publications highlight new medical device products being developed, that contribute to the quality of life for patients coping with various illnesses. However, these reports have not addressed the workforce development needs of medical device firms. The intent of this report is to add to the knowledge base on the industry, by contributing original research in this specific area, and by offering recommendations to community colleges on how to address the workforce challenges of the industry.

Industry Overview

California is home to over 24% of the nation's medical device manufacturers with large business concentrations in the Bay Area, Los Angeles/Orange County and San Diego County. Therefore, the medical device industry is a significant contributor to the economy in California, providing growing employment opportunities for workers and economic benefits for the regions where the industry is concentrated. The medical device industry can be viewed as an industry cluster that draws on the advanced manufacturing, biotechnology, and healthcare industries. The industry cluster is defined by the following NAICS[3] codes:

NAICS Codes	Medical Device Industry Sub-Sectors
334510	Electro Medical/Electro-therapeutic Apparatus Manufacturing
334516	Analytical Laboratory Instrument Manufacturing
334517	Irradiation Apparatus Manufacturing
339111	Laboratory Apparatus and Furniture Manufacturing
339112	Surgical and Medical Instrument Manufacturing
339113	Surgical Appliances and Supplies Manufacturing
339114	Dental Equipment and Supplies Manufacturing
339115	Ophthalmic Goods Manufacturing
339116	Dental Laboratories
621511	Medical Laboratories
621512	Diagnostic Imaging Centers
327215	Glass Product Manufacturing

Firms in this industry produce biomedical instruments and other health care products and supplies for diagnostics, surgery, patient care and clinical laboratories. New advanced manufacturing technologies and demographic trends are the main drivers fueling the growth in the medical device industry.

The demographic change influencing the industry is the nation's aging population. According to the U.S. Census Bureau, there will be 54 million people 65 and older by 2020 and more than 86 million people over 65 by 2050.[4] As baby boomers live longer, they require more sophisticated and longer-term health care. The changing health care needs of this population and the accompanying shift by health care providers regarding treatment approaches for people over 65 are driving the growth of the industry. This has created demand for advanced medical devices and raised expectations that new technologies will enhance the quality and length of patients' lives.[5]

New advanced manufacturing technologies, such as automation, rapid prototyping, photonics (laser, UV), advanced machining and nanotechnology are also driving growth in the industry. As these new technologies become more integrated into device

[3] North American Industry Classification System
[4] U.S. Census Bureau, "Projected Population of the United States, by Age and Sex, 2000 to 2050"
[5] Electronic News/Reed Business Information, "Baby Boomers Driving Growth of Medical Electronics", 2004

manufacturing processes, the sophistication of devices accelerates, thus opening up new clinical applications and fueling industry growth.

A Highly Regulated Industry

It is important to note that the medical device industry is a highly regulated industry. It is the Food and Drug Administration's (FDA) responsibility to ensure that the medicines and medical devices patients use are safe and effective. There are three FDA regulatory classifications of medical devices: Class I, Class II and Class III. The classifications are assigned by the risk the medical device presents to the patient. The higher classification levels indicate greater risk to the patient and more FDA regulatory control.[6]

Class I devices are subject to the general manufacturing regulatory controls (e.g. surgical gloves, bandages, hand held surgical instruments). Class II devices require special controls, such as special labeling and mandatory performance standards (powered wheelchairs, infusion pumps, x-ray machines). Class III is the most stringent classification in terms of regulatory control and is used for devices that maintain or sustain life, or that prevent impairment of human health or have a potential risk of injury or illness (defibrillators, heart stents). Medical devices using new technologies such as new drugs and combination medical devices (e.g. devices with biological components) are included in Class III. This report will focus on the more technologically advanced medical devices covered by Class II and Class III.

Because of the critical importance of patient safety in the use of medical devices, extensive documentation of the components, ingredients, and properties of operation of devices is required by the FDA. Technicians who understand regulatory issues, have the ability to write and have the critical thinking and analytical abilities to complete the documentation described above are valuable to employers.

Medical Device Sectors

The twelve (12) six-digit NAICS codes that define the medical devices industry can be classified into three sectors: advanced manufacturing (NAICS 33911-339116), medical and diagnostic laboratories (NAICS 621511, 621512), and biotechnology support (NAICS 327215, 334510, 334516, 33517).

In Los Angeles County in 2006, Advanced Manufacturing employed 7,865 individuals, Medical and Diagnostic Laboratories, 8,961, and Biotechnology Support, 7,875, totaling 24,701 for the Medical Device Industry.

Growth

Employment in the medical device industry is expected to continue to grow. According to an employer survey conducted by BW Research Partnership in collaboration with the

[6] FDA Regulation of Medical Devices, http://www.qrasupport.com/FDA_MED_DEVICE.html

Centers of Excellence, medical device employers in California expect to increase their number of employees by almost ten percent in the next 12 months. This would mean that almost 2,500 new jobs would be created in the industry in Los Angeles County.

Employers and industry leaders agree that workforce issues are becoming increasingly important for the medical device industry. Based on the survey results for Los Angeles County, 72.6% of employers indicated having difficulty recruiting employees with appropriate training and education, including 25% who stated having "great difficulty".

Economic Impact

In the United States, the annual production value of the medical device industry totaled over $82 billion in 2004.[7] In California, medical device businesses had a combined sales volume of $28.7 billion in 2007.

Table 1: Medical Devices Industry: Employment, Businesses, Employees and Wages (2006)

	Percent of Statewide Industry Employment	Number of Businesses	Average Employment per Business	Estimated Average Annual Wage
Los Angeles County	24.6%	1,073	23	$52,588
California	100%	4,068	24.7	$53,237

Source: BW Research and EDD data, for 2006

Los Angeles County has 24.6% of the medical device industry employment in the state. In terms of size of firms, Los Angeles County – with an average of 23 employees per business – is slightly lower than the state's average employment per business. Wages in Los Angeles County are comparable to the State's average.

Occupational Overview

The primary research component of this study focused on high-demand occupations within the medical device industry. To be selected for inclusion, the occupations had to meet at least one of the following criteria: high employment in the region, above average growth, or an occupation easily served by community college-level education and training programs. The following eight occupations were identified through executive interviews with industry leaders as key jobs needed within the industry and as being most relevant to community college students:

- Assemblers and/or Electrical & Electronic Assemblers
- Engineering & Operations Technicians
- Quality Control Technicians
- Research & Development Technicians

[7] U.S. Census Bureau, Annual Survey of Manufacturers, 2004.

- Supervisors/Managers of Technicians and Maintenance Workers
- Clinical Trials & Regulatory Assistants and/or Technicians
- Inspectors, Testers and Graders
- Safety, Hazmat, and Environmental Controls Technicians

The occupational data was compiled using the California Employment Development Department's (EDD) labor market information, and the results from telephone surveys with 113 medical device employers located in Los Angeles County, conducted by BW Research. Appendix B includes an overview of the survey methodology. Appendix D contains an occupational profile for each of the eight occupations studied.

Table 2: Summary of Los Angeles Employment Demand for the Occupations Studied

Occupation	Estimated 2006 Medical Device Employment	Absolute Growth Next 12 Months (from 2007 survey)	% Growth Next 12 Months (from 2007 survey)	Median Annual Wage
Assemblers and/or Electrical & Electronic Assemblers	1,690	405	24.00%	$27,592
Supervisors/ Managers of Technicians & Maintenance Workers	610	122	19.90%	$53,993
Clinical Trials & Regulatory Assistants and/or Technicians	1,082	199	18.40%	$48,498
Research & Development Technicians	465	76	16.30%	$45,478
Safety, Hazmat, and Environmental Controls Technicians	494	76	15.40%	$63,644
Quality Control Technicians	1,481	228	15.40%	$45,478
Engineering & Operations Technicians	1,410	157	11.10%	$50,706
Inspectors, Testers and Graders	810	23	2.80%	$39,930
SUMMARY	**8,042**	**1,001**	**12.45%**	

Table 2 shows estimated[8] 2006 Los Angeles County employment within the medical device industry, the number of expected openings from growth over the next 12 months for each of the occupations, and the median annual wage by occupation.

The employers surveyed anticipate double-digit growth for all occupations studied except Inspectors, Testers and Graders. The fastest growing occupations in Los Angeles County are expected to be Assemblers (+ 24%), Supervisors of Technicians and Maintenance Workers (+ 19.9%) and Clinical Trials and Regulatory Assistants and Technicians (+ 16.3%). The largest absolute job growth is anticipated for Assemblers with 405 new jobs projected for this occupation over the next 12 months, Quality Control Technicians with 228 new jobs, Clinical Trials & Regulatory Assistants and Technicians with 199, and Engineering & Operations Technicians, with 157.

Career Pathways

The industry has a defined career pathway which could provide community college students with excellent opportunities for career advancement if they continue their education and gain work experience. A chart representing the career ladder is available in Appendix C.

Employer Needs and Challenges

With the exception of safety, hazmat, and environmental controls technicians, the majority of employers indicated difficulty finding qualified applicants for each of the other seven occupations. Employers expressed the greatest difficulty finding qualified engineering and operations technicians (75.9%), quality control technicians (61.0%) and clinical trials and regulatory assistants and technicians (58.3%).

[8] Quality control technicians; research & development technicians; and safety, hazmat, and environmental controls technicians represent emerging occupations within medical devices and are not captured by the current SOC system. As such, employment for these three occupations was estimated from the survey data instead of the EDD data. Due to EDD data limitations, the same SOC data for wages was used for both quality control technicians and research and development technicians.

Figure 1: Difficulty Finding Applicants who Meet Hiring Standards

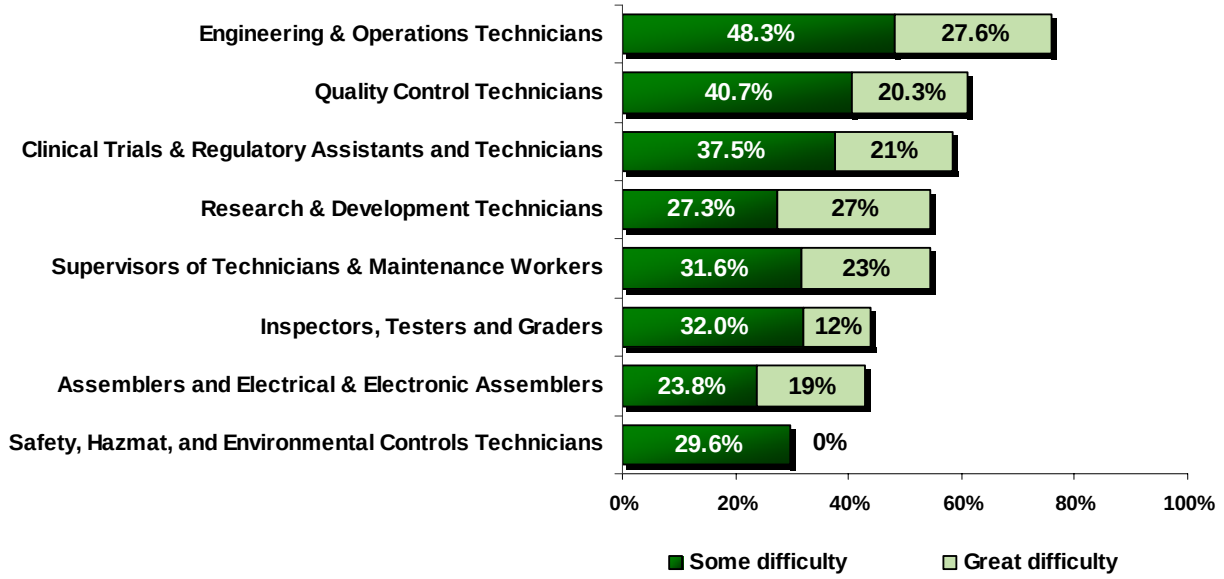
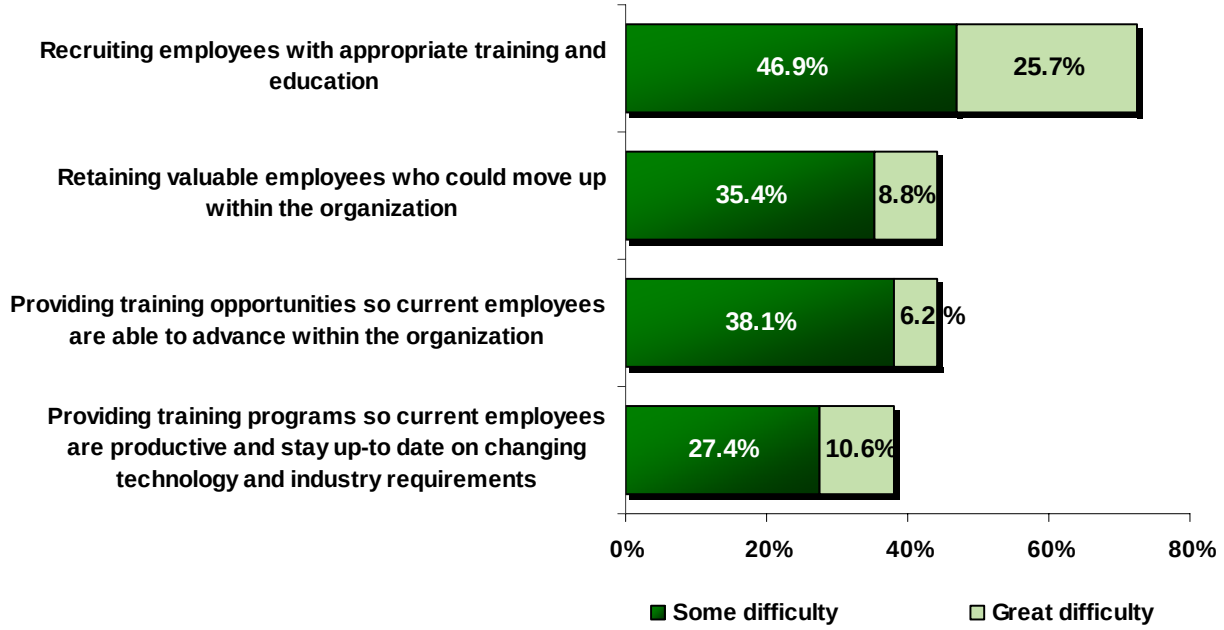


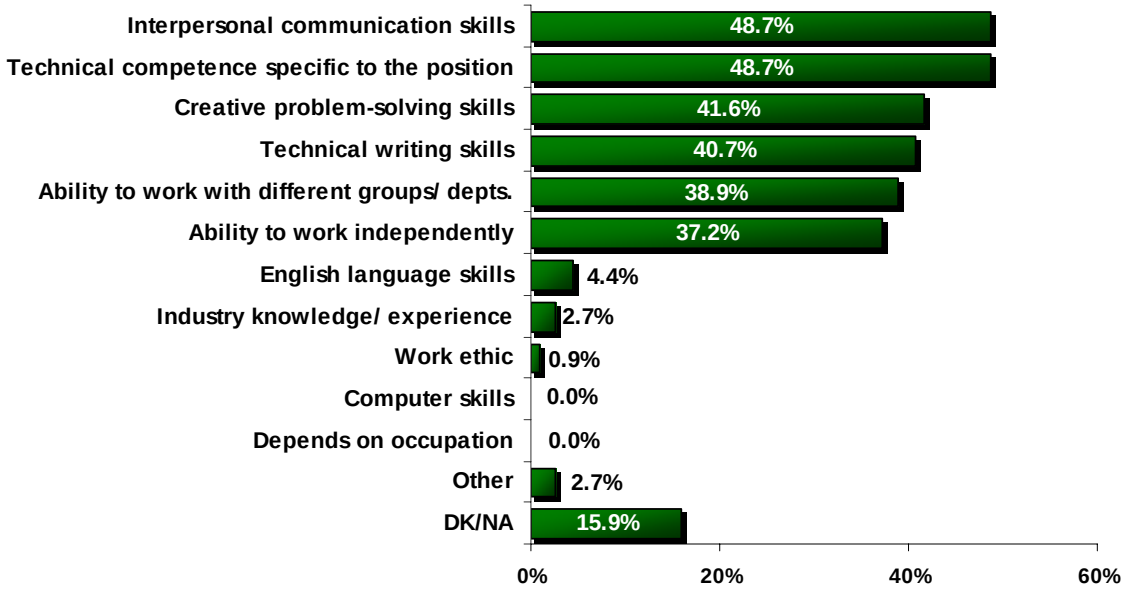
Figure 2: Workforce Challenges for Los Angeles County Employers



As presented on figure 2, 72.6% of employers surveyed indicated difficulty recruiting employees with appropriate training and education. Over 44% indicated having difficulty retaining valuable employees and providing training opportunities so employees could advance in the organization.

Occupational Skill Requirements

Figure 3: General Skill Deficiencies Among Recent Hires

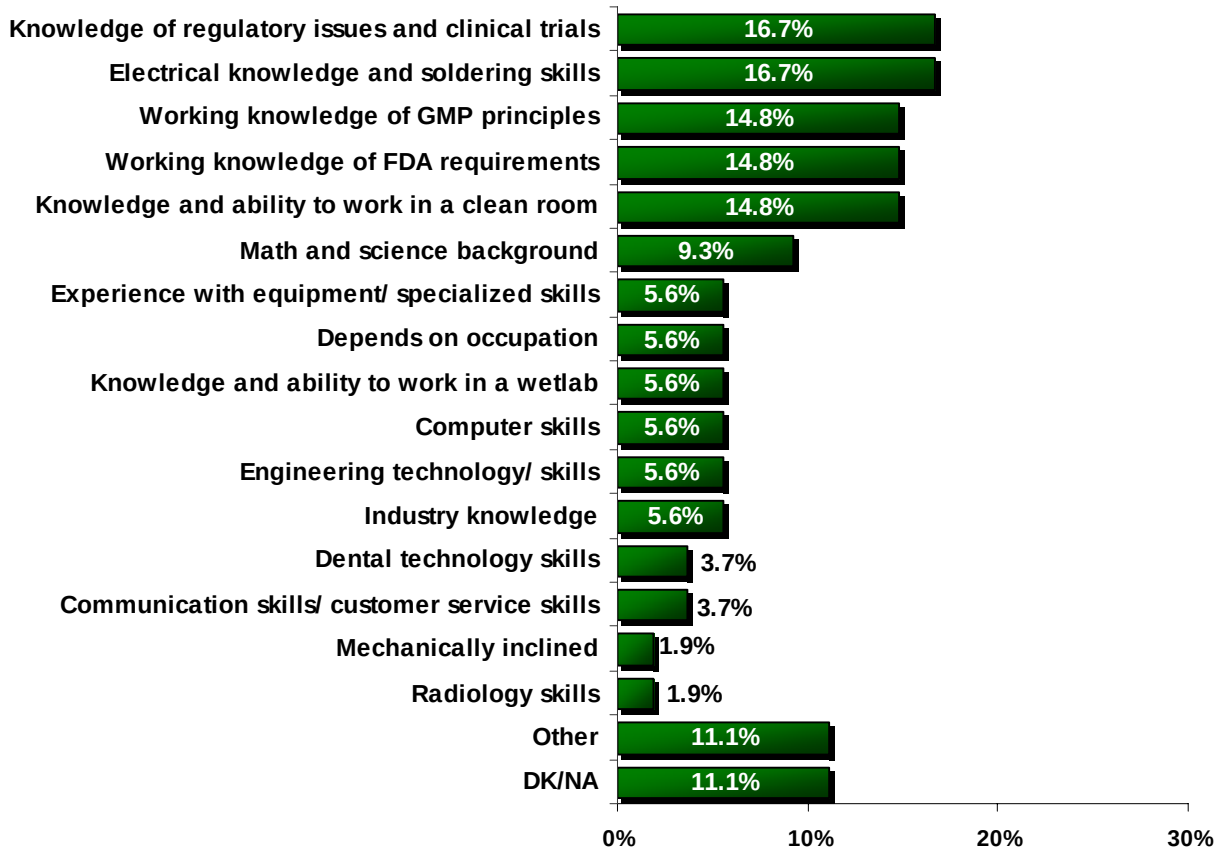


When asked to reflect on recent hires at their organization, almost half of employers stated that new hires were deficient in interpersonal communication skills and were lacking technical competence specific to the position.

They were then asked what the most important skills for technicians were. As presented on figure 4, technical skills and job specific skills are the most important. Although new hires often lack communication skills, it is not as crucial as their ability to do the job.

Within the skills needed by technicians, employers indicated that knowledge of regulatory issues and clinical trials (16.7%), and electrical knowledge and soldering skills (16.7%) were the two most important, followed by working knowledge of GMP principles, working knowledge of FDA requirements, and knowledge and ability to work in a clean room (14.8%).

Figure 4: Most Important Skills for Technicians

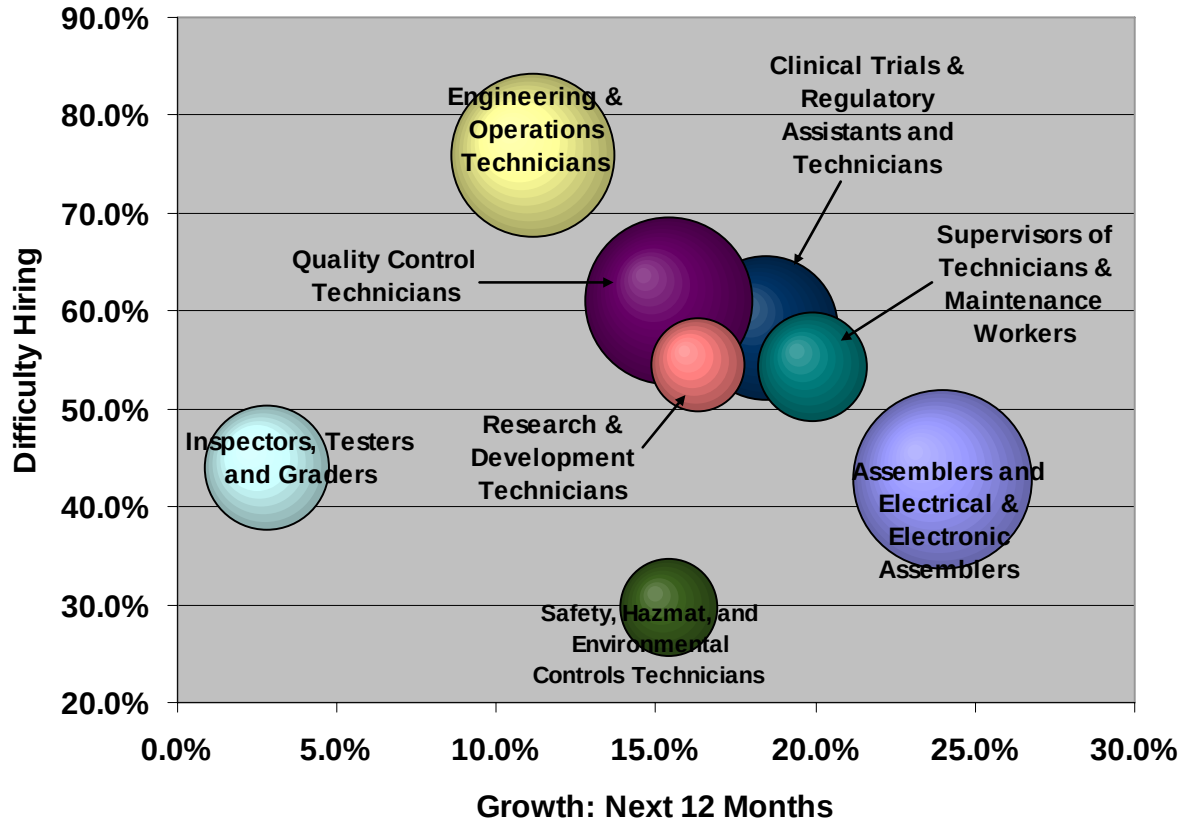


Occupational Outlook

Figure 5 displays the number of employees in each occupation (the size of each bubble) by difficulty in hiring and expected growth over the next 12 months.

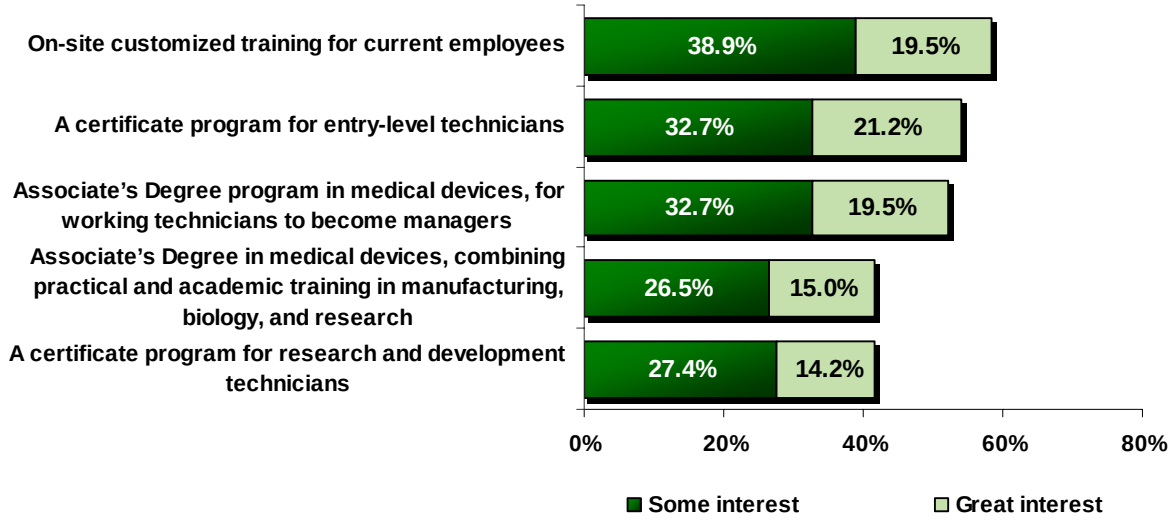
Engineering and Operations Technicians, Quality Control Technicians, and Clinical Trials and Regulatory Assistants and Technicians (near the top of the chart) emerge as the occupations with the most potential to be undersupplied in the future, due to employers' difficulty finding applicants who meet hiring standards. Assemblers and/or Electrical and Electronic Assemblers (to the far right of the chart) have the highest anticipated growth in the next 12 months, followed by Supervisors of Technicians & Maintenance Workers.

Figure 5: Occupational Employment, Difficulty Hiring, and Expected Growth



Workforce Opportunities

Figure 6: Employer Interest in Potential Community College Programs



Employers expressed the most interest in working with the community colleges for on-site customized training for their current medical devices employees (58.4%).

About half of employers also expressed some interest in a certificate program for entry-level technicians (54.0%) and a medical devices associate's degree program for working technicians to become managers (52.2%).

Additional discussions with local employers at a Medical Device conference, called MDM West, on 01/29/08, and individual and panel presentations made at the Southern California Biomedical Council's Human Resources Conference on 02/29/08 revealed that:

- To fill positions, medical device employers used to recruit employees from other companies by offering them better compensation or other benefits and advantages that were appealing to the employees. However, the industry is now facing a shortage of qualified workers, and employers need new strategies to create a pipeline of workers.
- Employers did express some interest in community college programs for their industry, however, most occupations require a higher level of education. The primary goal of community college programs would be to create a pipeline of workers, with the intent to encourage students to continue their education and obtain advanced degrees.
- While a program focused on medical devices would be beneficial to the industry, students may have more career options if they pursue a degree in Biotechnology for example, with an emphasis on medical devices. They would be well-prepared to enter the industry, without being overly specialized, which might limit their opportunities to work for employers in related fields.

Community Support and Resources

There are excellent opportunities for colleges, credit, non-credit and contract education departments, and Economic and Workforce Development (EWD) Initiatives to partner with employers, industry associations, and workforce agencies to meet the workforce needs of employers. Here is a list of potential strategic partners:

Partner	Type of Organization	Possible Contributions
California Applied Biotechnology Center (Pasadena CC)	Community College EWD-Funded Program	Technical assistance Curriculum development Incumbent worker training
Centers of Excellence (Los Angeles CCD and Mt. San Antonio College)	Community College EWD Program	Forecast industry workforce needs Industry research Partnership development
Centers for Applied Competitive Technologies and Affiliates (Cerritos College, El Camino College, Glendale CC, Long Beach CC, Los Angeles CCD)	Community College EWD Program	Technical assistance Curriculum development Incumbent worker training

Partner	Type of Organization	Possible Contributions
Medical Device Industry Education Consortium (MDIEC) www.mdiec.org	Education & Industry Consortium	Industry-defined education & training solutions Curriculum development Resources and technical assistance
Medical Device Training Initiative of Orange County (MDTIOC) (North Orange County Community College). *See appendix E.*	Community College EWD-Funded Program	Technical assistance Curriculum development Incumbent worker training
Regional Colleges and LA/OC Regional Consortium (LOWDL)	Workforce Training and Development	Education and training (Associate degrees, certificates, basic skills; incumbent worker training via contract education)
Regional Health Occupations Resource Centers (Mt. San Antonio College, Golden West College)	Community College EWD Program	Technical assistance Curriculum development
Southern California Biomedical Council www.socalbio.org	Industry association for medical devices and biotechnology.	Partnerships with Members for Advisory Boards, resources, possibly internships, adjunct faculty etc.
Workforce Investment Boards (WIBs) and WorkSource Centers	Workforce Development	Can refer students (job seekers) and facilitate partnerships with employers.

Southern California Biomedical Council

The Southern California Biomedical Council (SoCalBio) is the trade association of the life-science industry in Greater Los Angeles. The mission of SoCalBio is to represent and promote medical device and biotechnology industry in Los Angeles and Orange Counties as well as adjacent communities in the Inland Empire and Gold Coast[9]. SoCalBio has a Workforce Development Committee and is committed to helping businesses meet their workforce needs. Ahmed Enany, the President of the association agreed to help the community colleges interested in developing programs, connect with employers in their service area, and provide additional assistance/guidance, as needed. He is already working with Wendie Johnston, Director of the California Applied Biotechnology Center at Pasadena City College, and suggested that colleges interested in developing new workforce solution for the industry connect with Wendie before contacting him, to improve communication and collaboration. Their contact information is included in the list of references.

Medical Device Industry Education Consortium

The Medical Device Industry Education Consortium[10] (MDIEC) is comprised of ten community colleges in the U.S and Europe, plus employer representatives from the medical device industry. Created in 2005 with funding from the Department of Labor, MDIEC's mission is to develop and deliver curriculum to train technicians for employment in the medical device industry. The curriculum developed is endorsed by an industry advisory board.

[9] http://www.socalbio.org/
[10] http://www.mdtioc.org

The following occupations have been targeted for technicians: quality control, research and development, product development, manufacturing, biological/chemical analysis, compliance-related data management, and technology-related sales.

To date, MDIEC has developed or is in development of courses in the following four industry areas:

1) Medical Device Regulatory Affairs (two courses developed)
2) Quality Assurance/Quality Control
3) Medical Device Document/Information Management
4) Clinical Data Management.

Through grant funding from the National Science Foundation (NSF) obtained in 2006, MDIEC has been able to further assist several of its consortia-member community colleges to develop programs and curriculum. As a result of workforce data that shows California having the most medical device companies in the nation, MDIEC is looking to add an additional college in California to join its consortium, along with the potential of adding a new California industry advisor.

Currently, the only California member of MDIEC is located at the North Orange County Community College District (NOCCCD), School of Continuing Education. The college has a two-year Job Development Incentive Fund (JDIF) grant from the California State Chancellor's Office to develop medical device industry-relevant curricula and training programs. They are working with industry and local agencies to recruit new trainees, place new labor force entrants and CalWORKS students, and train incumbent workers. The college has developed partnerships to facilitate information exchange with MDIEC, St. Petersburg College, Anaheim Workforce Investment Board (ACWIB), Orange County Workforce Investment Board (OCWIB), and the City of Anaheim. A one-page overview of the NOCCCD project is located in Appendix E.

Model Medical Device Programs: Anoka-Ramsey Community College

Anoka-Ramsey Community College in Minnesota has developed a Biomedical Technology program focused on the medical device industry. Students can get an Associate in Science degree in Biomedical Technology to prepare for entry, career transition or advancement in the medical device industry - from manufacturing to clinical research. Students can also attain a Biomedical Technician Certificate or a Clinical Research Professional Certificate. Appendix F has additional information about these programs and links to the college website where curriculum information is available.

College Response

Existing Education Related to Medical Device Industry Occupations

There are no colleges within Los Angeles County that offer certificate or degree programs within the field of medical devices. However, come colleges offer biotechnology courses or programs, and several offer programs closely related to medical devices under the TOPS categories of Biological Sciences and Health:

Engineering and Industrial Technologies	TOPS CODE	College	Program
Biomedical Instrumentation	0934.60		
		Los Angeles City	Biomedical Electronics Technology
		Los Angeles Valley	Biomedical Equipment Technology
Biotechnology			
		Pasadena City	Biological Technician/Bio Technology
		Santa Monica	Biological Technician/Bio Technology
Industrial Quality Control	0956.80		
		Cerritos	Industrial Technology: Quality Assurance
		El Camino	Quality Assurance
		Los Angeles Southwest	Quality Control

Health	TOPS CODE	College	Program
Dental Laboratory Technician	1240.30		
		Los Angeles City	Dental Technology, including manufacture of prosthodontics
		Pasadena City	Dental Laboratory Technology

Conclusions and Recommendations

Based on the information presented in this report, including the findings from surveying 113 medical device employers in Los Angeles County, and additional discussions with regional employers, colleges have an opportunity to play a role in the industry's workforce development. The main opportunity identified is to provide on-site customized training to upgrade employees' skills.

In addition, it is recommended that one or two college(s) consider creating or adapting programs to help the medical device industry create a pipeline of workers. To accomplish this goal, colleges should:

1. Create partnerships with local medical device employers and industry associations to meet workforce development needs.

- Join SoCalBio and participate in the Workforce Development Committee to gain valuable information about industry job openings, trends, hiring practices and assistance in developing connections to local medical device employers.
- Develop credibility and prove capability, as the community colleges are not perceived to be traditional training and education providers for the medical device industry, by developing very-high quality programs with industry input and seeking technical assistance from the Medical Device Training Initiative of Orange County (MDTIOC) and the California Applied Biotechnology Center at Pasadena City College (contact information included in the references).
- Form a regional Industry Advisory Board to obtain up-to-date input from employers. The Centers of Excellence can provide lists of companies and information on their geographic concentration, by industry code.
- Partner with local employers to develop curriculum and training programs that are aligned with industry standards.

2. Create partnerships with EWD Centers, regional colleges and WorkSource Centers, to build the capacity to respond to industry needs.

- Work with North Orange County Community College District's Office of Continuing Education, a member of the Medical Device Industry Education Consortium (MDIEC). They can serve as a valuable model and resource for other colleges interested in developing medical device programs.
- Work with Community College Economic and Workforce Development (EWD) Centers[11] such as the California Applied Biotechnology Center at Pasadena City College, for technical assistance with program development, curriculum development and building industry partnerships to implement these report recommendations.

[11] California Applied Biotechnology Center (Cal ABC), Centers for Applied Competitive Technologies (CACTs) and Regional Health Occupation Resource Center (RHORC)

- Work with regional WorkSource Centers (Workforce Investment Board) to develop workforce development strategies, including recruitment, re-training and career transition programs for job seekers interested in the industry (the industry has had success retraining and hiring workers exiting the aerospace industry).

3. Create/adapt college offerings to address industry needs.

- Review Anoka-Ramsey Community College (in Minnesota) Associate Degree and Certificate programs in Biomedical Technology, which are focused on the medical device industry to determine what elements should be incorporated into college programs.
- Promote the career opportunities in the medical device and biotechnology industries to students to create a pipeline of workers entering the industry.
- Encourage students to continue their education, and as much as possible, try to articulate with university medical device programs (programs exist at the University of Southern California, UC Irvine and San Diego State).

In conclusion, the medical device industry needs assistance from the community colleges to create a pipeline of workers. Currently, community colleges in Los Angeles County do not have specific programs focused on medical devices. However, colleges that offer biotechnology, biomedical technology, biomedical instrumentation/electronics, engineering and health sciences courses or programs can adapt or create courses to serve this industry. Creating courses or programs will require colleges to be responsive to industry standards, and changes driven by technology, scientific research and FDA regulations. Developing partnerships with industry associations, public workforce agencies, local employers, and EWD Centers related to this industry will help colleges be successful in creating programs and enrolling students.

Credits

This report has been adapted from the San Francisco Bay and Greater Silicon Valley Regions Medical Device Manufacturing Industry scan, and customized for Los Angeles County, using survey responses and employers' input exclusively from companies located in Los Angeles County.

Data Limitations

During the development of this report, significant limitations were encountered with EDD data on the industry. Because EDD data did not identify the full range of occupations specific to the industry, the projected job growth and skill requirements for these occupations were not available. In addition, using EDD data to perform a "crosswalk" from industry NAICS codes to the related SOC codes (occupational titles) showed multiple industries employing most of the occupations identified, not just the medical device industry. Therefore accurate projections could not be made regarding what part of the projected growth for occupations could be attributed to the medical device industry.

This gap in available data created a need for primary research to identify high-growth and high-demand occupations that could be filled with community college students (excluding positions that require more education than an Associate Degree), obtain employment projections and define the community colleges' role in the medical device industry's workforce development. The employer survey results include information from over 100 businesses located in Los Angeles County, and were validated through additional conversations with local employers.

References and Resources

BIOCOM/San Diego, http://www.biocom.org

Biotechnology Jobs in California, California State EDD LMID, http://www.labormarketinfo.edd.ca.gov/cgi/career/?PAGEID=3&SUBID=136

BW Research Partnership, www.bwresearch.com

California's Biomedical Industry, PriceWaterhouseCoopers & California Healthcare Initiative, 2006

California State EDD LMID, http://www.labormarke info.edd.ca.gov

Counseling for Careers in Biotechnology & Medical Devices, http://www.biotechwork.org/

Electronic News/Reed Business Information, "Baby Boomers Driving Growth of Medical Electronics," 2004, http://www.edn.com/article/CA421823.html

Growing the Nation's Bioscience Sector: A Regional Perspective, Battelle, January 2007; A Companion Document to *Growing the Nation's Bioscience Sector: State Bioscience Initiatives 2006*

Medical Device Industry Education Consortium, http://www.mdiec.org

Medical Device Link, http://www.devicelink.com

Medical Devices Manufacturers' Association, http://medicaldevices.org

North American Industry Classification System, http://www.census.gov/epcd/www/naics.html

The San Francisco Bay and Greater Silicon Valley Regions Medical Device Manufacturing Industry scan, available at: www.cccewd.net/industryscans

U.S. Census Bureau, Annual Survey of Manufacturers, 2004.

U.S. Census Bureau, "Projected Population of the United States, by Age and Sex, 2000 to 2050", 2004, http://www.census.gov/ipc/www/usinterimproj/natprojtab02a.xls

U.S. Food and Drug Administration, Center for Devices and Radiological Health, http://www.fda.gov/cdrh, and FDA Regulation of Medical Devices, http://www.qrasupport.com/FDA_MED_DEVICE.html

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Appendix A: How to Utilize this Report

About Us - Description of BWPI

The Business and Workforce Performance Improvement (BWPI) initiative is focused on building the capacity of the colleges in the area of economic and workforce development to enhance their ability to deliver education and training services to businesses and workers in high growth industries, new technologies, and other clusters of opportunities.

The Centers of Excellence (COE) within BWPI provide information regarding workforce trends, increasing awareness and visibility about the colleges' economic and workforce development programs and services, and building partnerships with business and industry.

The goal is to position the colleges as the workforce partners of choice to business and industry and ensure that college programs are current and responsive. This will contribute to the overall economic vitality of the communities in which they serve.

How to Use This Report

The Centers of Excellence within the Business and Workforce Performance Improvement Initiative of the California Community College Economic and Workforce Development Program have undertaken Environmental Scanning to provide targeted and valuable information to community colleges on high growth industries and occupations.

This report is intended to assist the decision-making process of California community college administrators and planners in addressing local and regional workforce needs and emerging job opportunities in the workplace as they relate to college programs. The information contained in this report can be used to guide program offerings, strengthen grant applications, and support other economic and workforce development efforts. This report is designed to provide current industry data that will:

- Define potential strategic opportunities relative to an industry's emerging trends and workforce needs.
- Inform local college program planning and resource development.
- Promote a future-oriented and market responsive way of thinking among stakeholders.

Important Disclaimer

All representations included in this industry scan report have been produced from a secondary review of publicly and/or privately available data and/or research reports. Efforts have been made to qualify and validate the accuracy of the data and the reported findings. The purpose of the Environmental Scan is to assist the California

Community Colleges to respond to emerging market needs for workforce performance improvement. However, the Business and Workforce Performance Improvement Centers of Excellence, COE host-college and California Community Colleges Chancellor's Office are not responsible for applications or decisions made by recipient community colleges or their representatives based upon this study including components or recommendations.

Additional Information

The Business and Workforce Performance Improvement Initiative is funded in part by the Chancellor's Office, California Community Colleges, Economic and Workforce Development Program. The total grant amount (grant number 07-305-016 for $205,000) represents funding for multiple projects and written reports through the Center of Excellence.

Our mission is to strengthen California's workforce and advance economic growth through education, training and job development.

Appendix B: Survey Methodology

The table below briefly outlines the methodology for this project. Two phases of primary research were conducted - qualitative executive interviews with human resource and training managers and directors within the medical devices industry and a quantitative telephone survey of 500 medical devices employers across the state.

Table 1 Telephone Survey Methodology

Technique	Telephone Survey of Medical Devices Industry Employers
Universe	Firms with at Least Five Employees: 2,500
Number of Respondents	500
Field Dates	July 24 to August 21, 2007

Below is the breakdown of interviews by region:

Table 2 Telephone Surveys by Region

	# Interviews	Percentage
Bay Area	103	20.6%
Central Valley	35	7.0%
Far North	35	7.0%
Inland Empire	40	8.0%
Los Angeles	113	22.6%
Orange	83	16.6%
San Diego	51	10.2%
Ventura	40	8.0%
Statewide	**500**	

Appendix C: Medical Devices Career Ladder

Advanced Level: Bachelor's Degree or equivalent and proven technical or managerial skills that can be demonstrated through industry experience.

Quality Control Analyst $47k to $68k/year	Supervisors of Technicians & Maintenance Workers $41k to $71k/year

Mid Level: Associate Degree or Bachelor's Degree and equivalent training and experience including related on-the-job experience.

Quality Control Techs. $36k to $58k/year	Clinical Trials & Regulatory Techs. $41k to $58k/year	Research & Development Techs. $36k to $58k/year

Entry Level: Associate Degree or equivalent training and experience in vocational schools or on-the-job experience.

Assemblers & Electrical or Electronic Assemblers $24k to $37k/year	Inspectors, Testers and Graders $28k to $45k/year

Source: Information taken from BW Research Employer Survey and "Counseling for Careers in Biotechnology & Medical Devices", http://www.biotechwork.org/

Appendix D: Descriptions of Occupations

Clinical Trials & Regulatory Assistants and/or Technicians

The work of clinical trials and regulatory assistants and/or technicians involves assisting or performing complex medical laboratory tests, evaluating test results, developing and modifying procedures, and establishing and monitoring programs to ensure the accuracy of tests.

The critical skill sets include a strong science and mathematics background, good analytical judgment, close attention to detail, and ability to work under pressure.

This is an entry to mid-level position, with most occupations in this category requiring at least a vocational or associate's degree, and some requiring a bachelor's degree.

Engineering & Operations Technicians

The work of engineering and operations technicians involves applying the principles and theories of science, engineering, and mathematics to solve technical problems. Many engineering technicians assist engineers and scientists, especially in research and development.

The critical skill sets include a strong engineering and mathematics background, mechanical aptitude, good analytical judgment, and close attention to detail.

This is an entry to mid-level position, with most occupations in this category requiring vocational training or an associate's degree.

Quality Control Technicians

The work of quality control technicians involves the performance and record keeping associated with quality control testing and implementing corrective and preventive action plans for non-conformances.

The critical skill sets include knowledge of production and processing, knowledge of engineering and technology, mechanical aptitude, the ability to conduct quality control analysis, and strong troubleshooting, problem solving, and record-keeping skills.

This is an entry to mid-level position, with most occupations in this category requiring training in vocational schools, related on-the-job experience, or an associate's degree.

Research & Development Technicians

The work of research and development technicians involves supporting new product development or product revisions by implementing aspects of research, construction, testing, documentation, problem correction, and related tooling.

The critical skill sets include knowledge of production and processing, strong science, mathematics and/ or engineering skills, detail-oriented nature, and troubleshooting and problem solving skills.

This is an entry to mid-level position, with most occupations in this category requiring training in vocational schools, related on-the-job experience, or an associate's degree, and some requiring a bachelor's degree.

Supervisors/ Managers of Technicians & Maintenance Workers

The work of supervisors or managers of technicians and maintenance workers can vary greatly depending on the work environment. Duties can include directing and coordinating the activities of employees, enforcing safety and sanitation regulations, inspecting materials, products, or equipment to detect defects or malfunctions, and interpreting specifications, blueprints, job orders, and company policies and procedures for workers.

The general skill sets for supervisors or managers of technicians and maintenance workers include mechanical and technical aptitude, ability to coordinate the work of others, leadership, communication skills, and any appropriate agency-specific knowledge.

This is a mid-level position, with most occupations in this category requiring training in vocational schools, related on-the-job experience, or an associate degree. Some may require a bachelor's degree.

Assemblers and/or Electrical & Electronic Assemblers

The work of assemblers and/or electrical and electronic assemblers involves assembling or modifying electrical, electronic, or electromechanical equipment or devices as well as performing precision assembling or adjusting.

The critical skill sets include knowledge of production and processing, knowledge of engineering and technology, mechanical aptitude, the ability to conduct quality control analysis, troubleshooting, understanding of equipment selection, and sound judgment and decision making skills.

This is an entry-level position, with most occupations in this category requiring training in vocational schools, related on-the-job experience, or an associate's degree.

Inspectors, Testers and Graders

The work of inspectors, testers and graders involves monitoring or auditing quality standards for manufactured products and they are involved at every stage of the production process. Job duties, even within one company, vary by the type of products produced or the stage of production.

The critical skill sets include mechanical aptitude, math and communication skills, and good hand-eye coordination and vision. As automated inspection equipment and electronic recording of results is common, computer skills are also important.

This is an entry-level position, with the training requirements dependent on the responsibilities of the inspector, tester, or grader. For basic “pass/fail” tests of products, a high school diploma and basic in-house training is generally sufficient. However,

postsecondary training and more in-depth on-the-job training is often required for a position responsible for more advanced tests of products.

Safety, Hazmat and Environmental Controls Technicians

The work of safety, hazmat and environmental controls technicians involves identifying where controls need to be implemented to reduce or eliminate potential hazards in systems, equipment, products, facilities, or processes. As necessary, they conduct training sessions for management, supervisors, and workers on health and safety practices and regulations to promote an understanding of a new or existing process. After implementation, they may monitor and evaluate the program's progress, making additional suggestions when needed.

The critical skill sets include training and/or certification in the applicable laws or inspection procedures, strong science and mathematics background, good communication skills, and a detail-oriented nature.

This is an entry to mid-level position, with most occupations in this category requiring training in vocational schools, related on-the-job experience, or an associate's degree. Some may require a bachelor's degree.

Appendix E: Model Workforce Development Project

Medical Device Training Initiative of Orange County (MDTIOC) Job Development Incentive Grant (JDIF) Project, hosted by North Orange County Community College District, Office of Continuing Education

The North Orange Community College District's (NOCCCD) School of Continuing Education was awarded a two-year grant to develop medical device industry-relevant curricula and training for new and existing workers. Through this grant the Medical Device Training Initiative of Orange County (MDTIOC) was created and is able to offer training programs at no cost to companies and employees during the grant period.

This project directly responds to the needs of medical device companies for qualified workers. Orange County possesses one of the largest concentrations of medical product manufacturers in the world. Recent surveys and focus groups with local employers, confirmed by national and regional statistics on skills gaps in the medical device industry, indicate that the industry is not effectively meeting its need for highly skilled employees. These skill deficiencies impair medical device companies' ability to compete and grow, implement new productivity improvements or deploy new products.

NOCCCD, School of Continuing Education is working with industry and local agencies to recruit new trainees, place new labor force entrants and CalWORKS students, train incumbent workers, and facilitate information exchange and communication between the industry, workforce agencies, and training providers. MDTIOC is working in partnership with the Medical Device Industry Education Consortium (MDIEC), St. Petersburg College, the Anaheim Workforce Investment Board, the Orange County Workforce Investment Board and the local medical device industry.

The establishment of MDTIOC in 2006 was funded by the Economic & Workforce Department through the California Community Colleges. The Economic & Workforce Department serves to advance California's economic growth and global competitiveness through high quality education and services focusing on continuous workforce improvement, technology deployment, and business development, consistent with the current needs of the state's regional economies.

The following tasks have been accomplished:

- Developed five short-term, non-credit medical device industry-specific curricula
- Developed three training program tracks for entry and supervisory workers

Working toward:

- Will train 400 incumbent workers in the medical device industry
- Will introduce 150 new workers into the medical device industry
- Will conduct 120 hours of industry-specific customized training

Additional information regarding the program can be obtained by visiting http://www.mdtioc.org or contacting Sharon Dalmage, Program Director at 714-808-4575, sdalmage@sce.cc.ca.us.

Appendix F: Model Programs

Anoka-Ramsey Community College
http://www.anokaramsey.edu/

Biomedical Technology

Get started on a Certificate or Degree Program in Biomedical Technology. These programs and courses are designed to prepare workers for entry, career transition or advancement in the Medical Device Industry--from Manufacturing to Clinical Research.

This fast-growth industry has created a need for skilled workers who are knowledgeable about the industry, technology-competent, as well as proficient in oral and written communication, interpersonal skills, critical thinking and problem-solving skills. These programs are designed to meet entry-level employment needs as well as provide career transition and promotional opportunities.

Biomedical Technologist
Associate in Science Degree: http://www.anokaramsey.edu/resources/pdf/degrees/BMED_AS.pdf

This program prepares you for entry-level positions or promotional opportunities in biomedical device and biomedical product companies and for transfer toward a bachelor's degree at specific colleges. Successful graduates will work in manufacturing, product development and testing.

Biomedical Technician
Certificate: http://www.anokaramsey.edu/resources/pdf/Certificates/BiomedicalTechnician.pdf

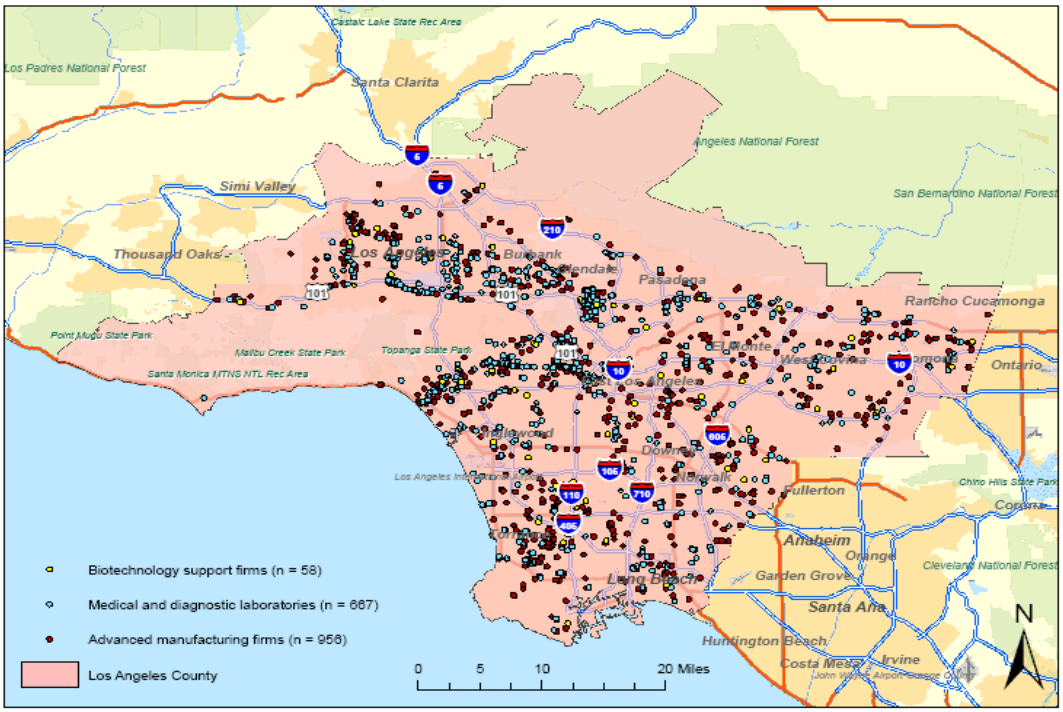
This program prepares you for an entry-level position, or if you have previous education or work experience for career transition or advancement in biomedical device and biomedical product companies. This program also transfers to the Biomedical Technologist Associate in Science degree program. Successful graduates may work in manufacturing, product development, testing or other areas depending upon previous education and experience.

Clinical Research Professional
Certificate: http://www.anokaramsey.edu/resources/pdf/Certificates/ClinicalResearchProfessional.pdf

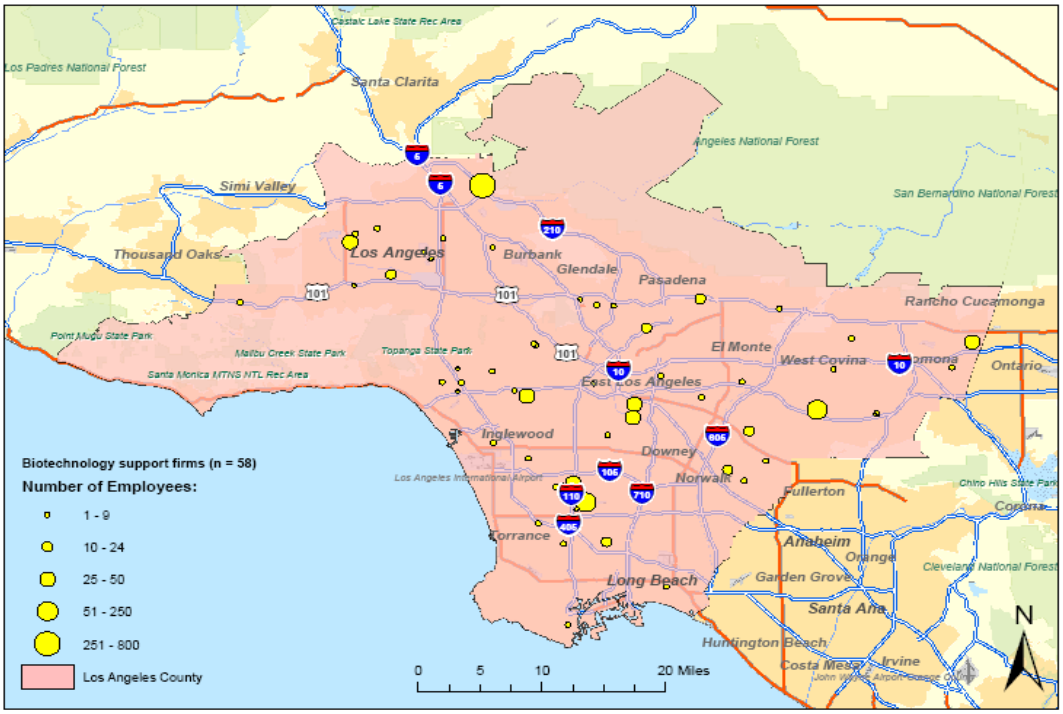
Do you already have a degree in nursing, pharmacology, or biological sciences? This program prepares you to move into positions such as clinical research monitoring, clinical research coordination, clinical data management, and regulatory affairs.

Appendix G: Employer Locations

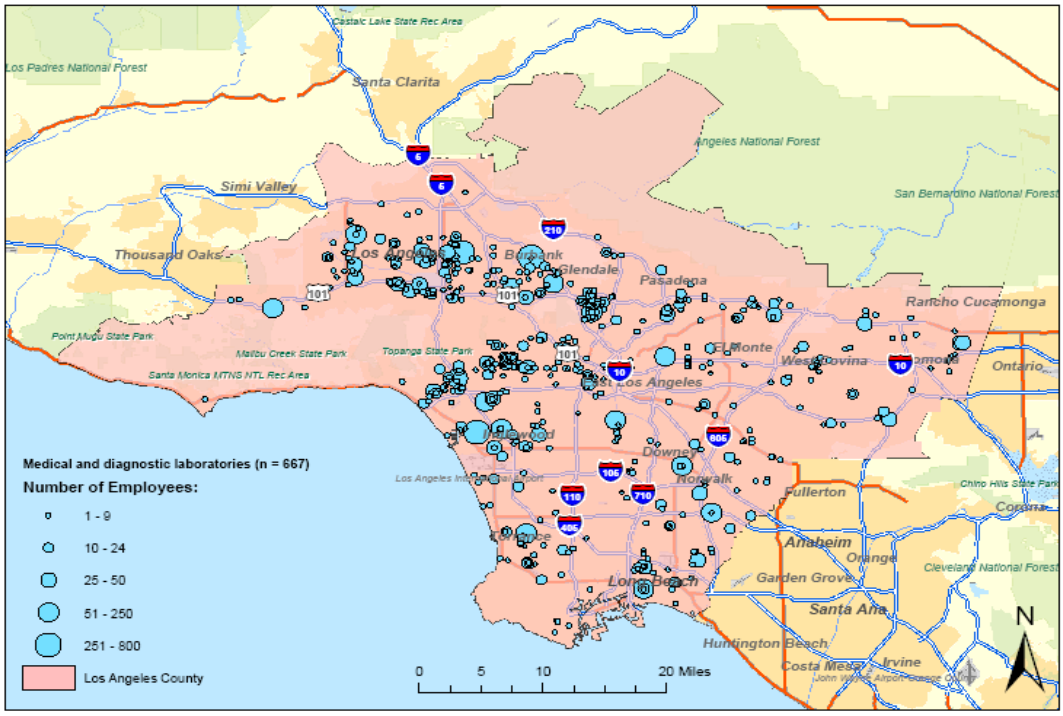
Medical Device Industry Firms in Los Angeles, 2007



Biotechnology Support Firms in Los Angeles, 2007



Medical and Diagnostic Laboratories in Los Angeles, 2007



Medical Device Advanced Manufacturing Firms in Los Angeles, 2007