Medical Device Manufacturing Cluster in Southwest Ohio

2016

Sinclair Community College

“This study was prepared under contract with the Wright State University, Ohio, with financial support from the Office of Economic Adjustment, Department of Defense. The content reflects the views of the Wright State University and does not necessarily reflect the views of the Office of Economic Adjustment.”

Table of Contents

Executive Summary

In an effort to support economic diversity and assess the workforce needs in the Southwest Ohio region, a study was conducted to identify opportunities to grow the medical device manufacturing cluster. The medical device industry is a highly concentrated industry with 60% of all revenue accounted for by the top 50 companies. Of the $350 billion global annual revenue, the U.S. accounts for 27% or $95 billion. The U.S. market is comprised of 7,000-11,000 companies with more than 60% of the revenue concentrated within the top five companies. Despite this concentration, small companies are able to compete by specializing in particular markets, performing subcontracting services, or becoming an integrator for the larger manufacturers.

This cluster has been consistently growing over the past ten years and is projected to grow by an additional 23 percent by 2023. As the cluster is comprised of similar skillsets required in most advanced manufacturing, the foundation to address future challenges is in place. The specific workforce gaps that require attention in the near term are SOC *17-2112 Industrial Engineers* (Bachelor's Degrees typically required), *17-3026 Industrial Engineering Technicians* (Associate's Degrees typically required), *51-2092 Team Assemblers, 51-4041 Machinists,* and *51-4011 Computer-Controlled Machine Tool Operators, Metal and Plastic.* Additionally, *51-9081 Dental Laboratory Technicians, 51-9082 Medical Appliance Technicians, 51-9083 Ophthalmic Laboratory Technicians,* and *29-2091 Orthotists and Prosthetists* require further assessment to determine what, if any, academic programs exist and if they have the capacity to meet increasing demand.

The region has significant federal contracts in the form of services and support contracts. Federal contracted manufacturing awarded to prime contractors in FY13-15 was $3.6 billion, this was 43.64 percent of all federal contracts for the period of performance. During that same time period, $1.3 billion in subwards for all federal contracts were awarded with only 12.08 percent of those comprising manufacturing subawards. Both prime manufacturing and subcontract manufacturing for federal agencies are highly concentrated in a small number of Southwest Ohio businesses.

Apart from the federal contractors, there are support industries which may be well positioned to support the cluster through integration, subcontracting, or even product development. These companies will need to be aware of the business challenges unique to this sector, the capital investment that may be required, an assessment of their workforce requirements compared to regional production, and the regulatory environment.

There are specific skillsets that have been identified apart from an academic program that would benefit from industry and academic partnerships. Many of these are reflective of the advancing technology and the increasing integration of sensors in medical devices. There are possible opportunities to develop training programs to develop local talent with skill gaps despite their academic attainment.

Medical Device Manufacturing

In an effort to support economic diversity and assess the workforce needs in the Southwest Ohio region, a study was conducted to assess opportunities to grow the medical device manufacturing cluster. Existing manufacturers in the region, including manufacturers receiving federal contracts, have been impacted by major economic events like the automotive downturn and sequestration. To stay competitive these businesses have several options: downsize, find new markets for their products, or enter new markets by manufacturing new products. Medical Device Manufacturing is a fast growing industry and an opportunity for manufacturers in the Southwest Ohio considering expanding into new markets.

The medical device industry is a highly concentrated industry with 60% of all revenue accounted for by the top 50 companies. Of the $350 billion global annual revenue, the U.S. accounts for 27% or $95 billion. This is the largest single concentration of revenue among global competitors (Hoovers, 2016). The U.S. market is comprised of 7,000-11,000 companies with more than 60% of the revenue concentrated within the top five companies: Johnson & Johnson, General Electric, Medtronic, Baxter International, and Cardinal Health (Market Realist, 2015). Other major manufacturers include: Boston Scientific (U.S.), Essilor (ophthalmic supplies, France), Smith & Nephew (joint and bone products, UK), Terumo (disposable medical supplies, Japan), Covidien (disposable medical and surgical products, Ireland), and B. Braun (medical and surgical products, Germany). Despite this concentration, small companies are able to compete by specializing in particular markets, performing subcontracting services, or becoming an integrator for the larger manufacturers.

Surgical and medical instruments (syringes, surgical clamps, and stethoscopes) and surgical appliances and supplies (surgical dressings, orthopedic devices, and hospital furniture) account for 80% of the market revenue. The industry is expected to grow both domestically and internationally due to aging populations, innovations in technology and advances in healthcare policies in developing countries. Of particular interest is in sensors technology. As this technology area grows, demand for smart medical devices will continue to expand. These sensors are designed to predict impending device failure, introduce automation into medical procedures, and infection detection. This breakthrough market allows for opportunities for manufacturers that may not have current processes or expertise compatible for traditional medical device manufacturing.

There are risks for small companies wishing to enter this industry. Due to the fast growing innovation in the industry, patents are important, must be defended, and larger companies are prone to buying smaller companies with promising technology.

Of the $350 billion global annual revenue in the medical device industry, the U.S. accounts for 27% or $95 billion. This is the largest single concentration of revenue among global competitors.

U.S. imports and exports rates are relatively equal at 35% for both incoming and outgoing products. The largest sources of imports are Mexico, China and Ireland while the largest destinations for exports are Netherlands, Canada and Japan (Hoovers, 2016). The import market is largely disposable devices and could be an opportunity for Southwest Ohio Manufacturers to enter the industry if they can produce these devices at competitive prices.

Most Medical Device Manufacturing is labor-intensive as the majority of the devices require detailed machining, assembly, or sterility which is difficult to achieve within a mass production line. For this reason, large companies rely heavily on integrators, purchasing of sub-assemblies, and refined chemical or petrochemical products. In order for smaller companies to compete with larger companies they often select particular specialties/products. This leads to an increased need for subcontracting services which also provides an opportunity to outsource to regions like Southwest Ohio which have strong manufacturing capabilities. There are two primary pathways for integration and subcontracting: Manufacturers of low-tech product (latex gloves, tape, syringes, and gauze) and specialize in diagnostic and therapeutic devices requiring technological innovation and precision. Major materials in the supply chain include stainless steel, silicone or latex rubber, plastic, aluminum, polymers, glass, paper, and natural fabrics.

The medical device manufacturing industry is a specialized sector of the advanced manufacturing industry. Workforce trends are expected to be similar to the larger industry requirements with some targeted focus areas. However, manufacturing processes are diverse, from precision laser manufacturing to additive manufacturing. Due to the relatively small number of companies established in this sector and the diversity of processes and applications, drawing general conclusions about sector requirements may vary from one company to another when taking a regional view.

Workforce trends are expected to be similar to the larger industry requirements with some targeted focus areas.

The industry at large is growing, expanding and offers a compelling opportunity for existing manufacturers not already operating within the industry to enter the vertical segment through subcontracting, integration, or new product development.

Industry Overview

The medical device manufacturing cluster has been defined by the Greater Minneapolis Saint Paul region in Minnesota is a leader in the Medical Device cluster, recognized by the Investing in Manufacturing Communities (IMCP) for this strength. Their cluster is a good benchmark to identify business and workforce development opportunities. Using the defined cluster, the Southwest region jobs within the cluster are projected to increase 23 percent by 2023.

Eight NAICS (North American Industry Classification System) comprise this cluster (**table 1**). Devices manufactured in these NAICS are as large and complex as MRI equipment or as small and common as syringes. Table one provides an overview of the NAICS and some examples of devices manufactured in each category.

Table 1. Medical Device Cluster Description and Examples

NAICS	NAICS Description	Devices Manufactured
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	Magnetic resonance imaging (MRI) equipment, medical ultrasound equipment, pacemakers, hearing aids, electrocardiographs, and electromedical endoscopic equipment.
334516	Analytical Laboratory Instrument Manufacturing	Instruments and instrumentation systems for laboratory analysis of the chemical or physical composition or concentration of samples of solid, fluid, gaseous, or composite material.
334517	Irradiation apparatus manufacturing	Irradiation apparatus and tubes for applications, such as medical diagnostic, medical therapeutic, industrial, research and scientific evaluation. Irradiation can take the form of beta-rays, gamma-rays, X-rays, or other ionizing radiation.
339112	Surgical and Medical Instrument Manufacturing	Syringes, hypodermic needles, anesthesia apparatus, blood transfusion equipment, catheters, surgical clamps, and medical thermometers.
339113	Surgical Appliance and Supplies Manufacturing	Orthopedic devices, prosthetic appliances, surgical dressings, crutches, surgical sutures, personal industrial safety devices (except protective eyewear), hospital beds, and operating room tables.
339114	Dental Equipment and Supplies Manufacturing	Dental equipment and supplies used by dental laboratories and offices of dentists, such as dental chairs, dental instrument delivery systems, dental hand instruments, and dental impression material and dental cements.
339115	Ophthalmic Goods Manufacturing	Prescription eyeglasses (except manufactured in a retail setting), contact lenses, sunglasses, eyeglass frames, and reading glasses made to standard powers, and protective eyewear.
339116	Dental Laboratories	Dentures, crowns, bridges, and orthodontic appliances customized for individual application.

Overall, the subclusters that comprise the Medical Device cluster have several strengths (**table 2**). Three subclusters, *334510 Electromedical and Electrotherapeutic Apparatus, 334516 Analytical Laboratory Instrument Manufacturing,* and *33912 Surgical and Medical Instrument Manufacturing* are projected to have significant job growth by 2023. Although *339113 Surgical Appliance and Supplies Manufacturing* is projected to have a job loss of seven by 2023 it is the largest subcluster for jobs and should also be benchmarked and monitored for workforce needs. The 2015 number of establishments is also benchmarked in the '# of Est" column. This data can be used to monitor growth within the region, identify industry partners for future data validation and focus strategies for businesses considering entry into the Medical Device cluster. There is little regional competition in *334510 Electromedical and Electrotherapeutic Apparatus, 334517 Irradiation apparatus Manufacturing, 339114 Dental Equipment and Supplies Manufacturing,* and *339115 Ophthalmic Goods Manufacturing*.

JOBS

Compared to the national leaders in medical device manufacturing, the region has a relatively small number of jobs within the cluster; however, the projected job growth is 23 percent by 2023.

2023 Job Growth +18%

LOCATION QUOTIENT

The location quotient (LQ) measures the concentration of jobs within a geographical region compared to the national average. As a general rule, an LQ greater than 1.25 is considered a strong concentration and can drive economic development. The Southwest Ohio region's medical device cluster is currently not driving economic growth. Concentrated efforts to grow this cluster will require a strong strategic plan to ensure the workforce and support industries can support measured growth.

Table 2. Medical Device Cluster in the Southwest Ohio Region

NAICS	NAICS Description	2015 Jobs	2023 Jobs	Change	% Change	# of Est	LQ
334510	Electromedical and Electrotherapeutic Apparatus	69	92	23	33.3%	2	0.17
334516	Analytical Laboratory Instrument Manufacturing	210	310	100	47.6%	11	0.96
334517	Irradiation apparatus Manufacturing	<10	<10	--	--	1	0.05
339112	Surgical and Medical Instrument Manufacturing	452	654	202	44.7%	8	0.57
339113	Surgical Appliance and Supplies Manufacturing	720	713	(7)	(1.0%)	22	0.78
339114	Dental Equipment and Supplies Manufacturing	13	22	9	69.2%	1	0.15
339115	Ophthalmic Goods Manufacturing	116	115	(1)	0.9%	6	0.51
339116	Dental Laboratories	293	303	10	3.4%	39	0.66
	Total	1,873	2,209	336	17.9%	90	

Source: 2016.2 – QCEW Employees and Self-Employed

THE SOUTHWEST OHIO REGION

The region is defined as an eleven county area in Southwest Ohio. This includes the traditional counties defining the Dayton region's MSA with additional counties that include the Sinclair Community College service area. The eleven counties include: Butler, Clark, Clermont, Clinton, Darke, Greene, Hamilton, Miami, Montgomery, Preble, and Warren.

Staffing Pattern

The Medical Device Manufacturing Cluster is comprised of 49 primary occupations. Fifteen of these occupations require an associate's degree or higher for typical entry level positions (**table 3**). SOC *41-4011 Sales Representatives, Wholesale and Manufacturing, Technical and Scientific Products, 13-1109 Business Operations Specialists, All Other,* and *13-1023 Purchasing Agents, Except Wholesale, Retail, and Farm Products* are classified as requiring an associate's degree and above and the gap for these occupations when comparing annual openings to annual completions appears significant; however, this is likely due to a narrow definition of the regional degrees that qualify the workforce for the entry level jobs. Industry validation is required to determine if the available talent in the region is sufficient. The occupational areas that require the most attention are *17-2112 Industrial Engineers* (Bachelor's Degrees typically required) and *17-3026 Industrial Engineering Technicians* (Associate's Degrees typically required).

Table 3. Medical Device Cluster Staffing Pattern, Associates Degree or Above Required for Entry Level, Southwest Ohio

SOC	Description	Employed Industry Group (2015)	Employed Industry Group (2023)	Change	% Change	% of Total Jobs in Industry Group (2016)	Median Hourly Earnings	Annual Openings	Regional Completions (2014)	Gap
41-4011	Sales Representatives, Wholesale and Manufacturing, Technical and Scientific Products	48	55	7	15%	2.5%	$33.17	210	7	(203)
13-1199	Business Operations Specialists, All Other	10	13	3	30%	0.6%	$32.00	190	15	(175)
17-2112	Industrial Engineers	65	80	15	23%	3.5%	$37.59	211	57	(154)
13-1023	Purchasing Agents, Except Wholesale, Retail, and Farm Products	19	23	4	21%	1.0%	$31.55	156	3	(153)
17-3026	Industrial Engineering Technicians	17	19	2	12%	0.9%	$27.09	210	182	(28)
17-3029	Engineering Technicians, Except Drafters, All Other	12	14	2	17%	0.6%	$29.91	51	75	24
15-1132	Software Developers, Applications	19	25	6	32%	1.1%	$38.99	364	453	89
17-2031	Biomedical Engineers	24	33	9	38%	1.3%	$33.13	9	144	135
17-2199	Engineers, All Other	13	14	1	8%	0.7%	$41.88	112	412	300
17-2141	Mechanical Engineers	20	25	5	25%	1.1%	$35.37	160	585	425
13-2011	Accountants and Auditors	13	16	3	23%	0.7%	$29.67	453	909	456
11-3031	Financial Managers	11	13	2	18%	0.6%	$50.72	249	851	602
13-1161	Market Research Analysts and Marketing Specialists	17	22	5	29%	0.9%	$26.71	211	901	690
11-1021	General and Operations Managers	26	32	6	23%	1.4%	$44.88	573	2447	1874
11-9199	Managers, All Other	15	16	1	7%	0.8%	$34.93	262	2366	2104

Source: 2016.2 – QCEW Employees and Self-Employed

A gap analysis is not possible for jobs with no education requirements using secondary data sources (**table 4**). These jobs account for 58.9 percent of the occupations in the industry cluster and will require industry feedback to determine over and under production. SOC *51-9081 Dental Laboratory Technicians, 51-9082 Medical Appliance Technicians, 51-9083 Ophthalmic Laboratory Technicians,* and *29-2091 Orthotists and Prosthetists* would all benefit from industry feedback regarding academic attainment for entry level jobs and a survey of programs to determine over or under production. Not surprisingly, *51-2092 Team Assemblers, 51-4041 Machinists,* and *51-4011 Computer-Controlled Machine Tool Operators, Metal and Plastic* top the list for the most projected change. These occupational areas would benefit from additional industry feedback across clusters to determine how workforce development professionals could assist in meeting the annual demand for these positions. Also important to note for these three occupations is that while the change in jobs for the industry appears small, the annual openings are significant indicating a large churn. Industry feedback can assist in determining major factors for the turn-over and possible workforce development strategies

Table 4. Medical Device Cluster Staffing Pattern, No Education Requirement for Entry Level, Southwest Ohio

SOC	Description	Employed Indus-try Group (2015)	Employed Industry Group (2023)	Change	% Change	% of Total Jobs in Industry Group (2016)	Median Hourly Earnings	Annual Openings
51-9081	Dental Laboratory Technicians	197	233	36	18%	10.4%	$18.99	16
51-2092	Team Assemblers	156	179	23	15%	8.3%	$14.41	543
51-4041	Machinists	53	66	13	25%	2.9%	$19.96	472
51-2022	Electrical and Electronic Equipment Assemblers	40	53	13	33%	2.2%	$12.58	93
51-9061	Inspectors, Testers, Sorters, Samplers, and Weighers	53	62	9	17%	2.8%	$17.70	232
51-4011	Computer-Controlled Machine Tool Operators, Metal and Plastic	27	35	8	30%	1.5%	$17.24	275
51-1011	First-Line Supervisors of Production and Operating Workers	43	51	8	19%	2.3%	$25.72	177
51-9082	Medical Appliance Technicians	42	49	7	17%	2.2%	$17.69	5
43-4051	Customer Service Repre-sentatives	33	39	6	18%	1.8%	$14.49	822
51-2099	Assemblers and Fabricators, All Other	41	45	4	10%	2.1%	$12.25	265
43-5061	Production, Planning, and Expediting Clerks	15	19	4	27%	0.8%	$21.27	122
51-4081	Multiple Machine Tool Setters, Operators, and Tenders, Metal and Plastic	30	34	4	13%	1.6%	$17.29	124
51-9083	Ophthalmic Laboratory Technicians	40	44	4	10%	2.1%	$13.17	10
51-2023	Electromechanical Equip-ment Assemblers	22	26	4	18%	1.2%	$17.00	28
43-5071	Shipping, Receiving, and Traffic Clerks	32	36	4	13%	1.7%	$14.69	308
49-9071	Maintenance and Repair Workers, General	19	22	3	16%	1.0%	$18.47	451
41-4012	Sales Representatives, Whole-sale and Manufacturing, Except Technical and Scientific Products	15	18	3	20%	0.8%	$27.02	392

43-9061	Office Clerks, General	27	30	3	11%	1.4%	$13.95	643
29-2091	Orthotists and Prosthetists	17	20	3	18%	0.9%	$26.35	3
43-5081	Stock Clerks and Order Fillers	19	22	3	16%	1.0%	$11.35	796
51-6031	Sewing Machine Operators	20	23	3	15%	1.1%	$12.43	48
51-9111	Packaging and Filling Machine Operators and Tenders	13	15	2	15%	0.7%	$14.66	273
51-9199	Production Workers, All Other	16	18	2	13%	0.9%	$15.80	104
43-1011	First-Line Supervisors of Office and Administrative Support Workers	11	13	2	18%	0.6%	$23.39	243
43-6014	Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	15	17	2	13%	0.8%	$15.70	274
53-7062	Laborers and Freight, Stock, and Material Movers, Hand	16	18	2	13%	0.8%	$11.62	1177
53-7064	Packers and Packagers, Hand	17	19	2	12%	0.9%	$9.74	378
51-9198	Helpers-Production Workers	19	21	2	11%	1.0%	$12.00	197
51-2041	Structural Metal Fabricators and Fitters	11	12	1	9%	0.6%	$16.58	45
53-3033	Light Truck or Delivery Services Drivers	15	16	1	7%	0.8%	$13.78	266
43-3031	Bookkeeping, Accounting, and Auditing Clerks	17	18	1	6%	0.9%	$17.10	185
51-4072	Molding, Coremaking, and Casting Machine Setters, Operators, and Tenders, Metal and Plastic	21	21	0	0%	1.1%	$14.28	95

Source: 2016.2 – QCEW Employees and Self-Employed

Regional Workforce Demand

Initial feedback from existing Medical Device Manufacturers were surveyed to identify primary workforce, training, and certification requirements. While the survey was not able to determine statistical significance, this information is intended to assist economic and business development professionals in identifying pathways for manufacturing companies established in the region to enter the medical device manufacturing cluster.

The skillsets identified for entry level positions in advanced manufacturing were:

- CS, ECE, ME, Systems
- Ethics, standards
- Professional Responsibility
- Imagination to apply robotics in new ways
- Solve real-world problems
- Math, Science, Engineering skills
- Design/conduct experiments
- Analyze/Interpret Data
- Communication skills
- Digital Signal Processing
- Path Planning
- Embedded Systems
- Languages: C/C++, Java, Matlab, Verilog
- Software: Solidworks, CAD, Microsoft Office

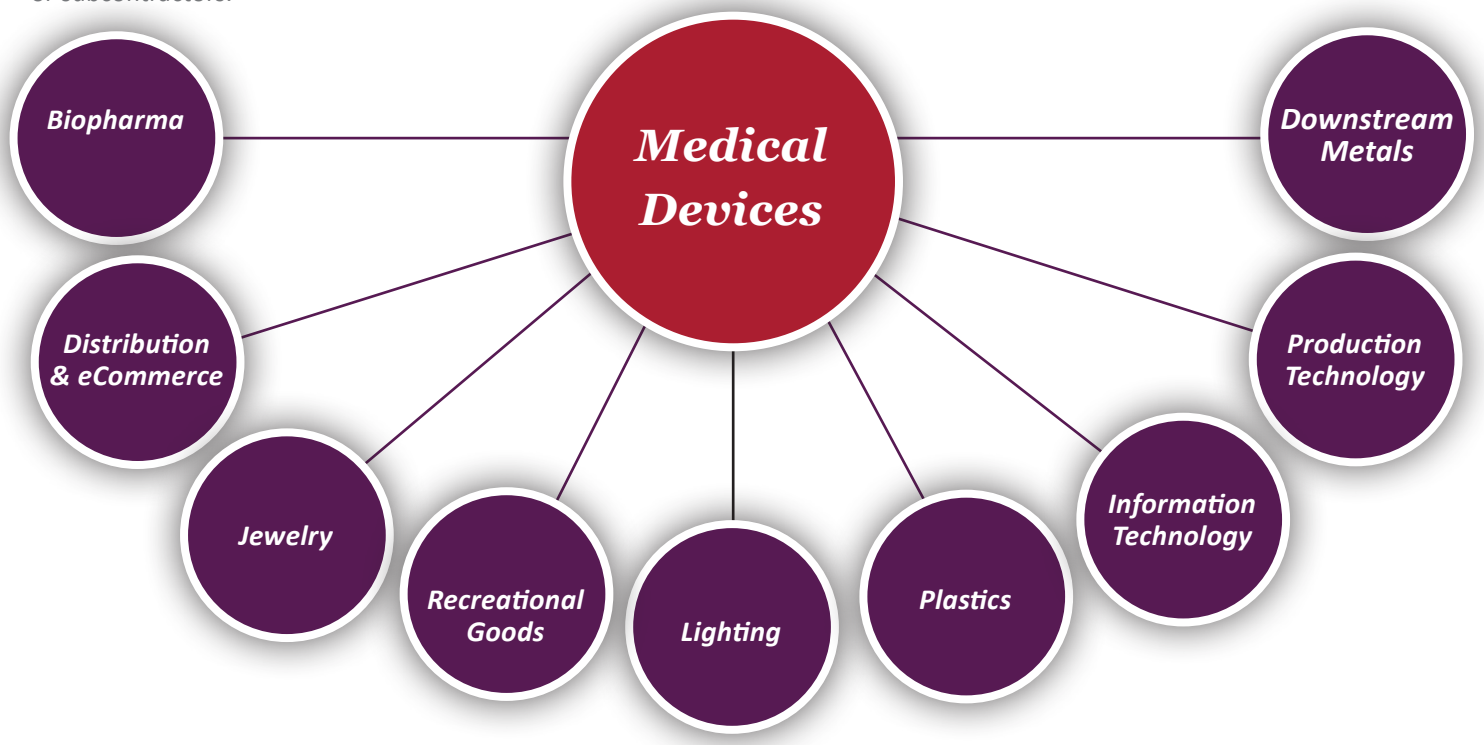
Additional skillset required for the workforce were:

- Systems architect, design, integration
- Embedded Design
- Logic device programming
- Ethernet protocols
- Artificial intelligence
- Develop, test, and evaluate software
- Computer Vision
- Web Interface
- Driver Development
- Autonomous Behaviors
- Documentation of designs, interfaces, and procedures
- Safety
- Oral and written communication skills
- Foreign language
- Leadership skills
- Organizational skills
- Languages: C/C++, Assembly, Python, MATLAB, Java, PLC
- Software: Solidworks, Windows, Microsoft Office

Support Clusters

Medical device companies rely heavily on integrators and subcontractors for various support functions. As devices increase in technology innovation, data analysis and communication across platforms require Medical Device Integration (MDI) expertise which is not typically employed by advanced manufacturers. Additionally, functions like assembly, packaging, and other parts manufacturing not tied to regulatory controls may be subcontracted. These support functions are opportunities for the robust manufacturing services in the Southwest Ohio region.

Harvard Business School's Institute for Strategy and Competitiveness partnered with the U.S. Department of Commerce and the U.S. Economic Development Administration to analyze more than 50 million open source data records to map networks and connections within more than 50 industry clusters. This U.S. cluster mapping project defines the Medical Device Cluster by two major subcategories *Surgical and Dental Instruments* and *Supplies.* There are nine support clusters which link back to Medical Devices. These support clusters have some natural network connections with medical devices. An analysis of these support clusters can identify regional strengths and opportunities to grow connections to the Medical Device Manufacturing Cluster as integrators or subcontractors.



Region support cluster strengths

Over a ten year period there were fluctuations in the rankings of the region within these linkages; however, some trends did arise that could assist the region in identifying areas of strength and opportunities to facilitate growth in the medical device industry.

Production Technology

This support cluster includes: Agricultural and Construction Machinery and Components, Process Equipment and Components, Industrial Machinery, Air Handling Equipment, Moving and Material Handling Equipment, and Commercial and Service Industry.

2014 Jobs: 16,454	*2005-2014 change: ↓ 155*	*10yr Avg Rank: 18 of 179*

Plastics

This support cluster includes: Plastic Products and Plastic Materials and Resins. Lighting includes: Electrical Equipment, Electrical Components, Lighting Fixtures and Parts, and Storage Batteries. Machinery. Out of 179 economic regions, the region consistently fell within the top quartile for jobs over a ten year period.

2014 Jobs: 7,775	*2005-2014 change: ↓ 2,346*	*10yr Avg Rank: 27 of 179*

Information Technology

This support cluster includes: Software Publishers, Process and Laboratory Instruments, Electronic Components, Semiconductors, Medical Apparatus, Computers and Peripherals, Software Reproducing, and Audio and Video Equipment. Out of 179 economic regions, the region averaged in the top quartile for jobs over a ten year period, but experienced some large fluctuations.

2014 Jobs: 3,745	*2005-2014 change: ↓ 450*	*10yr Avg Rank: 44 of 179*

Downstream Metals

This support cluster includes: Metal Products, Fabricated Metal Structures, Ammunition, and Metal Containers. Out of 179 economic regions, the region averaged just short of the top quartile for jobs over a ten year period, with three years performing in the top 25 percent.

2014 Jobs: 3,139	*2005-2014 change: ↓ 1,153*	*10yr Avg Rank: 46 of 179*

Medical Devices

The job losses in each of the highlighted support clusters could indicate an opportunity and capacity to increase integration and subcontracting support to medical device manufacturers. Over the same time period, medical device manufacturers increased in jobs by more than 71 percent and moved up the rankings from 55 to 44 out of 179. The relatively rapid growth in this cluster, coupled with the projected growth rate of 23 percent by 2023 are all positive signs that the region is poised for strategic growth. It's critical the region understand the future workforce requirements to ensure the talent is ready to support continued growth. Additionally, these cluster linkages can be used to identify companies within the region that already have strong ties to the medical device cluster, may already be serving as integrators to the cluster, or are candidates to consider medical device manufacturing in future operational changes.

2014 Jobs: 1,670	*2005-2014 change: ↑695*	*10yr Avg Rank: 50 of 179*

Table 5. U.S. Cluster Data, 2005-2014

Year	Medical Devices		Production Technology		Plastics		Information Technology		Downstream Metals	
	Jobs	Rank	Jobs	Rank	Jobs	Rank	Jobs	Rank	Jobs	Rank
2014	1670	44	16454	17	7775	25	3745	50	3139	45
2013	1093	49	16538	16	7532	27	3883	48	2770	49
2012	1234	48	14991	18	7924	25	4426	44	2812	47
2011	1114	52	14521	16	6240	31	7525	31	3063	41
2010	1138	52	1256	22	6480	29	4476	41	2857	48
2009	1195	54	13800	21	7386	27	6702	34	2749	56
2008	1349	47	17006	17	8962	27	4008	50	3274	51
2007	1600	41	16292	16	9552	25	4048	50	3547	49
2006	1081	52	16235	17	9866	26	4305	46	4132	40
2005	975	55	16609	16	10121	27	4195	47	4292	37
10-yr change	695	11	-155	-1	-2346	2	-450	-3	-1153	-8

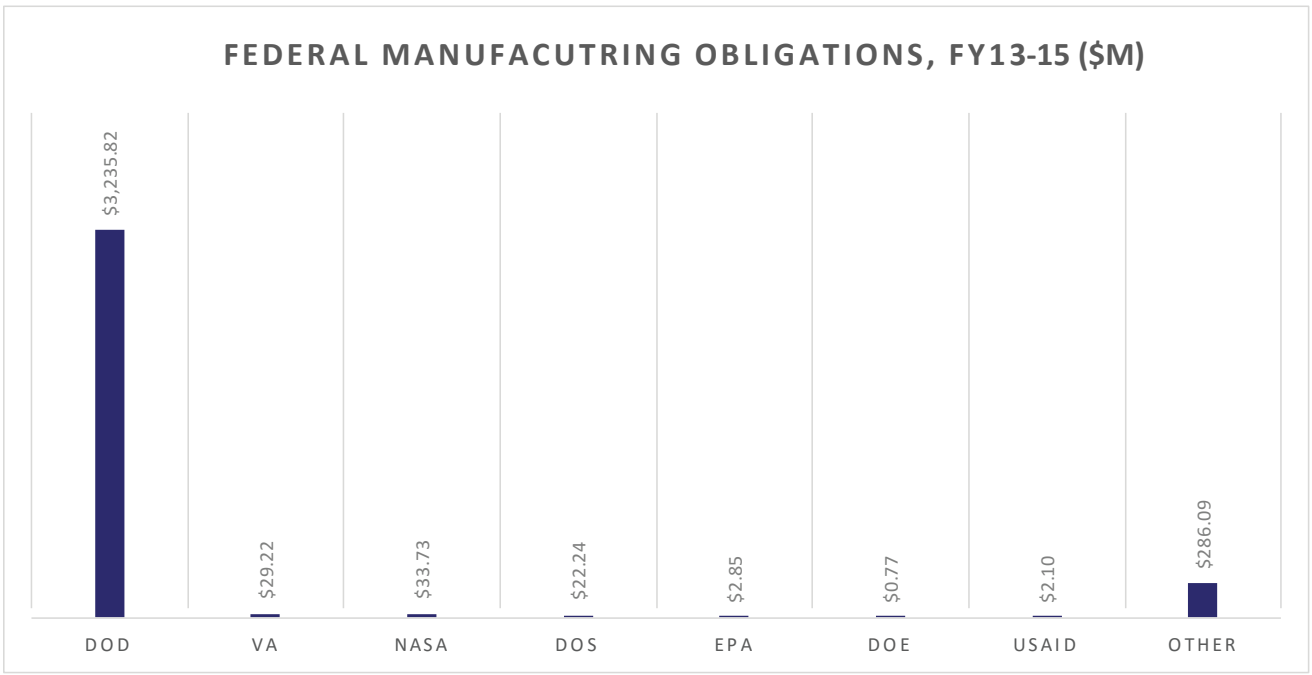
Source: U.S. Clustermapping Project

Assessment of Defense Manufacturers

The initial driver of this report was to identify opportunities for defense manufacturers to reduce their reliance on federal funding and reshape their production to support or enter the medical device manufacturing sector. Although the region has a history of government contracting concentration, the number and amount of manufacturers relying upon federal contracts for prime manufacturing appears to be a less critical concern than assumed when this study began.

Despite federal government cut backs and sequestration, defense spending continues to be a critical source of funding to economic stability within the 11 county, Southwest Region of Ohio. The dependency on this funding stream creates risk to economic outlook and limits the growth within the industry sectors that depend on government contracts.

In Fiscal Years 2013-2015, a total of 40,908 federal contracts were active for manufacturing services in the Southwest Region. The total obligation of federal dollars over that time period was $3.6 billion in manufacturing out of more than $8.3 billion in total contract dollars. Over the same time period, more than $1.3 billion in subcontract work were awarded to regional companies, but only $170.2 million of those subawards were for manufacturing services. Of the Prime Manufacturing contracts, 89.57 percent were obligated from the Department of Defense and 96.30 percent of subawards were obligated from DoD contracts.



Source: USASpending.gov

More than 75 percent of all federal manufacturing contracts were awarded to Hamilton County businesses.

More than 66 percent of subawards were won by Butler and Hamilton County businesses (table 7).

Nearly 60 percent of Federal Manufacturing Contracts awarded to Ohio companies were won by Southwest Ohio businesses (table 8).

Only 12 percent of subawards in Ohio were won by Southwest Ohio businesses (table 8).

REGION ANALYSIS

More than three-fourths of the federal manufacturing contracts were awarded to Hamilton County businesses fiscal years 2013 to 2015. **Table six** breaks down each county. Bulter and Hamilton county accounted for 29.51 and 37.01 percent respectively of subawards (**table 7**).

Table 6. Manufacturing Contracts by County, FY13-15

County	All Agencies	DoD
Butler	$44,975,265	$14,397,298
Clark	$24,626,973	$18,955,723
Clermont	$9,925,275	$5,208,020
Clinton	$612,927	$99,269
Darke	$17,170,988	$3,884,887
Greene	$82,347,861	$67,013,186
Hamilton	$2,753,170,799	$2,532,259,038
Miami	$48,831,433	$48,233,812
Montgomery	$543,424,237	$497,462,659
Preble	-$5,022	-$12,694
Warren	$87,734,269	$48,321,013

Table 7. Manufacturing Subawards by County, FY13-15

County	All Agencies	DoD
Butler	$50,221,809	$50,221,809
Clark	$2,056,843	$2,056,843
Clermont	$27,877	$27,877
Clinton	$0	$0
Darke	$0	$0
Greene	$15,670,879	$15,670,879
Hamilton	$62,994,582	$60,891,330
Miami	$5,370,573	$5,370,573
Montgomery	$29,206,116	$25,665,402
Preble	$0	$0
Warren	$4,665,588	$4,015,960

Source: USASpending.gov

CONTRACT & SUBAWARD ANALYSIS

Of the total contracts awarded to Ohio companies, 52.73 percent were awarded to Southwest Ohio companies for a total of $8.3 billion. Of those contracts, 43.64 percent were for manufacturing services. When analyzing subawards, 42.04 percent of all Ohio subawards for contract services were won by Southwest Ohio businesses, but only 12.80 percent of the manufacturing subawards in Ohio were won by regional companies.

Table 8. Comparison of Prime Contracts and Subawards by Type, FY13-15

County	Total Prime Contracts	Manufacturing Prime Contracts	Total Subawards	Total Manufacturing Subawards
Butler	$178,376,532	$44,975,265	$67,598,388	$50,221,809
Clark	$46,467,432	$24,626,973	$6,763,740	$2,056,843
Clermont	$41,370,497	$9,925,275	$14,962,322	$27,877
Clinton	$929,841	$612,927	$1,885,260	$0
Darke	$25,871,469	$17,170,988	$38,731,144	$0
Greene	$518,910,284	$82,347,861	$141,783,336	$15,670,879
Hamilton	$4,368,881,671	$2,753,170,799	$344,666,851	$62,994,582
Miami	$190,159,459	$48,831,433	$25,414,676	$5,370,573
Montgomery	$2,789,871,857	$543,424,237	$726,132,044	$29,206,116
Preble	$135,537	-$5,022	$0	$0
Warren	$117,799,087	$87,734,269	$14,769,572	$4,665,588
Total	$8,278,773,666	$3,612,815,005	$1,382,707,332	$170,214,266
% of All Ohio	52.73%	58.92%	42.04%	12.80%

Source: USASpending.gov

TOP PRIME MANUFACTURING COMPANIES IN SOUTHWEST OHIO

The top 25 regional companies receiving federal contracts for manufacturing services account for 89.05 percent of all manufacturing contracts in Southwest Ohio (**table 9**). This suggests the federal manufacturing industry is highly concentrated. More than 630 smaller companies account for the remaining ten percent. When considering the amount of federal obligations to the top 25 companies' compared to their three-year reported revenue, only six had more than 15% of their revenue source coming from prime, federal manufacturing contracts. This suggests the top companies have a variety of vertical markets. Manufacturers that would benefit the most from diversifying into new markets may be included in the 630 smaller businesses.

Table 9. Top 25 Prime Manufacturing Vendors by Amount Obligated in the Southwest Ohio Region, FY13-15

Vendor Name	County	Amount Obligated	Percent of Federal Contracts to Revenue
GENERAL ELECTRIC COMPANY	Hamilton	$1,648,309,782	0.31%
CFM INTERNATIONAL, INC.	Hamilton	$324,482,246	1.17%
WORNICK COMPANY, THE	Hamilton	$283,681,490	42.50%
GOVERNMENT ACQUISITIONS, INC.	Hamilton	$106,127,361	19.21%
L-3 FUZING & ORDANCE SYSTEMS INC	Hamilton	$104,535,088	0.29%
INTEGRATED PROCUREMENT TECHNOLOGIES	Montgomery	$96,533,325	78.48%
GE AVIATION SYSTEMS LLC	Montgomery	$87,934,977	0.02%
TRIMBLE NAVIGATION LIMITED	Montgomery	$87,305,347	0.58%
L-3 FUZING AND ORDNANCE SYSTEMS, INC.	Hamilton	$85,066,147	0.24%
GE ENGINE SERVICES, INC	Hamilton	$62,716,566	0.01%
DRS ICAS, LLC	Greene	$53,030,679	0.08%
GOODRICH CORPORATION	Miami	$47,506,946	0.25%
L-3 COMMUNICATIONS CINCINNATI ELECTRONICS CORPORATION	Warren	$46,150,185	0.10%
GOVERNMENT ACQUISITIONS INC	Hamilton	$34,519,086	16.76%
HDI LANDING GEAR USA, INC.	Clark	$23,735,559	2.34%
ADVANCED PRODUCTS SERVICES INC.	Montgomery	$18,702,209	2.13%
HOWDEN NORTH AMERICA INC.	Butler	$18,126,785	0.30%
MIDMARK CORPORATION	Darke	$16,802,093	1.44%
GAYSTON CORPORATION	Montgomery	$16,423,985	24.88%
JTM PROVISIONS COMPANY, INC	Hamilton	$16,020,331	4.62%
O'GARA-HESS & EISENHARDT ARMORING COMPANY LLC	Butler	$30,768,011	20.35%
YSI INCORPORATED	Greene	$14,596,902	7.60%
MACAULAY-BROWN, INC	Montgomery	$13,173,247	4.62%
CDO TECHNOLOGIES, INC.	Montgomery	$12,731,235	13.17%
SCOTT INDUSTRIAL SYSTEMS, INC.	Montgomery	$11,967,974	9.97%

Source: USASpending.gov

TOP SUBAWARD MANUFACTURERS IN SOUTHWEST OHIO

With 95.24 percent of all manufacturing subawards going to the top 25 companies, its clear subcontacts for manufacturing services is even more concentrated than the prime awards (**table 10**).

Table 10. Top 25 Subaward Manufacturing Vendors by Amount Obligated in the Southwest Ohio Region, FY13-15

Vendor Name	County	Subaward
MAGELLAN AEROSPACE INC.	Butler	$39,768,000
L-3 FUZING AND ORDNANCE SYSTEMS, INC.	Hamilton	$30,142,781
METALEX MANUFACTURING INC.	Hamilton	$23,115,654
EXCELITAS TECHNOLOGIES CORP.	Montgomery	$17,789,893
ATK SPACE SYSTEMS INC.	Greene	$9,284,057
DRS ICAS, LLC	Greene	$5,997,457
GENERAL TOOL COMPANY	Hamilton	$3,651,440
SENSOR TECHNOLOGY SYSTEMS, INC.	Montgomery	$3,515,714
G & W PRODUCTS LLC	Butler	$3,362,235
HARTZELL PROPELLER INC.	Miami	$3,308,538
O'GARA-HESS & EISENHARDT ARMORING COMPANY LLC	Butler	$3,243,872
VEGA AMERICAS, INC.	Hamilton	$2,103,252
ARMOR METAL GROUP, INC	Butler	$1,995,004
GLOBE MOTORS, INC.	Montgomery	$1,932,404
ARMOR METAL GROUP MASON, INC.	Warren	$1,801,372
GE AVIATION SYSTEMS LLC	Montgomery	$1,501,695
SELECTTECH GEOSPATIAL, LLC	Clark	$1,347,064
LORD CORPORATION	Montgomery	$1,253,268
L-3 COMMUNICATIONS CINCINNATI ELECTRONICS CORPORATION	Warren	$1,219,242
SSK INDUSTRIES, INC	Warren	$964,371
MODAL SHOP, INC., THE	Hamilton	$889,356
FIRST STUDENT, INC.	Hamilton	$873,800
CTL-AEROSPACE, INC.	Hamilton	$835,825
THE CAPTOR CORPORATION	Miami	$745,390
G & W PRODUCTS, LLC	Butler	$697,839

Source: USASpending.gov

Business Challenges

In order to best support the growth of the Medical Device Manufacturing Cluster and assist existing manufacturing companies seeking an opportunity to enter this cluster, an understanding of the workforce demand and the business challenges unique to the industry is needed.

Companies that are considering entry into this industry sector will need to consider business challenges that are common to the sector. Patents and IP protection are important to companies developing their own products or processes but can be costly. Up to 10 percent of revenue may be invested in protecting IP. Similar to IP protection, liability is always a concern for medical device companies. Manufacturers can be found liable for injuries resulting from their products and can face costly efforts if sued or if their product is recalled. Liability insurance must be considered for any company considering this industry.

Federal compliance can lead to increased cost for records management and manpower. The FDA has established a unique device identifier (UDI) labeling system. This impact on device and package labeling may not impact new devices, but products already on the market require updating. Additionally the Physician Financial Transparency Report (Sunshine Act) requires manufacturers to submit annual reports on payments and transfers to physicians and teaching hospitals.

Arguably the biggest challenge companies entering the Medical Device Manufacturing Cluster must overcome is competing with large, established businesses. Hospitals are often part of larger buying groups. It's common practice for large companies to negotiate exclusive contracts with these groups which do not allow the hospitals to buy from other sources.

Due to rapid advances in technology medical device manufacturing must constantly look for opportunities to advance their technology to keep up with new technology and ensure their product will not be replaced by a new, more advanced products. This is particularly true of data collection and analysis. Sensors technology has created opportunities for more informed treatment plans but add a layer of complexity to devices in addition to their primary purpose. It's recommended that small manufacturers focus on a limited number of product lines to ensure they have the customer base, the ability to upgrade their product, and can offer a unique solution that cannot be undercut by larger competitors.

Small manufacturers should focus on a limited number of product lines to ensure they have the customer base, the ability to upgrade their product, and can offer a a unique solution.

National Workforce Demand

Primary data is required to validate the workforce demand. Several mechanisms can be used to gather primary data. For this report, a survey was conducted of local Medical Device Manufacturers in conjunction with an analysis of a job search site popular with medical device manufacturers. Surveying job postings is another mechanism that can be applied to gather primary data. When analyzing the workforce requirements of the medical device industry a search of the ***Indeed*** job posting site was conducted. The following postings were captured as new postings between 7/20/2016 and 8/4/2016.

Associate's Degree or Higher

Within the search period there were almost 4,000 jobs posted that typically Requiring an Associate's Degree or Higher (**table 11**). The majority of these positions were considered mid-level positions, which is not unexpected for jobs that typically require an education credential. Engineers, Market Research Analyst, and Managers were the top in-demand fields for the search period. The MSA with the highest concentrations were Irvine, CA; Boston, MA; Chicago, IL; San Diego, CA; and Phoenix, AZ. These MSA should be the regions in which a more thorough staffing pattern analysis is completed to determine what strengths or gaps may exist in the region as they develop strategies to expand their competitiveness in this industry cluster.

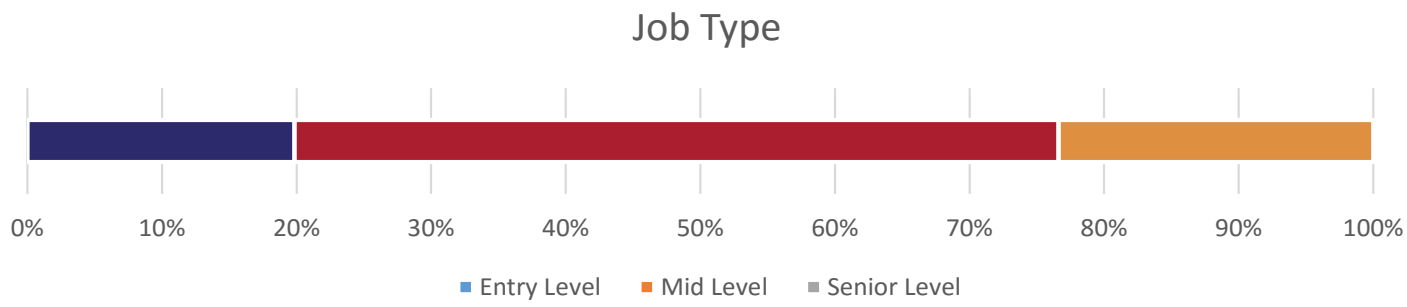


Table 11. Jobs Posting by Medical Device Manufacturers Typically Requiring an Associate's Degree or Higher

Description	# of Postings	Top 5 Locations	Top 5 Companies	Experience Desired
Sales	521	Irvine, CA (34) Boston, MA (26) Phoenix, AZ (13) South Jordan, UT (12) Chicago, IL (12)	B. Braun Medical Inc (32) Merit Medical (28) Cook Medical (20) Cambridge Consultants Ltd (18) ON Semiconductor (15)	Mid Level (256) Entry Level (98) Senior Level (79)
All Engineers	858	Irvine, CA (20) San Diego, CA (19) Boston, MA (18) Sunnyvale, CA (14) Lawrence, MA (11)	Medtronic (42) Adecco: USA (20) NxStage Medical, Inc. (10) Cambridge Consultants Ltd (10) Protingent (10)	Mid Level (417) Senior Level (197) Entry Level (99)
Mechanical Engineers	60	Massachusetts (7) Cincinnati, OH (3) San Diego, CA (3) Agoura Hills, CA (2) California (2)	Legacy MedSearch (7) Illumina, Inc. (4) Protingent (2) Caldera Medical (2) Systel (2)	Senior Level (24) Mid Level (19) Entry Level (8)
Business Operations	27	Valencia, CA (2) Clackamas, OR (2) Thousand Oaks, CA (1) Denver, CO (1) Boulder, CO (1)	Siemens (5) Boston Scientific Corporation (4) W. L. Gore & Associates (2) Precision Castparts Corp. (2) Medtronic (1)	Senior Level (10) Mid Level (8) Entry Level (7)
Technicians	304	Salt Lake City, UT (7) Denver, CO (6) Carlsbad, CA (6) Los Angeles, CA (5) Riverview, FL (5)	Acadian Ambulance (16) Adecco: USA (13) STERIS (12) Medtronic (9) Sonsray Machinery (7)	Entry Level (138) Mid Level (123) Senior Level (8)
Accountants and Auditors	98	Southborough, MA (4) Irvine, CA (3) Atlanta, GA (3) Boston, MA (3) Plymouth, MN (2)	Medtronic (6) Allergan (5) Siemens (5) Regulatory & Quality Solutions LLC (3) ABBOTT LABORATORIES (3)	Mid Level (40) Senior Level (31) Entry Level (8)
Market Research Analysts and Marketing Specialists	892	Irvine, CA (40) Boston, MA (30) Chicago, IL (15) Phoenix, AZ (15) San Diego, CA (12)	B. Braun Medical Inc (32) Merit Medical (28) Medtronic (27) Boston Scientific Corporation (26) Cambridge Consultants Ltd (19)	Mid Level (416) Senior Level (197) Entry Level (133)
All Managers	722	Irvine, CA (21) Glens Falls, NY (14) Boston, MA (13) Queensbury, NY (12) Chicago, IL (11)	AngioDynamics Inc. (26) Medtronic (17) Acadian Ambulance (16) ABBOTT LABORATORIES (14) Securitas Security Services USA (13)	Mid Level (363) Senior Level (129) Entry Level (122)
Architectural and Engineering Managers	385	Irvine, CA (15) Boston, MA (12) Chicago, IL (7) Salt Lake City, UT (7) San Jose, CA (5)	Medtronic (10) Spectranetics (9) ABBOTT LABORATORIES (8) Cambridge Consultants Ltd (8) Siemens (8)	Entry Level (17) Mid Level (7) Senior Level (1)

No Degree Required

For the same time period, nearly 1,600 jobs that typically carry no education attainment requirement were listed (**table 12**). These jobs were evenly mixed as entry- and mid-level jobs. Maintenance and Repair was the most sought after position, followed by customer service representatives and Inspectors, Testers, Sorters, Samplers, and Weighers. The largest employer in this category was a staffing agency; however, Medtronic and B. Braun were also in the top 5. The regions with the greatest concentration in this occupation grouping were Irvine, CA; Queensbury, NY; Glens Falls, NY; Brooklyn Center, MN; and Santa Ana, CA. This suggests that integration and subcontracting may be more prevalent in these MSAs compared to the development and operations management in the previous occupation groups. Irvine, CA is the only region to appear as the top hiring area for both groupings. An analysis of the staffing patterns in those regions may provide insights into the strengths and gaps of the Dayton region to expand its role in integration and subcontracting. The following postings were captured as new postings between 7/20/2016 and 8/4/2016.

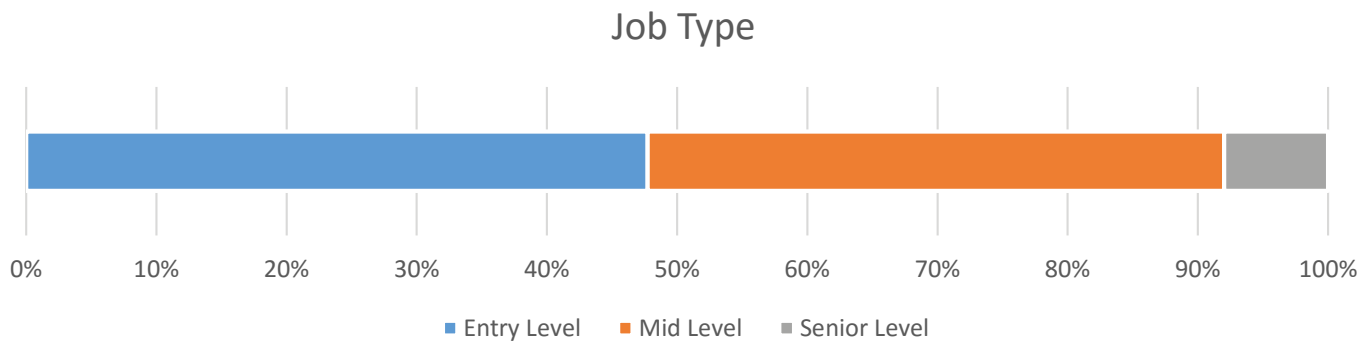


Table 12. Jobs Posting by Medical Device Manufacturers Typically Requiring no Education

Description	# of Postings	Top 5 Locations	Top 5 Companies	Experience Desired
Assemblers	108	Queensbury, NY (13) Glens Falls, NY (10) Brooklyn Center, MN (7) Maple Grove, MN (7) Plymouth, MN (7)	AngioDynamics Inc. (22) THE RIGHT STAFF (19) Indrotec (11) Medtronic (9) Haemonetics Corp. (6)	Entry Level (90) Mid Level (11) Senior Level (3)
Machinists	23	Tempe, AZ (2) Sunnyvale, CA (2) Zachary, LA (1) New Orleans, LA (1) Brooklyn Center, MN (1)	Adecco: USA (2) RHP Enterprises, LLC (2) Safari Solutions (1) Straton Industries (1) Hollister Incorporated (1)	Mid Level (13) Entry Level (8) Senior Level (2)
Electrical and Electronic Equipment Assemblers	20	Shoreview, MN (4) Lompoc, CA (2) Irvine, CA (2) Longmont, CO (2) Fajardo, PR (1)	THE RIGHT STAFF (5) Den-Mat Holdings LLC (2) Contract Engineering Services, Inc. (2) Staco Systems (1) Meso Scale Diagnostics (1)	Entry Level (11) Mid Level (5)
Inspectors, Testers, Sort-ers, Samplers, and Weighers	109	Santa Ana, CA (3) Redmond, WA (3) Eau Claire, WI (3) Somerset, WI (3) Shoreview, MN (2)	THE RIGHT STAFF (12) Adecco: USA (4) Medtronic (4) Phillips Medisize (3) BAYER (2)	Entry Level (50) Mid Level (43) Senior Level (4)
Customer Service Repre-sentatives	260	Irvine, CA (12) Morrisville, NC (5) Santa Ana, CA (5) Chicago, IL (5) Boston, MA (4)	Rollins (8) Sonsray Machinery (7) Lubrizol Corporation (6) Lubrizol Corporation (6) Merit Medical (5)	Mid Level (115) Entry Level (71) Senior Level (20)

Table 12 continued. Jobs Posting by Medical Device Manufacturers Typically Requiring no Education

Description	# of Postings	Top 5 Locations	Top 5 Companies	Experience Desired
Multiple Machine Tool Setters, Operators, and Tenders, Metal and Plastic	120	Irvine, CA (10) Madison, WI (4) Brea, CA (4) Portland, OR (3) San Diego, CA (3)	B. Braun Medical Inc (9) Sonsray Machinery (7) THE RIGHT STAFF (7) Adecco: USA (5) DePuySynthes Products Inc (5)	Entry Level (71) Mid Level (43) Senior Level (2)
Maintenance and Repair Workers, General	725	Irvine, CA (20) Queensbury, NY (15) Glens Falls, NY (13) San Diego, CA (9) Brooklyn Center, MN (8)	AngioDynamics Inc. (26) Medtronic (25) Acadian Ambulance (16) B. Braun Medical Inc (15) Securitas Security Services USA (13)	Mid Level (361) Entry Level (207) Senior Level (79)
Machine Operators	59	Irvine, CA (10) Brea, CA (4) Burlington, NC (2) Leetsdale, PA (2) Draper, UT (2)	B. Braun Medical Inc (8) Adecco: USA (4) Advanced Manufacturing Careers (4) THE RIGHT STAFF (4) Haemonetics Corp. (4)	Entry Level (41) Mid Level (18)
Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	31	San Luis Obispo, CA (4) Salt Lake City, UT (3) Springfield, IL (3) Chicago, IL (2) Ridgefield, NJ (1)	Novasyte (4) Novasyte, LLC (3) New Roots Solutions (3) Cal Poly State University - College of Engineering (2) Karl Storz Endoscopy (1)	Entry Level (21) Mid Level (8) Senior Level (1)
Laborers and Freight, Stock, and Material Mov-ers, Hand	25	Santa Ana, CA (4) Kalamazoo, MI (2) Irvine, CA (2) Huntington Beach, CA (2) Fountain Valley, CA (1)	Triumph Group, Inc. (4) Hammaker East (2) Thermo Fisher Scientific (2) Russell Standard Corporation (1) Lehman-Roberts Company (1)	Entry Level (25)
Packers and Packagers, Hand	21	Somerset, WI (4) Draper, UT (3) Star Prairie, WI (2) Minnesota (2) Osceola, WI (2)	THE RIGHT STAFF (10) Haemonetics Corp. (3) Makro Scientific (1) Companies of J J Young (1) Volt Workforce Solutions (1)	Entry Level (18) Mid Level (2)
Light Truck or Delivery Services Drivers	56	Grapevine, TX (6) Ludlow, MA (2) Winston-Salem, NC (2) Newton, MA (2) Worcester, MA (2)	Mckesson (33) DEAN FOODS COMPANY (5) Ferguson Enterprises, Inc. (3) Hammaker East (2) B. Braun Medical Inc (2)	Entry Level (54) Mid Level (2)

Recommendations

The data analysis has provided greater understanding of the projected workforce and business challenges. The federal database analysis uncovered a highly concentrated cluster of Southwest Ohio businesses winning prime or subcontracts. With this baseline understanding its important establish industry feedback to validate secondary data and trends within the primary data.

FACILITATED ROUNDTABLE DISCUSSION

Establish industry roundtable meetings to include regional companies currently manufacturing Medical Devices. These businesses, along with selected industry and academic partners already operating within the cluster are best equipped to project their workforce challenges should the industry continue its significant growth trends. As the cluster is currently not a driver industry, establishing a taskforce would ensure workforce and support industry infrastructure are prepared to meet future needs.

STAFFING PATTERN ANALYSIS

Complete an analysis of the staffing patterns of the MSAs which have strong concentrations in the Medical Device Manufacturing Cluster defined in this report. This will provide an established baseline for the future workforce requirements as the cluster grows and develops in the region. MSAs with a incremental increase of jobs and strong LQs should be selected to develop a progressive growth model.

FEDERAL PRIME AND SUBAWARD COMPANIES

More than six hundred Southwest Ohio companies account for less than 10 percent of the federal obligated contracts FY13-15. These companies may represent a cluster of companies seeking additional markets. Analyze companies receiving prime and subcontract awards from federal prime contractors to determine identifying manufacturing companies that would benefit from new industry opportunities.

Sinclair Community College
444 W 3rd St, Dayton, OH 45402
Phone: (937) 512-3000

Sinclair
Community
College