

MedTech Connect

Medical Device Manufacturing and Supply Chain Analysis in South Central Minnesota



This work represents a collaboration among many people and organizations. First and foremost, it would not have been possible without participation from the many business owners and leaders who took time away from their busy schedules to share their insights and perspectives on this industry.

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Finally, the Minnesota Medical Manufacturing Partnership and the Medical Alley provided guidance, support, and review throughout the process. We thank them for sharing their time and expertise, as well. On behalf of the Board of Commissioners and all of us at Region Nine Development Commission, thank you.

Sincerely,

Vinne Grienf. Mickey-

Nicole Griensewic Mickelson

About Region Nine Development Commission

Region Nine Development Commission (RNDC) serves nine counties included in Region Nine: Blue Earth, Brown, Faribault, Le Sueur, Martin, Nicollet, Sibley, Waseca, and Watonwan. RNDC takes great pride in working with and on behalf of these counties and their cities, townships, and school districts. Since 1972, being a partner for progress has led to the development of programs in the areas of economic development, business development, healthy communities, transportation, community development, and leveraging regional resources. RNDC is governed by 40 regional leaders. These leaders include elected officials representing nine counties, 72 cities, 147 townships, 32 school districts, the Minnesota Valley Council of Governments, and special interest groups including, Health and Human Welfare, Minority Populations, and Youth.

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About RNDC cont.

RNDC receives an annual planning grant from the Federal Economic Development Administration (EDA) to conduct economic development planning activities within the district. Activities range from developing and annually updating the Comprehensive Economic Development Strategy (CEDS), leading regional based economic development goals and strategies, facilitating the regional Community and Economic Development Committee, hosting summits, such as broadband, workforce forums, and assisting communities who are interested in seeking Federal EDA funding.

About the Project

This study was motivated by the need to develop a conceptual framework that inventories and supports medical device manufacturing (MDM) activities in Region Nine, as either formal or informal components of larger supply chains. It examines how and how well manufacturing and related industries leverage their geographic proximity to the MDM hub in the Twin Cities and innovations at Mayo Clinic in Rochester, both within approximately a 90-minute drive from Mankato, Minnesota.

Findings of this project demonstrate that supporting industries such as plastics, electronics, packaging, design, engineering, and laboratory services are numerous yet dispersed. As most regional enterprises also produce commodities and services for other industries, methods of optimizing integration and output are complex. The research was therefore conducted through both qualitative and quantitative methods.

Qualitative methods consisted of one-onone interviews with industry professionals who have different interests and perspectives across the medical device supply chain. Examples include consultants and engineers,



Figure 1. MDM in Region Nine is diversified but poorly integrated. Dozens of firms engage MDM at various points along the supply chain. However, they are frequently unaware of each other's activities. Therefore, future public investments and infrastructural support systems should facilitate collaboration around a single market, such as medical device suppliers, while providing opportunities for industry-initiated partnerships and greater exchanges of ideas.

and testing service providers, mechanical service providers and technicians, and many others. Interviewees were asked about challenges and barriers associated with accessing and integrating into the overall supply chain in addition to the primary benefits of conducting business in this region. Interestingly, most companies self-identified as something other than a medical manufacturer. For example, one company considers itself a microcircuits company that happens to work with the medical device industry.

Results of these semi-structured interviews reveal three common themes:

- 1. Nearly all facets of medical device development and supply are conducted throughout the region
- 2. Few participants are aware of the activities of others, and therefore are likely missing potential synergies and economies of scale
- 3. Workforce shortages and access to capital represent major barriers to sustainable growth

The quantitative methods used in this study included economic analysis of regional industry metrics and supply chain characteristics. A cluster analysis was performed to examine how the production of commodity products utilized in the medical device industry relate to other industries in the region. Additionally, the industry was analyzed in comparison to national level data, industry specific data, and the Mankato-North Mankato Metropolitan Statistical Area (MSA) level data to discover which of these perspectives best reflects the primary dependent variable, sustainable growth in MDM. This is especially relevant for this industry, not just because of its inherent focus on commodity production, but also because the industry lacks a full regional footprint.

The industry's investment and production activities are unequally distributed across the region. First, the findings suggest that there are large differences in how production is done among organizations, and that in the absence of process congruency (i.e., similar procedures for generating similar products) supply-chain integration becomes difficult. Second, when examining data from different levels of analyses (and with different geographic scopes) the results highlight challenges deriving from relying on local workforces when a mismatch exists between organizational and end-user (e.g., the large medical device companies) needs. Overall, the findings suggest that opportunities for regional organizations to integrate with the larger supply chains and the Twin Cities hub exist if efforts are coordinated within the region. However, the inability to generate synergy utilizing the same supply chains appears to be problematic. Thus, the report recommends a cooperative approach to workforce

coordination and resource procurement and sales.

About the Study Process

This report represents the culmination of a four-phase pyramid approach, in which each step builds higher upon the last and becomes more focused based upon the previously established foundation:

- 1. Background research and business inventory
- 2. Leadership interviews and qualitative study
- 3. Data collection and quantitative analysis
- 4. Recommendations and reporting

The following databases were searched for companies in the nine-county area for any mention of medical, pharmaceutical, or related activities:

- North American Industry Classification System (NAICS)
- Food and Drug Administration (FDA):

-Medical Device Listing and Registration¹ -Drug Establishment Current Registration Site (DECRS)² -Wholesale Distributors and Third-Party Logistics Providers Database³



Recommendations

RIMS-II Quantitative Analysis and Summary

Leadership Interviews and Qualitative Study

Background Research and Business Inventory

Figure 2. Study framework is built on a foundation of background research and time-intensive business inventory, culminating in comprehensive recommendations, which are based on both qualitative and quantitative analyses of initial inventory.

¹ http://www.accessdata.fda.gov/premarket/ftparea/contact_addresses.zip. Accessed on 3/20/2018.
 ² http://www.accessdata.fda.gov/cder/drls_reg.zip. Accessed on 3/20/2018.
 ³ https://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/wdd.cfm. Accessed on 4/11/18

The geographic scope of the study include the nine counties encompassing the South Central region of Minnesota, which form Region Nine.

	Indicators	Region Nine	U.S.
Trends	Population, % change, 2000-2016	3.8%	14.5%
	Employment, % change, 2000-2016	2.4%	17.1%
	Personal Income, % change, 2000-2016	26.4%	32.1%
	Average Earnings per Job, % change, 2000-2016	14.9%	4.7%
	Per Capita Income, % change, 2000-2016	21.8%	15.4%
Prosperity	Avg. Earnings per Job, 2016	\$44,980	\$59,598
	Per Capita Income, 2016	\$44,715	\$50,280
	Services, Avg. Annual Wages, 2016	\$35,330	\$52,806
	Non-Services, Avg. Annual Wages, 2016	\$49,731	\$63,393
	Government, Avg. Annual Wages, 2016	\$45,824	\$55,359
Stress	Unemployment Rate, change 2000-2016	0.5%	0.9%
	Unemployment Rate, 2016	3.8%	4.9%
Structure	Proprietors, % of Jobs, 2016	23.6%	22.6%
	Non-labor Income, % of Personal Income, 2016	39.7%	36.8%
	Services, % of Jobs, 2016	57.5%	72.9%
	Non-Services, % of Jobs, 2016	25.4%	14.5%

Table 1. Summary of economic trends, prosperity, stress, and structure for the nine-county region in comparison to national averages is provided below. Source: Headwater Economics.



Demographics

Population

The MSA encompasses the counties of Blue Earth and Nicollet and represent the largest population center within Region Nine, in which 100,016 residents live. Outside the MSA, just five cities have populations of more than 5,000 residents: New Ulm (13,539), St. Peter (11,807), Fairmont (10,353), Waseca (9,124), and New Prague (7,585). Collectively, Region Nine accounts for 9.32% of the state's population outside the seven-county Minneapolis-St. Paul region.^{4,5}



Figure 3. Population throughout Region Nine from 2010-2017. Source: U.S. Census Bureau.

According to the Minnesota State Demographic Center (SDC) and the U.S. Census Bureau (USCB), the population of Region Nine in the last 15 years grew slower (4% growth rate) compared to the State of Minnesota (11% growth rate). The region's growth is concentrated primarily in three of the nine counties: Blue Earth (19.2% growth rate), Nicollet (11.7% growth rate) and Le Sueur (7.8% growth rate). The other six counties ranged between 3.8% to 14.17% population decrease, with the largest loss occurring in Faribault.⁶



Figure 4. Percent change in population from 2010-2018. Source: Headwaters Economics.

⁵ Minnesota State Demographic Center 2016 Population Estimates
 ⁶ Minnesota State Demographic Center Population Estimates 2001-2016

Age

Region Nine exhibits two dominant trends among age demographics:

First, population projections from the Minnesota SDC forecast populations aged 65+ and 85+ will increase quickly over the next 30 years. This is consistent with the state and nation, which are preparing for unprecedented numbers in both of these age groups. This increase can be attributed to the large baby boomer population and longer life expectancies. Nationally and statewide, these two age groups are expected to outnumber all others by 2030.

In contrast, Blue Earth and Nicollet counties highest and second-highest age brackets are young adults aged 18 to 34 years old. Blue Earth County's 18 to 34 age group accounts for 22.9% of its total population, more than double the state average (9.5%). In particular, young adults in the City of Mankato account for nearly half of its total population (48%). This is more than five times the state average. A large draw for this age group is the area's abundance of educational opportunities.



2010 2016

Figure 5. Median age of residents in each county of Region Nine in 2010 (gold) and 2016 (blue). These data illustrate a trend toward aging populations in all but two counties: Watonwan and Waseca. Source: Headwaters Economics.



Race

Based on 2012-2016 American Community Survey Estimates (ACS), Region Nine counties are predominantly white ranging from 90.7% to 97.6% of the total population in these counties. The most racially diverse county in the region is Blue Earth County with the population consisting of 91.6% white, 3.3% black or African American, 2.1% Asian, and 2.1% of two or more races. Faribault County is one of the least diverse counties in the region, with a 97.5% white population.

Unique to the Region Nine, Watonwan County has a growing Hispanic or Latino population, with 22.6% of the total population being Hispanic or Latino and 20.4% of the population speaking a language other than English at home. This large Hispanic and Latino population is a growing influence in the local workforce and economy.⁷



Figure 6. Hispanic population, as percentage of total population in Region Nine in 2016. Source: Headwater Economics.

⁷ U.S. Census Bureau, 2012-2016 American Community Survey 5-year Estimates

Education

Education is vital when aligning worker skills with the needs of employers, which is critical to increasing productivity and growing the region's economy. Nicollet County has the highest percentage of people who have obtained a bachelor's degree or higher at 32.3%. Blue Earth County has the second highest with 31.7%, in comparison to the State of Minnesota which has 34.2%. Both Mankato and North Mankato have the highest percent of population that has completed a bachelor's degree or higher with 36.1% and 36.2% respectively.⁸

Collectively, all of Region Nine's counties have a slightly lower percentage of high school graduates than the state. Blue Earth County has the highest percentage of graduates at 94.2% and Watonwan has the lowest at 84.9%. Additionally, seven out of the nine counties in the region have a larger percentage of individuals who have an associate's degree comparatively to the state's 11%.⁹



Figure 7. Educational attainment throughout Region Nine in 2016. Blue represents no high school degree; gold is bachelor's degree or higher. Source: Headwater economics.

Region Nine has several higher educational institutions that offer a wide variety of disciplines and programs including: Minnesota State University, Mankato; South Central College; Bethany Lutheran College; Rasmussen College; Gustavus Adolphus College; and Martin Luther College. Minnesota State University, Mankato is a four-year, public university which offers 130 programs of study. South Central College is a community technical college that offers 50 technical career and professional programs. South Central College has established partnerships with regional businesses and industries and delivers customized education through its Center for Business and Industry. Bethany Lutheran College is a private liberal arts college that offers 24 majors, 24 minors, and eight pre-professional programs. Rasmussen College is a private college offering approximately 40 programs ranging from the certificate and diploma level through the associate's, bachelor's, and master's level. Gustavus Adolphus College is a private college is a private set and 12 interdisciplinary programs. Martin Luther College is a private college that offers 72 majors and 12 interdisciplinary programs. Martin Luther College is a private college that offers and 12 interdisciplinary programs. Martin Luther College is a private college that offers over a dozen majors as well as graduate degrees in education.

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Regional Economy

Historic industry trends for the region include employment growth from 2010 to 2016, as well as the number of firms by industry, average wages, and national projected growth from 2016 to 2026 for employment and output. For the manufacturing sector, national manufacturing capacity utilization is also provided as an indicator of expansion potential.

As of 2016, which is the most current data available at this level of industry detail, there were 105,739 people employed in the region at 6,361 firms. Employment has increased by about 5,995 people since 2010 when the national recession recovery was beginning, although the number of firms has decreased slightly, down from 6,507 in 2010. Overall, employment in the region has grown by six percent since the end of the recession, compared to 14% growth nationally.

The largest growth in employment has been in the trade, transportation, and utilities sector with close to 1,700 added workers since 2010, followed by manufacturing with 1,166 added workers, and construction with just over 900 added workers. The increase in employment for manufacturing demonstrates the strength of this sector in the region and represents a combination of gains in industries such as stone products, electronics, motors and generators. There was modest growth in the natural resources, mining, education, and health services sectors, while the financial and information sectors sustained net job losses between 2010-2016.



Figure 8. Employment by major industry category throughout Region Nine in 2016, the most recent year for which data are available. Percentages in Region Nine are sorted from largest (bottom) to smallest (top). Source: Headwater Economics.

The largest growth, in terms of absolute number of jobs, has been in services with close to 1,700 new jobs over six years followed by construction with 980 new jobs and agriculture with 850 new jobs. The manufacturing sector, which is particularly strong in this region, added close to 750 jobs. This represented a combination of gains in industries such as stone products, electronics, motors and generators, and current-carrying wiring devices offset by significant losses in animal slaughtering, wireless communication equipment, and commercial printing.¹⁰

Additionally, Region Nine ranks among the nation's most prolific hog producers. Minnesota is currently one of the largest producers of hogs, with five counties in this region ranking among the state's top ten. This is pertinent to the medical manufacturing because hogs represent an important medical analog to humans and are increasingly utilized for synthesis of medical products and in biomedical research. For example, porcine heart valves are routinely used for implantation in faulty human hearts. Insulin for maintenance of diabetes, some treatments for HIV, engineered tissue for joint replacements, and many more represent additional medical products that come from hogs.

Employment and Workforce

The major employment industries in Region Nine are manufacturing, health care, retail trade, education, and food services. Every major industry has recovered from the Great Recession, although as a whole, Region Nine has lost 0.9% of its jobs since 2007. Manufacturing remains the third leading industry in the region but has been particularly slow at recovering from the recession.

The unemployment rate for Region Nine has generally mirrored the state historically. However, all nine counties in the region have enjoyed lower rates than the state. The MSA had an unemployment rate that fell below 3% in 2014 and has consistently remained between 3% to 3.5% into 2017. Sibley (5.5%) and Le Sueur (5.3%) counties had the highest unemployment rates in the region but were still less than the statewide rate (5.6%). Consequently, the Region Nine as a whole has been inching towards full employment, creating challenges for businesses seeking to hire additional workers.



Figure 9. Employment by subcategory throughout Region Nine from 2001 to 2016. Note that manufacturing is the highest segment throughout this period, and has been climbing steadily since 2014. Source: Headwater Economics.

¹⁰ Minnesota Department of Employer and Economic Development Quarterly Census of Employment and Wages, 2010-2016



Figure 10. Individuals (blue) and families (gold) living below the federal poverty level in each of the Region Nine counties and throughout the Region and U.S. in 2016. Source: Headwaters Economics.

As of the first quarter of 2017, Region Nine has the second-lowest median hourly wage among Minnesota's nine development regions. This was approximately \$2.63 below the state median. However, according to Minnesota's Department of Employment and Economic Development (DEED), the region's cost of living is about 19% lower than the state average, translating into a \$0.77 overall advantage in individual purchasing power.



Figure 11. Wages (left) and number of jobs (right) by industry throughout Region Nine in 2016. Source: Headwaters Economics.

About 77% of workers within Region Nine either live and work in the region or live outside the region and work within the region. In other words, approximately 33% of Region Nine residents commute outside the area. The top work destination in the region is the MSA, which accounted for 18% of employment in 2014. New Ulm accounts for 4.8% of employment, Fairmont for 3.8%, and Waseca for 3.6%. The top commuters into the region were from Minneapolis, Owatonna, and St. Paul. Of the 32,000 residents of Region Nine who work outside the nine counties, many are employed in Bloomington, Owatonna, and Minneapolis-St. Paul.



Figure 12. Personal income distribution throughout Region Nine in 2016. Source: Headwaters Economics.

Despite successful recovery efforts, the region faces a decreasing labor force participation rate. This is most likely the result of an aging workforce and delayed entry into the workforce by younger workers seeking higher educational opportunities. The ACS data reflect this trend in Region Nine with workers aged 20-to-24 years and 55-to-64 years representing the lowest percentages of working age adults.



Figure 13. Average earnings per household throughout Region Nine in 2017. Source: Headwaters Economics.

Economic Resiliency

Economic resiliency in a regional context requires intergovernmental agility when anticipating risks, evaluating impacts on economic assets, and increasing responsive capacity. The EDA recognizes that regional economic prosperity is linked to an area's ability to recover quickly from a shock, the ability to withstand a shock, and the ability to avoid the shock altogether. When considering economic resilience, it is important for local economic practitioners and organizations to consider their role in both preparation for potential economic disruptions and recovery from those disruptions. Local economic practitioners and organizations can assist with post-incident coordination, information dissemination, responding to external inquiries, and the lead grant administrator for federally funded recovery initiatives. The regional CEDS document and subsequent annual performance reports are critical mechanisms that identify regional vulnerabilities and mitigates or helps respond to economic disruptions. Woven throughout the 2016-2021 CEDS and the 2017 Annual Performance Report, are components of economic resilience. Much of the region's unique vulnerabilities are articulated in both the Strengths, Weakness, Opportunities, Threats (SWOT) analysis and throughout several goals and strategies in the plan. The goals and strategies construct a foundation for increased regional resiliency and support any economic mitigation efforts for future natural or economic disasters. In addition, throughout the CEDS and annual performance report planning processes, Region Nine established and continues to strengthen a network of cross-sector stakeholders that collaborate and communicate about existing and potential future challenges.11

The EDA defines economic resiliency as, "The ability of an area to prevent, withstand, and quickly recover from major disturbances (e.g. economic shifts, natural disasters, etc.) to its underlying economic base."¹²

Transportation

Transportation networks are critical to supporting the region's economic vitality and quality of life. The movement of goods and services is essential for thousands of manufacturing, retail, wholesale, and agricultural businesses in Minnesota. Strong transportation connections link area workers with jobs, raw materials with manufacturers, and products with markets. Local communities must evaluate transportation needs and the implications related to land use, community and economic development decisions.

In South Central Minnesota, U.S. Highway 169 is a major transportation corridor for funnelling freight from the southwestern and South Central region to the Minneapolis/St. Paul metro. Similarly, U.S. Highway 14 represents a major trucking corridor across the southern half of the state, connecting Rochester, Mankato, and southwest Minnesota to Interstates 35 and 90. These regions produce large quantities of hogs, corn, soybeans, and ethanol, all of which contribute to Minnesota being one of the nation's largest producers of these commodities. Other commodities that utilize this transportation network are aggregates, clay and sand, manufactured goods, and food products.

Additionally, there are eight airports in Region Nine, including the Mankato Regional Airport, which can accommodate aircraft the size of most domestic commercial flights.

Regional trade centers serve as economic and service centers for surrounding areas. The City of Mankato can be classified as the top trade center for the region with shopping centers, education institutions, and a world-class health system, the Mayo Health System. New Ulm, Fairmont, and Waseca are also classified by the Minnesota Department of Transportation (MnDOT) as regional trade centers.

Region Nine is a part of MnDOT District 7, which includes 13 counties in South Central and southwestern Minnesota. This includes all of Region Nine's counties as well as Cottonwood, Jackson, Nobles, and Rock counties. MnDOT District 7 directly supports 1,330 miles of state and federal highways, 146 miles of interstate, 484 bridges, 4,188 miles of county and state aid highways, 492 miles of rail line, 14 airports, and nine county and three city transit systems. District 7's fiscal year budget in 2016 is \$27.4 million or 7.1% of the total statewide budget. From 2016-2019, the average cost of a construction project is \$90.1 million with an average of 12 projects being employed between 2016-2019.¹³



Regional Manufacturing

Manufacturing represents a cornerstone of the region's economy. According to labor market studies by DEED, manufacturing accounts for 22% of jobs across the region. Although food manufacturing dominates, the region exhibits great diversity from a product standpoint. Examples include fabricated metal, machining, plastics, electrical components, printing, and many more. The potential to expand the footprint of the MDM industry in Region Nine is apparent.

Expanding on the Minnesota Medical Manufacturing Partnership (MMMP) region, which includes the Twin Cities and southeastern Minnesota, Region Nine is within one-hour drive from one of the nation's major MDM clusters.¹⁴ As a share of total employment, Region Nine hosts more manufacturing jobs than anywhere else in the state.¹⁵



Figure 14. Total contribution to GDP by industry throughout Minnesota in 2016. Source: Department of Employment and Economic Development.

Statewide, manufacturing represents the largest contributor to gross domestic product (GDP) by almost a 20% margin, according to DEED.¹⁶ DEED does not aggregate these data at the regional level. However, in Region Nine, manufacturing represents the largest percentage of total employment and the highest earnings among all industries.¹⁷



Figure 15. Manufacturing as a percentage of total employment in each of Minnesota's six planning regions.

¹⁴ Minnesota Department of Employment and Economic Development, Quarterly Census of Employment and Wages, Compiled by Region Nine Development Commission

¹⁵ Region Nine encompasses about one-third of southwest Minnesota's land area and accounts for 50 percent of its population.

¹⁶ Manufacturing Is the Cornerstone of Minnesota's Economy. Minnesota Department of Employment and Economic Development. Available at: https://mn.gov/deed/business/locating-minneso-

 ¹⁷ Manufacturing Profiles by Planning Area, 2017. Minnesota Department of Employment and Economic Development. Available at: https://mn.gov/deed/business/locating-minnesota/indus-tries-sectors/manufacturing/regional/. Accessed on 8/7/2018.

Medical Device and Component Manufacturing

Medical devices play a critical role in the delivery of health care services. Broadly defined, a medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory that is not absorbed or metabolized by the body. The term "device" applies to everything from common medical supplies, such as latex gloves and syringes, to advanced imaging equipment and implantable technologies, like cardiac defibrillators.¹⁸ Increasingly, medical devices also encompass software that is intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.¹⁹ The medical device industry is an important component of the larger health care system and plays an essential role in improving the ability to diagnose and treat illness.²⁰



Figure 16. Earnings by industry throughout Region Nine. In 2016 the three industry sectors with the largest earnings were manufacturing (\$1.4 billion), health care and social assistance, and retail trade.

¹⁸ https://www.fda.gov/MedicalDevices/DigitalHealth/SoftwareasaMedicalDevice/default.htm; accessed on 5/1/2018.

¹⁹ Software as a Medical Device (SaMD). https://www.fda.gov/MedicalDevices/DigitalHealth/SoftwareasaMedicalDevice/default.htm; accessed on 5/1/2015.
²⁰ https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm; accessed on 5/1/2018.

National and International Scope and Market

There is no standard way of defining the medical device industry, and as a result, estimates of the industry's size vary. Studies by the Congressional Research Service (CRS), BMI Research, and industry trade association Advanced Medical Technology Association (AdvaMed), have estimated that total U.S. spending on medical devices was \$127 billion in 2013 and \$172 billion in 2015. These estimates indicate medical devices account for roughly four to six percent of total U.S. spending on health care. As a percentage of overall healthcare spending in the U.S., the portion directed to medical devices has changed very little over time, suggesting that spending on medical devices has expanded proportionately to the broader health care sector.

The U.S. medical device market is the world's largest, accounting for 40% of spending despite having fewer than five percent of the world's population. Per capita expenditure on medical devices, at \$399 per person-year, is also the highest in the world. Furthermore, seven of the world's top 10 medical device manufacturers by total sales are U.S. companies. These include Baxter, Boston Scientific, Covidien, General Electric, Johnson & Johnson, Medtronic, and Zimmer.²¹ The global market for Medical Device Technologies reached nearly \$521.2 billion in 2017 and is expected to reach \$674.5 billion by 2022, at a compound annual growth rate (CAGR) of 5.3%.²² The U.S. MDM industry encompasses more than 5,800 companies and employs approximately 356,000 people. Of these 5,800 companies, 80% employ 50 or fewer people. ^{23,24,25}

Category	Level of risk to patient	Examples	Type of review before device can be marketed		
Class I	Low	 Elastic bandages Examination gloves Handheld surgical instruments 	Most devices required only to register; a small share must submit a 510(k) notification.		
Class II	Moderate	 Powered wheelchairs Infusion pumps Surgical drapes 	Most devices must submit a 510(k) notification; a small share of devices is required only to register.		
Class III	High	 Heart valves Silicone breast implant Implanted cerebella stimulators 	Devices must submit a PMA application; in the past, a significant number of devices were able to submit a 510(k) notification.		

Table 2: Food and Drug Administration's (FDA) classification of medical devices, based on potential patient risk and type of device.²⁶

²⁴ Laxmi V. Medical Devices: Technologies and Global Markets. BCC Research Report Overview. March 2018. https://www.bccresearch.com/market-research/nealthcare/medical-devices-technologies-and-global-markets-hlc170c.html; accessed on 5/1/2018.
 ²⁴ Donahoe G and King G. Estimates of medical device spending in the United States. Washington, DC: Advanced Medical Technology Association. 2015. http://www.advamed.org/sites/default/files/resource/94_100515_guy_king_report_2015_final.pdf; accessed on 5/1/2018.
 ²⁴ Laxmi V. Medical Devices: Technologies and Global Markets. BCC Research Report Overview. March 2018. https://www.bccresearch.com/market-research/healthcare/medical-devices-technologies-and-global-markets-hlc170c.html; accessed on 5/1/2018.
 ²⁵ Johnson JA. EDA Regulation of Medical Devices. Congressional Research Service. 2012. https://archive.org/details/R42130FDARegulationofMedicalDevices-crs; accessed on 5/1/2015.
 ²⁶ Chonson JA. EDA Regulation of Medical Devices. Congressional Research Service. 2012. https://archive.org/details/R42130FDARegulationofMedicalDevices-crs; accessed on 5/1/2015.

ohnson JA. FDA Regulation of Medical Devices. Congressional Research Service. 2012. https://archive.org/details/R42130FDARegulationofMedicalDevices-crs; accessed on 5/1/2015

²¹ Chicotsky B. Medical Devices Are the Quiet Growth Sector, Seeking Alpha. Sept. 21, 2017. https://seekingalpha.com/article/4108542-medical-devices-qui et-growth-sector; accessed on 5/1/2018.

² Laxmi V. Medical Devices: Technologies and Global Markets. BCC Research Report Overview. March 2018. https://www.bccresearch.com/market-research/healthcare/medical-devices-technolo-

Regional Scope and Scale

A comprehensive analysis of the North American Industry Classification System (NAICS) was completed for each of the nine counties throughout Region Nine and then compiled into a list of employers and their related primary industry.

Twenty-three NAICS codes were identified as potentially having relationships with the medical device industry and/or supplying the industry with goods and services. This technique was utilized because many of the manufacturers and producers in the region do not self-identify as participating directly in the medical device supply chain. Rather, as discussed previously, many produce for a variety of industries, with MDM representing only a portion of their overall portfolio. In the nine-county area, 44 business were identified as supplying components, services, textiles, office supplies, transportation, or other.

Industry classification	NAICS code
Cut and Sew Apparel Contractors	315210
Men's and Boys' Cut and Sew Apparel Manufacturing	315220
Women's, Girls', and Infants' Cut and Sew Apparel Manufacturing	315240
Other Cut and Sew Apparel Manufacturing	315280
Medicinal and Botanical Manufacturing	325411
Pharmaceutical Preparation Manufacturing	325412
Other Pressed and Blown Glass and Glassware Manufacturing	327212
Glass Product Manufacturing Made of Purchased Glass	327215
Electromedical and Electrotherapeutic Apparatus Manufacturing	334510
Analytical Laboratory Instrument Manufacturing	334516
Irradiation Apparatus Manufacturing	334517
Surgical and Medical Instrument Manufacturing	339112
Surgical Appliance and Supplies Manufacturing	339113
Dental Equipment and Supplies Manufacturing	339114
Ophthalmic Goods Manufacturing	339115
Dental Laboratories	339116
Testing Laboratories	541380
Graphic Design Services	541430
Research and Development in the Physical, Engineering, and Life	
Sciences (except Nanotechnology and Biotechnology)	541715
Hazardous Waste Treatment and Disposal	562211
Medical Laboratories	621511
Other Electronic and Precision Equipment Repair and Maintenance	811210

Table 3. NAICS codes identified as potentially related to the medical device supply chain. Source: U.S. Census Bureau.

More than 250 companies were identified as producing goods and services among the above NAICS codes. A search of websites and telephone interviews led to the identification of the 44 companies selected for further analysis. Among these 44 companies, annual receipts and sales volumes ranged from \$150,000 to more than \$52 million. The average annual sales volume was \$34,191,000 with a median of \$29,901,000.

In addition to the NAICS search, a regional cluster analysis was conducted to visualize the interconnectedness of MDM throughout Region Nine. Six of the nine counties have MDM as 20% or more of their total manufacturing portfolio.

Sales volume of companies in MDM supply chain

Total	\$102,573,000
Average	\$34,191,000
Median	\$29,901,000

Table 4. Sales volume statistics for companies throughout Region Nine in 2016. Source: North American Industry Classification System, U.S. Census Bureau.



Figure 18. MDM as a percentage of the county's total in Minnesota. Region Nine is outlined in black. In six of the region's nine counties, MDM accounts for at least 20% of the overall manufacturing portfolio.

(ittsoi 9.2%

Industry Analysis

In the traditional supply chain, medical devices move to market directly from manufacturers, and through distributors, and are either sold to inventory or positioned in the market on a consignment basis. Expensive, non-consumable equipment is sent straight from the manufacturer to final clients under a make-to-order system. Typical products include imaging equipment, diagnostic and surgery capital equipment. Participants in the MDM supply chain must be able to handle mostly oversized equipment and have expertise in international logistics. These products can originate from anywhere in the world, so in-depth knowledge of the Unites States' regulations, restrictions, licensing, and permitting are critical.

Products that need constant replenishment necessitate in-house inventory. Typical products include consumables/disposables, implantable devices, and surgical procedure equipment. These items represent the majority of products in the medical devices supply chain. The supply chain also calls for adequately planned inventories with the means to reach highly distributed locations with fast and reliable delivery. In-house inventoried products can be owned or held as consignment inventory. Under the consigned sales model, a device maker positions inventory at customer sites throughout the healthcare network. Hospitals and device manufacturers agree to hold certain stock at the hospital (funded by the manufacturer) and replenish these items as the hospital uses up stock.²⁷

Industry insiders argue that there is a strong trend towards collaboration within MDM supply chains make these processes lean and more efficient. (See Table 5) One practice that would complement shared services supply chains is greater collaboration among all trading partners in the devices supply chain manufacturers, their customers, and the third-party logistics providers that support them.²⁸



Figure 19: Needs identified by medical device manufacturers, ranked by need as identified by survey sample. Source: How is your organization's supply chain responding to these industry trends today? Gartner, www.iqpc.com/media/1001844/20005.pdf.

Supply Chain Analysis

Semi-structured Interviews

Analysis of the medical device supply chain in Region Nine took a two-pronged approach, quantitative financial and employment analysis, as well as qualitative interviews with business owners and leaders throughout the industry. Semi-structured interviews were conducted with individuals from as wide a spectrum of producers and service providers as possible. Additionally, both suppliers and purchasers were interviewed to capture the full spectrum of perspectives and needs.

Supplier and Service Provider Interviews

Methodology for recruiting businesses into this process included email requests, mail solicitation, and follow-up telephone calls. Altogether, 18 businesses opted to participate in interviews. Topics of discussion included:

- 1. Number of employees
- 2. Annual sales
- 3. Innovation strategies
- 4. Workforce development and retention
- 5. Percentage of portfolio dedicated to medical devices and innovation
- 6. Interest and ability to penetrate MDM sector in Twin Cities
- 7. Interest and ability to penetrate MDM innovation in Rochester, MN

Discussions were not held explicitly to these topics, and when other points of discussion occurred, conversations were allowed to continue along a natural course. At the businesses' request, and to protect proprietary information, findings are compiled here into themes.

Workforce Development and Retention

"Recruiting workers at all levels—from basic labor to engineers and designers—is our biggest obstacle to growth."

The above comment comes directly from one of the interviews. It represents a sentiment that every one of the 18 companies interviewed cited as a challenge. Recruiting and retaining workers has slowed companies' ability to fully capitalize on the business boom occurring in the medical industry in Minnesota and elsewhere.

Attracting and retaining employees was the number one concern cited by nearly all businesses interviewed. From a strategic standpoint, several businesses cited difficulty attracting and retaining workers as their primary obstacle to growth.

For example, one firm of more than 1,000 employees reported ability to invest in new tooling and business infrastructure to increase production by 50%. However, they are having difficulty retaining workers at current production levels and cannot realistically increase production until at least 20-30 new laborers can be hired, trained, and transitioned into full-time work.

Similarly, a much smaller employer of two co-owners and five employees stated he and his business partner would like to expand production and design in their current facilities, but have been unable to identify the highly skilled expertise needed to utilize sophisticated CAD software and precision machinery.

"There's a great resource with MSU (Minnesota State University, Mankato) right here in town, but we need time to train graduates on our processes and customer interaction," said the employer. "And, a lot of times, they leave for bigger cities soon after they have some experience with us."

The two difficulties noted in the above quotation highlight another difficulty, emigration of skilled workers. This is a fundamental issue that applies to both the technical workforce and the laborer.



Figure 20. "Alumni Retention in United States Metropolitan Statistical Areas." Source: Cornell Policy Review.²⁹ Alumni retention ranks among the highest in the Twin Cities metropolitan area, above average in the Rochester area, while south central and southwestern Minnesota show poor retention of college graduates.

Recommendation: Assemble working group and develop proposals to increase desirability of Region Nine to graduates of the area's six institutions of higher learning.

Percentage of Portfolio Dedicated to Medical Devices and Innovation

Perhaps the most pertinent finding for this portion of the report is that many companies neither selfidentify as being a MDM business nor consider MDM a significant portion of their portfolio. Paradoxically, most consider MDM as a potential growth sector that could be lucrative and sustainable but difficult to penetrate.

Six of the companies interviewed (one third) are fully dedicated to medical device design and manufacturing. The remaining 12, however, considered themselves commodity producers who happen to deliver a portion of their components and services to the MDM industry.

Among the above-mentioned 12 companies (not accounting for those fully dedicated to MDM) the average MDM portfolio was approximately 25%. The median was 32. As a function of number of employees relative to MDM portfolio percentage, the average was 52%.

The implication of these data suggest that smaller companies are less diversified, while larger companies tend to serve a greater diversity of industries among their manufacturing and services portfolios, indicating that they depend more on MDM industry.

²⁹ Available at: http://www.cornellpolicyreview.com/alumni-retention-in-united-states-metropolitan-statistical-areas/?pdf=3615. Accessed on 8/6/2018.

Interest and Ability to Penetrate MDM Sector in Minneapolis-St. Paul, MN

Among the more surprising findings was that many companies identified MDM as a potential growth area but were uncertain of how to capitalize on the medical boom. For instance, one business founder and owner of a customized prosthetics company stated he has strong relationships with local clinics and physicians but would have no idea how to connect with larger suppliers, such as those based in the Twin Cities Metropolitan area. This successful start-up business is expanding into Minneapolis, but the owner has no ability to leverage larger producers just 10 miles away.

"It's easier for me to purchase components from Germany and Iceland than it is for me to work with suppliers and manufacturers in the (Twin) Cities." – Prosthetics designer and manufacturer in Region Nine.

Similarly, a design and build precision motor company noted that they currently have about 10% of their portfolio in medical equipment, primarily in larger machines such as MRI and CT scanners, robotic surgical equipment, and the like. The company also noted MDM as a high growth area that has been difficult to penetrate.

A handful of smaller manufacturers and beta testing laboratories compose most of their medical portfolio while larger medical device manufacturers are perceived as less accessible. Because of this, the company has opted to pursue other industries as their primary areas for growth.

Recommendation: Develop task force and center to open lines of communication among local innovators, Midwestern medical device manufacturers, and economic development professionals.

Interest and Ability to Penetrate MDM Innovation in Rochester, MN

Surprisingly, most companies interviewed for this project were only cursorily aware of the medical innovation boom currently being led by Mayo Clinic in Rochester, Minnesota. The non-profit clinic has partnered with the State of Minnesota, the City of Rochester, and Rochester Area Economic Development, Inc. to convert a portion of downtown into a medical innovation hub, complete with laboratory space, support for entrepreneurs, and seed funding for start-ups.

This \$5.6 billion total investment, called Destination Medical Center (DMC) represents the largest in Minnesota's history and is happening fewer than 50 miles from the eastern half of Region Nine territory.³⁰

One company interviewed suggested that accessing this investment and innovation potential would be too difficult for companies not already affiliated with Mayo Clinic. This represents a fundamental misunderstanding of the development's intent, which is "developed by entrepreneurs for entrepreneurs ... to equip and encourage aspiring innovators from idea to exit."³¹

Several others had not heard of the innovation component and mistakenly considered DMC as a platform for Mayo Clinic to expand, rather than convert the region into a medical innovation hub.

Recommendation: Develop mechanism and center to connect local innovators and manufacturers with entrepreneurs and developers in Rochester and with DMC.

³⁰ https://dmc.mn/discovery-square/. Accessed on 8/6/2018.

³¹ https://dmc.mn/discovery-square/. Accessed on 8/6/2018.

Purchaser and Final Product Manufacturer Interviews

A series of interviews with executives at one of the world's largest MDM firms revealed a number of interesting insights. Specifically, the executives identified three major developments that directly impact contract manufacturers and smaller producers.

First, supply chains are getting increasingly centralized. This suggests that outsourcing contracts are getting larger and more closely managed by the firm. Large MDM producers are therefore seeking preferred vendors that they can turn to, rather than rely on a large number of smaller producers to suppliers.

Second, there is less local purchasing than in the past. With increased speed in global supply chains, local markets may not be in a position to offset cost savings from contract manufacturers that are located further away.

Third, global management is becoming more pressing and commonplace. This suggests that the larger producers manage globally, such as an integrated international model for the management of sales, marketing, hiring, and finance practices.

The interviews also revealed that the executives view their industry and contract manufacturing as a duality: they seek out contract partners that can either do high-end precision work for them or perform low-level assembly. This suggests that companies that sit in the middle or are unable to specialize serve no purpose for the larger firm.

There also seems to be a trend within in the industry that successful suppliers find a niche, or a focused strategy, which they use to leverage their relationships with the final manufacturers. The larger companies view it as essential to work with start-ups and niche players, as much of the innovation takes place among such firms. Because there has been quite a bit of industry modification taking place (e.g., de-engineering in order to lower costs), the larger companies rely heavily on start-ups for innovation. Examples would be new ways to treat illnesses, visualization techniques, and device miniaturization.

The larger producers also confirmed that most of their contract manufacturers do not specialize in MDM products, as it is simply too risky. On the flip-side, margins would be higher when producing for the top tier companies. One of the executives pointed to thriving manufacturing hubs in Indiana where the larger MDM producers had opened plants and the rapid growth of innovation and entrepreneurial ventures that emerged as a result.

Finally, the larger MDM producers emphasized the need for world-class broadband such as redundant broadband and highways direct to port (e.g., highways to MSP airport) in areas of expansion. The broadband situation within Region Nine would not currently meet the needs by these producers.

End User and Medical Care Providers

Interviews with end users, (e.g., retailers and hospitals), revealed many insights regarding current trends. Retailers of Class 1 medical devices emphasized that they are buying from fewer vendors than in the past. In other words, they purchase their products from a select group of producers. This was attributed to economies of scale in which the larger producers can sell products at a lower price, marketing in which larger producers gain valuable brand recognition, and abilities to meet fluctuations in demand (e.g., restocking). Retailers, such as pharmacies, also emphasized that shelf-space for medical devices is limited as there has been a shift from independently owned pharmacies to corporate stores where larger portions of revenue are derived from other items (i.e., not pharmaceuticals or medical devices) and thereby limiting the space for medical devices.

Administrators responsible for procurement within hospital and health care clinic settings echoed the sentiments from retailers. Preferred suppliers are common in most hospital settings today and for Class 1 medical devices the supply chain administrators make most decisions regarding what they purchase and from whom. However, with respect to Class 1 and 2 medical devices physicians still exercise most of the control. Interviews did reveal that despite the vast number of producers, procurement has increasingly become more concentrated and that the large producers dominate their purchase orders.





In order to make sense of changes within the MDM industry, it is helpful to start with an analysis of the external environment. A PEST-D analysis (political, economic, socio-cultural, technological, and demographic) describes a framework of macro-environmental factors used in the environmental scanning component of strategic management. It is part of an external analysis when conducting a strategic analysis or doing market research and gives an overview of the different macro-environmental factors to be taken into consideration when attempting to make sense of an industry. It is typically used as an initial step in developing a strategic understanding of market growth or decline, business position, potential and direction for operations.³²



Political Changes

Recent healthcare reforms have increased the pressure to reduce costs within the industry, thereby changing the ways firms operate while intensifying competition based on cost. Healthcare reforms have also fundamentally changed the customer base, which was traditionally made up of physicians. In some instances, hospital administrators not physicians, are primarily concerned with reducing costs.

Uncertainty and inconsistency with respect to the regulatory process have made it difficult for producers to raise funds and plan for product introductions. Additionally, as a result of the unpredictable nature of the regulatory processes and the FDA having made the device approval process more rigorous, many MDM companies struggle to balance the need to reduce cost (by providing the minimal amount of clinical data possible) with providing enough data necessary to satisfy reviewers.



Federal tax and budget changes have also impacted the industry in recent years. A 2.3% tax on medical device sales was implemented as of January 1, 2013, under Section 4191 of the Internal Revenue Code. Additionally, a federal budget sequester has put capital pressure on the industry with an average nine percent decrease in overall funding. On the flip-side, small and mid-size businesses that employ engineers or outsource product testing have been allowed to claim Research and Development (R&D) credits. These credits have become more attractive for small companies in recent years because they have been simplified, can be transferred in an acquisition, and can be taken retroactively.³³

³³ Strategy &. Fit for GROwth in medtech. 2013. https://www.strategyand.pwc.com/media/file/Strategyand_Fit-for-Growth-in-Medtech.pdf. Accessed on 6/3/2018.

Economic Changes

Funding in the MDM industry has changed over the last decade. Capital investment continues shifting into more mature companies, rather than early start-ups, which a cautious marketplace views as overly risky. This makes it more difficult for entrepreneurs to access capital. This may be of some concern as smaller companies have traditionally been more innovative than their larger competitors. It may also stifle competition within the industry and lead to monopolization over time.

MDM manufacturers are also adjusting to the emergence of the super-consumer. A super-consumer is considered a consumer who has access to information previously reserved for experts only. As communications technologies continue democratizing access to information, healthcare consumer behaviors demonstrate an increasing preference for recognizable brands. This is a new trend, as patients have traditionally relied on their healthcare providers to select products and services on their behalf. As a result, design elements that promote ease of use have become more important for the industry.³⁴ It could also contribute to greater concentration within the industry as brand recognition becomes increasingly more important for consumers.

Socio-cultural Changes

Cosmetic surgery is on the rise, not only in the U.S. but in other parts of the world as well. Many of these surgeries include medical devices, such as breast and other implants. According to the American Society of Plastic Surgeons, cosmetic surgery has seen explosive growth in the US. Between 2000 and 2016, there was an increase of 132% in procedures, which does not include reconstructive surgeries in response to injury, disease, or gender confirmation.

While only 10.4% of the 17.2 million total cosmetic procedures in 2016 were surgical, those invasive operations added up to a cost of more than \$8 billion, which is nearly half of all money spent that year in the industry.

Technological Changes

The rise of mobile devices has shifted the internet to the cloud, giving rise to an interconnected mesh of devices now being called the "Internet of Things." Manufacturing has felt the impact of this development, with 19% of manufacturing departments using cloud apps by 2016, a figure expected to triple over the next few years. Medical manufacturers are increasingly producing wireless, wired and hybrid medical solutions to meet the rising demand for connected devices in hospitals and clinics, imaging, and diagnostic centers and home healthcare consumers. This segment of the market expected to grow to over \$1.3 billion by 2021.35

3-D printing is also impacting manufacturing and the production of medical devices. The 3-D printing industry is expected to triple in size between 2016 and 2020 for a total of \$21 billion annually. Fifteen percent of this growth is expected to come from medical manufacturing. Ninety-eight percent of hearing aids are already produced by 3-D printing.³⁶

Robotics is helping MDM catch up to other areas of manufacturing. Traditionally, strict regulatory requirements have delayed incorporation of novel manufacturing techniques into the medical device industry. However, improvements in manufacturing robotics are helping to close this gap. Medical robots are assisting with everything from pharmacy automation to surgery, and demand for medical robots is expected to almost triple in the five years between 2015 and 2020, growing from \$4.2 billion to \$11.4 billion over that time.³⁷

Demographic Changes

An aging population, driven by declining fertility rates and increasing life expectancy, represents a major demand driver for medical devices. The U.S. retirement age population (persons 65 and older) totaled 48 million in 2015 (15% of the population). The U.S. Census Bureau estimates that this population will more than double to 98 million by 2060, when retirement-age persons will represent 24% of the total U.S. population.

The elderly account for nearly one third of total healthcare consumption. Personal healthcare spending for the 65 and older population segment was \$19,000 per person (2012), which is five times the spending per child, and almost triple the spending per working-age person.

According to United Nations projections, the global percentage of retirement aged individuals will more than double from 8.3% of world population in 2015 to 18.1% of world population in 2060. Europe's elderly are projected to reach 28% of the population by 2060, making it the world's oldest region.³⁸

Individuals aged 65 years and older as percentage of total population						
Region	2015	2060	Change			
Europe	19%	28%	+47%			
United States	15%	24%	+60%			
Worldwide	8.3%	18.1%	+118%			

Table 5: Worldwide demographic shift in retirement-aged people (ages 65 and older), as cited by the United Nations

Internal Industry Developments

Medical device manufacturers are increasingly demanding more from their suppliers. It has become essential that contract manufacturers expand their capabilities and act as strategic partners to the larger MDMs. Contract manufacturers are under increasing pressure to meet ever-larger scalability requirements, which forces less-strategic contract manufacturers off approved supplier lists and effectively out of the supply chain and out of business.39

Developing Competitiveness Within the Industry

These new demands significantly impact the complexity of the work for contract manufacturers. In the past, most contract manufacturers were told what products to manufacture, in addition to how and how many to make. However, this relationship dynamic has shifted over the last 10 years. Increased competition among contract manufacturers has led smaller firms to establish novel value propositions that often include flexible services. Examples of these value-added services include product conceptualization and design, specialized manufacturing, supply chain management, and end-user delivery. Medical manufacturers view suppliers as valued partners that are tightly integrated into the supply chains of finished products. Top suppliers are also called upon to manage other smaller and nonstrategic suppliers on behalf of the larger MDM producers. Supply chain management for top contract manufacturers is therefore looked at as a competitive advantage and a sought-after capability for the larger MDMs. In order to become or remain competitive in the type of environment where consolidation is important, it appears critically important for consolidation within the contract manufacturing space to occur.

From an agnostic economic standpoint, companies have to generate a higher rate of economic profit than the average rate of profit within the same market in order to remain competitive within the MDM industry. Firms competing as contract manufacturers must develop competitive advantages in that market, typically viewed as the firm being able to create more economic value than rival firms. The quest for competitive advantages typically assumes one of three different forms of strategy formulation and industry positioning. In order of optimal alignment with industry demands, these advantageous positions are:

1. Cost-leadership position appears to align with industry demands and remain consistent with current trends. There appears to be demand for design efficiency among larger firms, which increasingly are turning to smaller, more agile R&D companies. The goal for design and development is to de-engineer (e.g., undesign) medical equipment in a way that strips it down to its essential parts for portability, lower power, and greater cost effectiveness. This provides both an opportunity and a threat for existing manufacturers and contract manufacturers. The trend within the industry appears to be to achieve cost effectiveness, rather than "innovation for the sake of innovation" according to industry insiders.⁴⁰ This would require regional manufacturing firms to attain competitive parity on the basis of differentiation relative to competitors, which would permit them to translate cost advantages directly into higher profits than competitors.

⁹ http://www.medicaldesignandoutsourcing.com. Accessed on 6/13/18. [•] Transformation of the U.S. Medical Device Supply Chain: An Evolution in America's Healthcare. A White Paper from the North American Leader in Supply Chain Management (exel).

- 2. **Differentiation** is one such option and may take many forms:
 - A. Building competitive advantage around prestige or brand image
 - B. Developing new technology
 - C. Driving innovation within a subset of the industry
 - D. Providing features not offered by competitors
 - E. Delivering exceptional customer service

F. Developing an extensive dealer network (Through interviews with regional manufacturers and executives at the end user state, this is the least likely of scenarios for success given the dynamics of the MDM industry)

3. **Focus** is based on the choice of a narrow competitive scope within the industry. Firms pursuing this type of strategy select a segment or group of segments (i.e., a niche) and tailor their strategies to serve them. Both of these strategies rely on providing better service than broad-based competitors who are trying to serve the focuser's target segment. This may be a viable option for niche players within the region that have a clearly defined market or product segment that they serve. This can take on two variants:

A. Cost focus where the firms strive to create a cost advantage in its target segment

B. Differentiation through which firms deliver niche products or services that target a smaller segment of the global market

Governing Dynamics of MDM Industry: Porter's Five Forces Model

Following the examination of the external environment, industry developments, and interviews with manufacturers, buyers, and other industry insiders, Porter's 5 Forces Model was used to assess the dynamics (i.e., the competition) of the MDM industry with the purpose of understanding the strategic choices facing regional firms. This strategic tool was created by Harvard Business School professor Michael Porter to analyze an industry's attractiveness and likely profitability. It has since become one of the most regarded business strategy tools among practitioners and strategy developers. Porter's 5 Forces Model identify five dynamics that make up the competitive environment and which can erode the firm's profitability and competitiveness. Each of the five dimensions were examined based on interviews and a review of relevant literature.⁴¹

- *Competitive Rivalry* refers to the number and strength of competitors. Where rivalry is intense, companies typically attract customers with aggressive price cuts
- Supplier Power refers to how easy it is for suppliers to increase their prices
- *Buyer Power* refers to buyers' ability to pressure pricing downward. When dealing with only a few savvy customers, suppliers have less power. Supplier power increases with more buyers
- *Threat of Substitution* refers to the likelihood of buyers finding different sourcing for similar products or services. Simple and inexpensive substitutes can weaken a firm's position, threatening profitability and competitiveness
- *Threat of New Entry* refers to the extent to which other firms enter the same market



Interviews with regional manufacturers and structural analyses of the MDM analyses confirm that small players without patents or unique products are forced to supply modified and standardized components to larger buyers that use these products for their final products. The bargaining power of these buyers, the high threat of new entrants, and the intense rivalry appear to force manufacturing companies supplying the MDM industry to compete on cost. Successful strategy formulation therefore depends on a firm's ability to identify resources and capabilities that enables them to utilize them in such a manner that they support the overall goals of the organization. Resources can be either tangible or intangible and include firm-specific assets and factors of production, such as patents, brand-name reputation, installed base, or human resources. Capabilities refer to activities that the firm does better than competitors that arise from the use of those resources. Identifying such capabilities would require the firm to examine the different functional area of its operations (i.e., a functional analysis) and to use a value chain analysis to identify how value is generated internally.

Identifying a firm's or local industry's capabilities through a value chain analysis can also serve as a starting point for the development of a SWOT (strengths, weaknesses, opportunities, and threats) analysis, which examines internal (strengths and weaknesses) and external (opportunities and threats) factors that contribute to long-term viability and sustainability. Two approaches that are commonly used:

- 1. A functional analysis identifying organizational capabilities in relation to each of the principal functional areas of the firm.
- 2. A value chain analysis separating the activities of the firm into a sequential chain (e.g., Michael Porter's) representation of the value chain distinguishes between primary activities.

		MDM
Category	Characteristics / explanation	Position
Threat of new entrants	Low barriers to entry	High
	Global competition	
Bargaining power of suppliers	Commodity production	Low
	High number of suppliers	
Bargaining power of buyers	 Few, but large, buyers 	High
Threat of substitutes	 Few substitutes exist for commodities required 	Low
	 Technology may change this dynamic 	
Rivalry	 Many companies offering nearly identical products 	High

Porter's Five Forces – Medical Device Manufacturing (MDM) Industry

Table 6: Assessment of Porter's Five Forces, as related to the MDM industry. Implications of this assessment include two things: (1) The industry is highly competitive from the suppliers' perspective and (2) Suppliers would benefit from increased competition on cost.

The goal for this type of analysis is to recognize that resources are not productive on their own. Organizational capabilities should ideally allow the firm to deploy resources for a desired result, such as meeting the production costs desired by the buyers. Some of these capabilities may be cross-functional. Given the changing nature of the MDM industry, firms may increasingly have to leverage new product development to necessitate operations, R&D, marketing and sales, and labor relations/human resource management. Other aspects may be more activity related, such as specific manufacturing capabilities.

Primary Activities	Secondary Activities			
Inbound Logistics	General Administration			
Operations	Human Resource Management			
Outbound Logistics	Technology Development			
Marketing and Sales	Procurement			

Table 7: Porter's Value Chain focuses on systems and how inputs convert into consumer-purchased outputs. Primary activities relate directly to the physical creation, sale, maintenance, and support of a product or service. Secondary activities support these processes. MDM companies create value by acquiring raw materials and using them to produce value. Each of these parts are therefore essential in generating competitive advantages.⁴²

Whether capabilities are examined from a functional or a value chain approach, it is evident that broad functions of value chain activities can be disaggregated into more specialist capabilities performed by smaller teams or resources. Most MDM firms consist of a hierarchy of capabilities where more general, broadly defined capabilities are formed from the integration of more specialized capabilities.

For instance, a hospital's capability in treating heart disease depends on its integration of capabilities pertaining to a patient's diagnosis, physical medicine, cardiovascular surgery, and pre- and post-operative care, as well as capabilities relating to various administrative and support functions.

Valuable?	Rare?	Difficult to replicate?	Non- Substitutable?	Competitive Implications
No				Competitive Disadvantage
Yes	No			Competitive Parity
Yes	Yes	No		Temporary Competitive Advantage
Yes	Yes	Yes	No	Temporary Competitive Advantage
Yes	Yes	Yes	Yes	Sustainable Competitive Advantage

Table 8. Evaluation of resources and capabilities. This framework supports a firm's larger strategic scheme. The basic strategic process that any firm goes through begins with a vision statement, and continues on through objectives, internal and external analysis, strategic choices (at both small business levels), and strategic implementation. Competitiveness of tactics increases from upper left (uncompetitive) to lower right (sustainably competitive) as related to long-term success.⁴³

SWOT Analysis

A SWOT analysis is a strategic planning method used to evaluate the Strengths, Weaknesses, Opportunities, and Threats involved in a project or business venture. Industry clusters or regional economies also utilize SWOT. Strengths and Weaknesses pertain to internal dimensions of the organization/industry while Opportunities and Threats assess external dimensions.

Strengths	Weaknesses
 Diversified manufacturing (production for other industries) Mature technology Relative workforce stability Six institutions of higher education Access to major U.S. and Interstate Highways 	 Low scale of production Poor high-speed broadband connectivity Expensive logistics Child care shortages Expensive workforce housing Lack of interconnectedness with other manufacturers (low synergy) Limited access to capital Limited access to qualified labor
Opportunities	Threats
 Location/proximity to MDM hub Changing demographics Consolidation Pooled logistics/procurement 	 Low barriers to entry Global competition Large buyers dominate industry Many substitutes for inputs

Table 9: SWOT analysis of MDM supply chain growth for Region Nine



Strengths

Local participants in the MDM supply chain often produce a variety of products and services. Many firms consider themselves commodities producers, which happen to sell some of their product to MDM companies. They also sell into other industries such as agriculture, consumer products, and electronics. Although some specialization exists, particularly with respect to research laboratories and specialized service providers, most derive significant revenue from other industries and segments of the economy. This form of customer diversification diminishes their sensitivity to demand fluctuations within a particular industry.

Many of the organizations have been in existence for several decades and have acquired technology over time, which allows them to adapt to purchase orders without incurring significant capital investments. Some of the plants have developed or acquired technology to easily accommodate flexible production schedules.

Region Nine has maintained a relatively stable workforce and many of the local MDM producers experience relatively low turnover. An experienced and qualified workforce should be considered a strength in an economy where turnover is costly.

Likewise, the region is home to six institutions of higher learning, including the largest university in the Minnesota State system:

- One state university Minnesota State University
- Four private colleges Bethany Lutheran College, Gustavus Adolphus College, Martin Luther College, and Rasmussen College
- One technical and community colleges South Central College

Weaknesses

Low Scale of Production:

Few regional plants are producing at a scale that compares to global competitors. Also, their business strengths in product diversity simultaneously diminish their attractiveness to larger MDM companies. In other words, most regional firms cannot achieve the economies of scale necessary to meet preferred supplier status among larger players in the MDM industry. While some of the producers have the ability to produce at a higher rate, and thereby reduce the average unit price, many firms lack the capital required to significantly increase production and reduce time from design-to-product. Others face geographic limitations when it comes to expansion. For example, some plants are located in older industrial parks and are unable to expand.

Poor Broadband Connectivity:

Broadband connectivity throughout Region Nine ranks among the worst in the State of Minnesota. While some incorporated city centers have access to broadband speeds of at least 100 Mbps download by 10 Mbps upload, coverage throughout many cities is varied and inconsistent. Future development in MDM and other industries will require significant investment in this basic infrastructural component.

Expensive Logistics:

There are few indications that producers of similar products within the boundaries of Region Nine utilize pooled logistics channels. This significantly increases procurement costs, which again puts them at a disadvantage in the MDM industry. Similarly, there is no indication that producers in Region Nine pool together to create leveraged purchasing power. Whereas competitors often collaborate to keep logistics and materials costs down, there is little indication that this is the norm within the region.

Many producers find it difficult to locate qualified labor. Although the region is experiencing relative workforce stability compared to other regions in the state or elsewhere, technical skills appear to be difficult to come by. Welders, electricians, and machine operators are in high demand, and firms producing for the MDM industry are experiencing similar challenges as colleagues in other parts of the state where candidates with technical training are in short supply.

Child Care Shortages:

Adding to the problem of locating qualified labor is the prominent problem of child care shortages and child care deserts within the region. A child care desert is any census tract with more than 50 children under age of 5 that contains either no providers or so few options that there are more than three times as many children as licensed child care slots.

Six of the nine counties in Region Nine have at least one census tract that meet the criteria for a child care desert, including one tract with zero providers, despite having a total population of 1,804 residents.⁴⁴

Housing/Poverty:

Housing is another issue identified as a weakness within the region. Nearly 48.6% of households in Blue Earth County spend more than 30% of their household income on housing costs. Residents in Martin and Nicollet counties also have more than 40% of households spending more than 30% of household income on housing. The seven other counties fluctuate between 31-39%. Le Sueur County has the highest median monthly mortgage cost of \$1,422, which is nearly as high as the national average, \$1,491.

Housing costs must be		Blue Earth	Faribault	Le Sueur	Martin	Brown	Nicollet	Sibley	Watonwan	Waseca	Region Nine	U.S.
considered up against	White	16.4%	12.4%	8.0%	11.5%	7.6%	10.3%	9.4%	11.0%	6.7%	11.3%	12.4%
poverty levels in the region. Whereas 16.4% (U.S. average:	Black or African American	51.3%	0.0%	86.9%	27.3%	68.4%	48.9%	29.5%	91.4%	65.6%	54.2%	26.2%
12.4%) of white people fall below the poverty line in	American Indian	22.2%	n/a	17.2%	50.0%	6.4%	57.7%	0.0%	22.7%	0.0%	23.3%	27.6%
Blue Farth County F1 20	Asian alone	26.5%	48.9%	0.0%	10.5%	1.4%	12.5%	53.6%	1.5%	14.0%	20.2%	12.3%
of African Americans in the	Native Hawaiian 8 Oceanic	0.0%	n/a	0.0%	0.0%	0.0%	n/a	33.3%	n/a	n/a	3.3%	20.1%
differences are even more	Some othe race	r 39.8%	23.1%	6.7%	84.8%	28.6%	12.1%	15.3%	16.6%	13.7%	19.3%	25.4%
pronounced in Le Sueur and Watonwan counties,	Two or more races	<mark>39.3%</mark>	10.4%	8.2%	9.4%	21.2%	29.7%	0.0%	0.0%	<mark>6.0%</mark>	24.6%	19.3%
where 8.0% and 11.0% of white people live below the	Hispanic or Latino	36.2%	37.7%	29.6%	28.9%	19.3%	13.5%	31.7%	20.5%	11.4%	25.6%	23.4%
poverty level respectively, compared to 86.9% and	Non- Hispanic/ Latino	15.9%	10.8%	6.7%	10.9%	7.3%	10.1%	7.5%	8.5%	6.6%	10.6%	10.6%

91.4% of African Americans. Similar discrepancies exist in *U.S. Department of Commerce and U.S. Census Bureau's American Community Survey Office.* Brown and Waseca counties. Hence, the need for affordable housing for all people should be considered a dire need within the region in order to support economic development. Although initiatives to provide affordable housing exist within RNDC, these grave disparities combined with relatively high mortgage costs in relationship to household income, manufacturers within the region may be challenged to attract workers from the entire regional population.

⁴⁴ Center for American Progress

Lack of Industry Synergy:

Unlike industry trends that indicate that producers increasingly collaborate to meet the demand of buyers, few instances of such arrangements appear to be common within the region. This lack of interconnectedness generates low synergy, which is viewed as critical in an industry where collaboration and lean manufacturing quickly becomes the norm.

Poor Access to Capital:

Businesses and entrepreneurs have limited access to capital. Local, regional, and national banks meet the basic funding needs of most regional small businesses. However, this analysis was unable to identify any venture capital funding or collaborative funding sources that can help nurture innovative products and services. In the Twin Cities metro area, dozens of venture capital firms both publicly traded and private exist primarily to fund medical innovation. However, they reported being unaware of companies or activities in Region Nine that could benefit entrepreneurs and innovators. This, despite both Minnesota State University, Manakto and its Center for Business and Entrepreneurship.

Opportunities

Producers in Region Nine are located in short proximity to the Medical Technology hub in the Twin Cities of Minneapolis and St. Paul and the medical center in Rochester. The Twin Cities are generally considered one of the three major MDM hubs in the nation. Large research and production centers are therefore within a one to two-hour drive for most of these producers. Several of the largest MDM manufacturers operate plants in the Twin Cities and contract out large portions of their production. Hence, partnerships with these firms would be both beneficial and natural due to the geographic proximity.

Consumer demand for MDM products appear to be on the rise and is projected to keep growing both domestically and globally. As the North American and European markets (the two largest MDM markets) grow older, the demand for medical technology will continue to grow with older populations and lifestyle related illnesses and conditions.

There are multiple opportunities for producers within the MDM industry, and for firms contributing commodity products to the industry, to consolidate operations and take advantage of cost savings. As the industry grows and technology evolves, the demand for consolidation, or at least cooperation, from the ten largest MDM producers appear to become more pressing. Opportunities to share production costs and possibly manage labor issues present themselves if firms collaborate to a greater extent than they do today.

As many of the firms produce products of a similar nature, there are opportunities to purchase collectively in order to reduce costs. This would not only reduce production costs, but possibly also inbound logistics costs. Similarly, pooled outbound logistics to the Twin Cities would contribute to the lean trend that is becoming the norm within the industry. These producers have a unique opportunity to provide just in time inventory due to their geographic proximity to major producers and their plants.

Threats

The MDM industry, although driven by innovation and new technology, is very much commodity based. The great majority MDM producers contribute materials or components for the use in final products. Hence, barriers to entry are relatively low and competition tends to be based on cost reduction. The threat of new entrants, both domestically and globally, contribute to a concentration of patents in the largest firms, while most of the producers compete as contractors.

Global competition has increased dramatically over the last decade. Off-shoring of production is the norm, and most of the larger producers source globally. Many of them operate plants worldwide, and with increased shipping speeds it is possible to supply parts or finished products internationally within a short amount of time.

Although most of the companies in the MDM industry are small, the larger firms dominate the revenue side of the industry. Whereas 83% of U.S. MDM companies had less than \$1 million in assets and 95% had less than \$10 million in assets, the top 1% of firms in the MDM industry accounted for 82% of total assets, with the top 0.2% of firms accounting for 56% of assets.⁴⁵ Globally, the ten largest MDM companies (eight of them being U.S. based) combined for \$160.3 billion of the industry's revenue in 2015. In other words, the concentration of capital is very high, which yields significant market power over other producers and contract manufacturers.

Much of the MDM industry is based on commodity-based production. Hence, potential substitutes generate intense price competition, which can lower revenue. Additionally, bringing a product to market is costly, particularly from a marketing perspective, so small producers are often forced to sell their patents, generate a niche market, or become contract manufacturers. This increased market concentration does not appear to be slowing down and may indicate a significant threat to small producers.



Regional Input-Output Modeling System (RIMS-II) Analysis

Regional Input-Output Modeling System (RIMS-II) system is a tool used by investors, planners, and public servants to assess the potential economic impacts of projects. The system is compiled and managed by the Bureau of Economic Analysis (BEA) of the U.S. Department of Commerce. Data are based on a series of national input-output (I-O) accounts, which show the goods and services produced by each industry and the use of these goods and services by both industry and final users. Like most regional I-O models, RIMS-II adjusts these national relationships to account for regional supply conditions.

The idea behind the results of RIMS-II is that an initial change in one economic sector results in other rounds of spending—for example, building a new road will lead to increased production of asphalt and concrete. The increased production of these commodities will lead to more mining. Workers benefiting from these increases will presumably spend more on other goods, services, and housing. Examples include eating at regional restaurants, spending more on entertainment, engaging in home improvements, etc.

Multipliers Selected and Rationale

RIMS-II multipliers apply to a wide range of projects. These include government/infrastructure, economic development/business investment, and private industry/for-profit growth. Some common examples include local impacts of government investment in specific industries and assessment of transportation and infrastructural projects. In the private sector, examples include assessment of new construction of hotels, grocery stores, manufacturers, etc.

For the purposes of this project, RIMS-II multipliers were utilized through the lens of economic development as it applies to companies producing goods and services related to the medical device supply chain.

Value-added (Gross Domestic Products) Analysis

The Bureau of Economic Analysis considers regional value-added outputs to be a surrogate for increased GDP in the geographic area for which they are provided. Larger value-added multipliers correlate with greater increases in regional GDP. Because increases to GDP are widely viewed as favorable indicators for robust economic health and stable growth, the first analysis was performed on the highest-ranking value-added industries related to MDM

in Region Nine.

Among these industries, all five offer a 65% or greater increase in regional GDP. In other words, for every dollar invested in these top five industries, total GDP in Region Nine increases by \$1.65 or more.

		value auueu
Rank	Industry	impact multiplier
1	Customized computer programming services	0.7629
2	Specialized design services	0.7580
3	Medical and diagnostic laboratories	0.7117
4	Pharmaceutical preparation manufacturing	0.6948
5	Medicinal and botanical manufacturing	0.6523

Table 11. The top five value-added industries related to MDM, in order of impact magnitude on regional GDP. Source: Bureau of Economic Analysis

A noteworthy finding in this exercise

is that 16 different industries, across a diverse spectrum of employment-skill levels and service-product offerings, deliver a 50% or greater return on initial investment. Furthermore, many of these top 16 industries are active and well-established within Region Nine. Examples include dental laboratories, both truck and rail transportation, printed circuit assembly, scientific research and development services, and printed circuit assembly.

Forecasts to changes in GDP include downstream impacts on other industries and calculate an overall impact based on dollar-value input. Scenarios in which these final-demand multipliers are applied offer an estimate of the total impact across all industries in the region. The multipliers are unable to forecast the degree to which investments in one industry will affect microeconomic changes to other related industries rather, the multiplier offers a macro perspective for the entire region. Output is the sum of intermediate and downstream change, in addition to taxes on production and imports of gross operating surplus.

Recommendation: Concentrate business development efforts around those industries with the largest value-added impact factors.

Employment Analysis for Region Nine

According to the Bureau of Economic Analysis (BEA), RIMS-II employment multipliers should be applied with caution because the system is unable to distinguish between full-time and part-time job creation. Industries that hire disproportionate numbers of part-time workers, therefore, tend to rank higher on job-creation lists than industries staffed predominantly by full-time employees.

For example, RIMS-II cites "performing arts companies" as the largest dollar-for-dollar job creator in Region Nine, with nearly 37 new jobs created per \$1 million invested. By contrast, the lowest-ranked employment multiplier, natural gas distribution, creates an estimated 2.3 jobs in Region Nine per \$1 million invested.

Following the "performing arts companies" example: the BEA classifies this industry as "businesses engaged in producing or organizing and promoting live presentations involving the performances of actors and actresses, singers, dancers, musical groups and artists, athletes and other entertainers, including independent (freelance) entertainers, and the businesses that manage their careers." Examples include agents, event promoters, live performances, circuses, theater and performing arts companies, racetracks, and others.⁴⁶

Presumably, many of these jobs are either temporary, part-time, or both. Additionally, the RIMS-II system assumes unlimited labor supply and cannot account for worker shortages and regional competition among different industries from a limited pool of employees.

Despite these deficiencies, the authors consider an employment-specific analysis to be an essential component of this evaluation. Findings presented here should be interpreted in the context of a highly competitive labor market in which workers are scarce across all skill levels and compensation tiers.

		Jobs created per \$1 million USD		
Rank	Industry	investment		
1	Specialized design services	13.7470		
2	Dental laboratories	10.9704		
	Optical instrument and lens	08.1415		
3	Manufacturing			
4	Medical and diagnostic laboratories	07.6913		
5	Truck transportation	07.1408		

Within Region Nine, none of the top 10 overall job creators include industries participating in the medical device

Table 12. Top five MDM industries for job creation in Region Nine.47

supply chain. Nine of these top 10 are services—the exception being "fruit and tree nut farming." This is consistent with the national trend toward a service-based economy.

 ⁴⁶ https://www.bea.gov/industry/pdf/2012_industry_code_guide.pdf. Accessed on 5/29/2018.
 ⁴⁷ Bureau of Economic Analysis.

Application of final demand multipliers requires careful consideration of scope of investment to obtain accurate results. Finaldemand employment multipliers return the number of new jobs expected to be created for every \$1 million invested in a particular industry. Absent from the multipliers are the inherent interdependences among industries and competition for labor among and between industries.

	Jobs created per Estimated ratio		
	\$1 million	of full-time to	
Industry	investment	total jobs*	
Performing arts companies	36.9132	0.82	
Other educational services	28.9876	0.85	
Fruit and tree nut farming	26.6058	0.86	
Civic, social, professional, and similar organizations	24.6781	0.85	
Personal care services	23.3811	0.85	
Promoters of performing arts and sports and agents for public figures	23.2624	0.82	
Child care services	21.8245	0.85	
Individual and family services	21.7799	0.92	
Transit and ground passenger transportation (excluding trucking)	21.1846	0.94	
Elementary and secondary schools	20.0063	0.77	
	Industry Performing arts companies Other educational services Fruit and tree nut farming Civic, social, professional, and similar organizations Personal care services Promoters of performing arts and sports and agents for public figures Child care services Individual and family services Transit and ground passenger transportation (excluding trucking) Elementary and secondary schools	Jobs created pIndustryinvestmentPerforming arts companies36.9132Other educational services28.9876Fruit and tree nut farming26.6058Civic, social, professional, and similar24.6781organizations23.3811Personal care services23.3811Promoters of performing arts and sports21.8245Individual and family services21.7799Transit and ground passenger21.1846transportation (excluding trucking)20.0063	

Table 13. Top ten job creation industries in Region Nine. Note that the BEA does not separate full-time and parttime employment in this analysis. Therefore, many high-creation industries include part-time and seasonal labor. Examples include performing arts, farming, promoters, ground livery services, and others.^{48,49}

For example, a \$10 million investment in the

"specialized design services" industry could be expected to create roughly 137 new jobs—both part-time and full-time. This analysis does not, however, account for competition for the same employees among different industries, and interdependent pressures among related industries for growth.

The 137 new positions created in the "specialized design services" industry could realistically be expected to apply pressure to existing employers to increase compensation and fringe packages to retain workers. Furthermore, well-documented current worker shortages would presumably introduce hiring challenges to companies seeking returns on private investment

		Employees [Thousands]			
		25		Ratio of full-	
Rank	Industry	Total	Full-time	time to total	
1	Electrical equipment, appliances, and components	381	376	0.9869	
2	Computer and electronic products	1048	1033	0.9857	
3	Plastics and rubber products	702	689	0.9815	
4	Fabricated metal products	1420	1387	0.9768	
5	Primary metals	375	366	0.9760	

Table 14. Top five MDM-related industries ranked by ratio of full-time to total employees. Higher ratios mean more full-time employment, while lower ratios mean more of the staff are hired on a part-time or temporary basis. National level data are presented here, as RIMS-II does not aggregate these data at the local level. Note that all of the top five MDM-related industries are active throughout Region Nine.

Recommendation: Focus job creation strategies around businesses that have higher full-time ratios, but consider the implications of attracting and retaining full-time workers in the highly competitive employment market.

While job creation should remain a core component of any public investment initiative, job growth in the MDM industry should be tempered and sustainably paced to accommodate current labor shortages and within the context of full-time vs. part-time employees.

Furthermore, ideal job-growth initiatives in any regional industry should be shaped to maximize employment at existing firms for a synergistic growth effect, rather than at a detriment to current employers.

Recommendation: Establish advisory panel of regional employers and educators to hedge job creation against excessive labor shortages and competition for workers.

⁴⁸ Bureau of Economic Analysis.

⁴⁹ Higher ratios mean more full-time employment in the industry nationwide, while lower ratios signal higher numbers of part-time workers.

Case Studies

The three leading MDM clusters by manufacturing density (not volume) are Flagstaff, Arizona; San Angelo, Texas; and South Bend, Indiana. The location quotients, or the measure of its relative size to the national average, were 37.80 (Flagstaff), 9.08 (San Angelo), and 5.81 (South Bend) in 2015. This means that Flagstaff's concentration of MDM production is nearly 38 times the national average. As each of these, possibly with the exception of South Bend, are located further from the three major MDM hubs on the west and east coasts, and in the upper Midwest than the firms in region nine locally, short case studies of these areas are intended to illustrate how these small towns developed high-density MDM production within the area. Below are some specifics about two of these clusters. Flagstaff's growth was specifically linked to one company locating a plant in town, while South Bend's growth is more closely linked to regional efforts and synergy with many other efforts at the state level.



Figure 21. Location quotients of top 20 MDM regions by relative density, compared to the national average. In Flagstaff, Arizona, production density is nearly 38 times the national average production density. Multipliers represent per-capita MDM times the national average.

Flagstaff, Arizona

Flagstaff is today the city in the United States with the highest location quotient with respect to MDM employment at 37.9 (i.e., 37.9 times the national average). Second on the list is San Angelo, Texas at 9.7. In other words, the impact of bringing a large MDM company to the area has had significant impact upon employment opportunities as they relate to MDM.

When W. L. Gore & Associates, Inc. (Gore) began operations in Flagstaff in 1967, the town was a relatively modest college town approximately two and a half hours drive from Phoenix. At the time, Flagstaff's population was roughly 20,000, and there were few large employers in the area. Fifty years later Flagstaff, with a population of approximately 70,000, is now home to roughly 2,000 Gore associates across 11 plants, making up Gore's thriving Medical Products Division headquarters.

Gore opened its first plant to manufacture electronic products for the computer and aerospace industries. In the 1970s, the focus shifted to the medical industry with Gore's first medical product, a vascular graft that entered the market in 1975. Since then, Flagstaff has been the birthplace of advanced treatment options for a variety of complex medical conditions, including heart defects, aortic aneurysms and peripheral artery disease, among others. Their Flagstaff location remains the home base of Gore's global Medical Products Division. Gore today is the city's largest private employer and a significant presence in the community.⁵⁰

Gore's strong growth within the MDM industry, has also contributed to great benefits for other business ventures in the area. Noteworthy examples include the Northern Arizona Center for Entrepreneurship and Technology (NACET) which is currently pivoting away from businesses incubation to recruitment of next-generation entrepreneurs.⁵¹

South Bend, Indiana

Indiana has been recognized as a national leader in the life sciences sector employment, and multiple regions of the state have sizeable employment in the related industries of drugs and pharmaceuticals and medical devices and equipment. The cities of Bloomington, Evansville, Indianapolis, Lafayette, Michigan City, South Bend and Terre Haute have generated strong clusters within the MDM industry.

Over the last decade, the state of Indiana has become a national leader, especially when it comes to employment, industry concentration and patents in the MDM industry. Notably, South Bend boasts the third-highest MDM quotient in the entire United States. This MDM cluster encompasses everything from research and development to manufacturing and distribution.

The success is attributed to collaborative efforts by BioCrossroads (www.biocrossroads.com), an organization dedicated to serve as a catalyst for the continued growth of Indiana's robust life sciences industry, the regional companies, and academic institutions, all in an effort to generate unique collaborations aimed to help fuel the advancement of the industry regionally.

Whereas the Bloomington MSA has been the number one small MSA (total private employment less than 75,000) in the Medical Devices and Equipment category for specialized employment concentration for the last three years, the South Bend-Mishawaka MSA ranks high in the "Research, Testing and Medical Laboratories" sub-sector. The type of collaborative initiatives found in South Bend has catapulted this region of Indiana to be a national leader when it comes to employment, industry concentration and patents.⁵²

⁵⁰ http://www.flagstaffbusinessnews.com/w-l-gore-associates-celebrating-50-years-flagstaff/

 ⁵¹ http://www.flagstaffbusinessnews.com/nacet-encouraging-tomorrows-entrepreneurs-shoot-stars/
 ⁵² http://www.tribstar.com/news/business_news/indiana-life-sciences-industry-maintains-national-top-ranking/article_b1e8445c-267a-57db-a861-813d4710b12a.html

Blacksburg, Virginia

The Blacksburg incubator "Tech Corridor" is concentrated around Virginia Tech and the VT Corporate Research Center. Many offshoots of this original hub for accelerating start-ups have since been established, and several companies and organizations now provide mentorship, education, and networking with potential investors for entrepreneurs. Blacksburg has also partnered with Roanoke and Northern Virginia regions to commit to growing its accelerator capabilities. The area has also focused specifically on high-tech and life science industries. This narrow focus creates a unique atmosphere and culture specifically qualified to nurture and maintain start-ups in technology fields rather than other sectors.

Funding start-ups is one of the biggest challenges business incubators face because a lack of venture capital causes start-ups to relocate and potential investors in the area to look elsewhere for investment opportunities. Several business accelerators in Blacksburg and the surrounding area try to foster investor networks and resources for start-ups so they can find the venture capital they need to continue growing. Access to this capital will be a deciding factor in the continued success of the Blacksburg incubator compared to other much larger incubators, such as San Francisco.

StartUp! Virginia is a statewide non-profit located in Richmond that works to connect start-ups in the state with mentors and investors. More narrowly focused on the Blacksburg area, VT Knowledgeworks seeks to connect start-ups with mentors and investors and a partnership between VT and Carilion Clinic. One challenge is maintaining a large enough venture capital fund for start-ups across its incubator network. Additionally, the region has experienced loss of high tech companies to larger incubators elsewhere in the country (e.g. San Francisco) so maintaining start-ups once they become successful is a long-term challenge to manage.

Urbana-Champaign, Illinois

Named as one of *Inc. Magazine's* "Top 3 College Town Incubators" and as one of *Forbe's* "12 Business Incubators Changing the World," EnterpriseWorks is an incubator facility and resource center for science and technology focused entrepreneurs. EnterpriseWorks is owned and operated by the University of Illinois to help launch successful start-up companies. The 43,000 square foot facility is at the heart of the Research Park's community building efforts. Its clients span from biotechnology and chemical sciences, software development and materials sciences. Through the commercialization of leading research from across the University of Illinois, its start-ups are working to "address challenges with transformative results."

The Research Park and EnterpriseWorks have fostered many strong partnerships: smaller businesses can work side by side with established Fortune 500 companies within the park. EnterpriseWorks provides events, training, and technical assistance to aspiring entrepreneurs. The more well-established companies also provide internship and mentorship opportunities for University students.



Recommendations and Future Studies

There are several practical implications associated with how regional MDM producers operate as there are significant differences in how these firms align themselves with the MDM hub in the Twin Cities and the medical hub in Rochester. As some of the organizations operate in multiple product and geographic markets, generalizable recommendations that can be applied to all firms would therefore be inappropriate. However, below are some recommendations that may be helpful based on the analyses performed as part of this study.

Regional Level

• Investments in Broadband Infrastructure

Region Nine needs major investments in broadband infrastructure if the region hopes to attract larger MDM producers. Larger MDM producers have made it clear that there are two prerequisites that need to be met for them to open plants or logistics channels in a region: direct transportation to port and redundant broadband infrastructure. The region meets one of the requirements, transportation. RNDC counties have relatively quick access to the Minneapolis-St Paul Airport via highway 169 and Interstate 35. Broadband service is, however, not up to par. Broadband infrastructure would have to improve significantly to attract any major MDM producers.

• Investments in Technical Training and Talent Retention

Although the region enjoys low unemployment and relatively stable workforce conditions, manufacturers have raised concerns about the access to qualified labor skills within the region. Electricians, machine operators, welders, and engineers are in high demand, but the supply is limited, which hinders expansion for many of the firms interviewed for this study. Many entities are doing a phenomenal job of retaining and attracting talented workers to the region, but there appears to be a mismatch when it comes to the skillsets needed for manufacturing industries to thrive. This may have to be viewed as a holistic issue where resources are used to present the region as a thriving community, but also down to the high school level and career counseling.

• Investments in Workforce Housing

Affordable housing has also been identified as a need for industrial growth to take place. Although the region enjoys relatively modest housing and living costs compare to the Twin Cities, many of the communities within the region would need significant investments in workforce housing if larger plants opened up. Larger employers look to the housing situation in a community as an indicator of a community's "readiness" for large investments in employment. Also, relatively large discrepancies in income and wealth between various populations within the region suggest that not everyone have access to adequate housing in the current market.

• Investments in Child Care Opportunities

The region struggles, as do many other areas in the state, with child care shortages. Region Nine is in dire need of more child care openings and the importance of such opportunities for working families has been well documented.

• Diversify Workforce/Opportunities for "Newcomers"

It appears to be critically important for the region to integrate immigrants and new residents into the workforce. Technical training opportunities, apprenticeships, and other ways of reaching new residents will become critically important as the region's demographics are changing. The larger MDM producers emphasized that it is important that a region presents itself as diverse and welcoming to new cultures as they draw heavily on labor from around the world and that they expect communities to embrace diversity.

Corporate Level

Firms would benefit from the development of operations strategies and capabilities that specifically target the MDM industry. This could improve the organizations' abilities to respond to industry and demand changes as it would allow them to match their overarching strategies with specific market conditions. This study had revealed that large MDM producers look for "preferred" manufacturers that can contribute specialized manufacturing that is too costly to do in-house.

Firm-level strategies that are formulated to meet MDM demands should not be solely based on production capacity but should also be based on specific market conditions. The MDM industry is growing increasingly concentrated, and the larger companies are increasingly looking for strategic partnerships to outsource product concept and development, the delivery to end consumers, etc.

Consolidation of operations could increase economies of scale and make smaller producers within the region more competitive. Such strategic arrangements may also allow local manufacturers to expand their capabilities jointly and become more attractive as potential strategic partners for organizations in the Twin Cities/Rochester areas.

Organizational Level

Based on the findings from this study, it appears to be critical for organizations to invest in system capabilities to facilitate MDM market specific forecasts. This would require investments in both lower level (e.g., product specific) and higher level (e.g., industry specific) data and tools needed to effectively monitor such changes. This may be too costly for the individual firm, so it would make sense for regional companies to pool resources and establish a regional resource or research center. Rather than having individual plants and organizations generate their own processes, organizations could develop system and organizational infrastructures that enhance the sharing of information so that required higher level forecasts can be generated and facilitate sound strategy formulation within each organization. This would allow for meaningful comparisons between different product markets and enable management to objectively evaluate investment opportunities in current and potential markets. With better tools to work with, managers may also reduce the amount of time they spend on market monitoring activities. Without sufficient resources, many organizations within the region appear to abandon forecasting efforts and instead rely on ad hoc approaches without an overarching strategy to align themselves with the larger industry and nearby clusters.

The findings suggest that production efficiency is enhanced if operations are strategically positioned to meet demand fluctuations and overall industry changes, and that production plans are generated based on these changes. However, this appears to be difficult for some of the smaller firms, as they have no direct link to the Twin Cities hub. With sufficient information sharing, each of the firms, typically producing different parts/products, should be able to more effectively respond to demand changes.



The challenges for many of the local organizations are associated with linking the overall organizational strategy with industry changes. It is simply too costly for these organizations to keep track of these changes and access data. Looking to research/resource centers in other rural areas, developing a cooperative arrangement that monitor changes, is one of many benefits of such centers. This would allow the individual organizations to develop process congruity where each organization is in a better equipped to adjust production systems in a timely and efficient manner.

Accessing adequate labor is another issue that regional resource or research centers could address. Research and case studies from other regions suggest that clusters of firms that pool resources are more likely to attract qualified labor. As many of the regional firms appear to struggle with this issue, it would benefit all if there was a unified organization that would actively recruit such talent.

A corporate resource/research center would also be able to work with local secondary schools, colleges, and vocational training institutions to market opportunities within the respective industries to potential students. The research centers in Blacksburg, Virgina and in Urbana, Illinois, have successfully partnered with not only Virginia Tech and the University of Illinois, but also with a number of other education institutions to strengthen the entrepreneurial and corporate efforts in their respective areas. Both centers are located geographically further away from major economic hubs than most locations within Region Nine, and each started as relatively modest efforts to address challenges for local businesses.

	Market Monitoring	Process/ Production Plan
Regional Resource/ Research Center	Yes	No
Individual Plant/ Organization	No	Yes

Table 15. The need for market monitoring and process congruity.

		Hiring/Talent
	Industry Advocates	Development
Regional Resource/	Yes	No
Research Center		
Individual	No	Yes
Plant/Organization		

Table 16. Shared efforts to identify and access qualified labor.

A key aspect of the clusters examined through the case studies and the corporate research/ entrepreneurial centers are the close ties that have been established between industry and academic communities at the large research universities nearby. Most of the firms in Region Nine are contract manufacturers and little innovation is taking place. As a result, these firms are dependent upon contracts with the large manufacturers, and few of them bring new products to the market. Research/resource centers could enhance entrepreneurial innovation in the area and thereby broaden the scope of MDM activity within the region.

Appendices

- 49 Tables
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Blue Earth

Brown

Faribault

Le Sueur

Martin

Nicollet Sibley

Waseca

Watonwan

58 Definitions and Acronyms



Tables

Title	Code	Common Keywords		
Cut and Sew Apparel Contractors	315210	Coats, non-tailored service apparel (e.g., laboratory, medical, mechanics'), cut and sew apparel contractors		
Men's and Boys' Cut and Sew Apparel Manufacturing	315220	Hospital service apparel, washable, men's and boys', cut and sewn from purchased fabric (except apparel contractors)		
Women's, Girls', and Infants' Cut and Sew Apparel Manufacturing	315240	Hospital service apparel, washable, women's and girls', cut and sewn from purchased fabric (except apparel contractors)		
Other Cut and Sew Apparel Manufacturing	315280	Gowns, hospital, surgical and patient, cut and sewn from purchased fabric (except apparel contractors)		
Medicinal and Botanical Manufacturing	325411	Enzyme proteins (i.e., basic synthetic chemicals), pharmaceutical use, manufacturing		
Pharmaceutical Preparation Manufacturing	325412	Cough medicines manufacturing		
Other Pressed and Blown Glass and Glassware Manufacturing	327212	Medical glassware made in glass making plants		
Glass Product Manufacturing Made of Purchased Glass	327215	Medical glassware made from purchased glass		
Electromedical and Electrotherapeutic Apparatus Manufacturing	334510	Audiological equipment, electromedical, manufacturing		
Analytical Laboratory Instrument Manufacturing	334516	Magnetic resonance imaging (MRI) type apparatus (except medical diagnostic) manufacturing		
Irradiation Apparatus Manufacturing	334517	Irradiation apparatus and tubes (e.g., industrial, medical diagnostic, medical therapeutic, research, scientific), manufacturing		
Surgical and Medical Instrument Manufacturing	339112	Bronchoscopes (except electromedical) manufacturing		
Surgical Appliance and Supplies Manufacturing	339113	Adhesive tape, medical, manufacturing		
Dental Equipment and Supplies Manufacturing	339114	Abrasive points, wheels and disks, dental, manufacturing		
Ophthalmic Goods Manufacturing	339115	Contact lens manufacturing		
Dental Laboratories	339116	Bridges, custom made in dental laboratories		
Testing Laboratories	541380	Biological (except medical, veterinary) testing laboratories or services		
Graphic Design Services	541430	Artists, independent medical		
Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)	541715	Medical research and development laboratories or services (except biotechnology and nanotechnology research and development)		
Hazardous Waste Treatment and Disposal	562211	Medical waste treatment facilities, hazardous		
Medical Laboratories	621511	Bacteriological laboratories, diagnostic		
Other Electronic and Precision Equipment Repair and Maintenance	811219	Medical and surgical equipment repair and maintenance services		

Table 19. NAICS Codes used in comprehensive search.

Industry	Final-demand value- added impact factor
Custom computer programming services	0.7629
Specialized design services	0.758
Medical and diagnostic laboratories	0.7117
Pharmaceutical preparation manufacturing	0.6948
Medicinal and botanical manufacturing	0.6523
Other electronic component manufacturing	0.652
Dental laboratories	0.6506
Relay and industrial control manufacturing	0.6348
Wiring device manufacturing	0.6326
Rail transportation	0.6265
Special tool, die, jig, and fixture manufacturing	0.6149
Optical instrument and lens manufacturing	0.5893
Truck transportation	0.5773
Scientific research and development services	0.5669
All other miscellaneous electrical equipment and component manufacturing	0.5575
Printed circuit assembly (electronic assembly) manufacturing	0.5094
Motor and generator manufacturing	0.4926
Other plastics product manufacturing	0.4321
Plastics packaging materials and unlaminated film and sheet manufacturing	0.4291
Paperboard container manufacturing	0.3589
Communication and energy wire and cable manufacturing	0.3484
Other basic organic chemical manufacturing	0.2804
Other basic inorganic chemical manufacturing	0
Plastics material and resin manufacturing	0
Biological product (except diagnostic) manufacturing	0
Semiconductor machinery manufacturing	0
Industrial mold manufacturing	0
Semiconductor and related device manufacturing	0
Electromedical and electrotherapeutic apparatus manufacturing	0
Electricity and signal testing instruments manufacturing	0
Analytical laboratory instrument manufacturing	0
Irradiation apparatus manufacturing	0
Manufacturing and reproducing magnetic and optical media	0
Storage battery manufacturing	0
Primary battery manufacturing	0
Carbon and graphite product manufacturing	0
Surgical and medical instrument manufacturing	0
Dental equipment and supplies manufacturing	0
Ophthalmic goods manufacturing	0
Air transportation	0
Water transportation	0

Table 20. All MDM related industries in Region Nine, ranked by value-added impact factor. Source: Bureau of Economic Analysis.20All MDM-related industries in Region Nine, ranked by value-added impact factor. Source: Bureau of Economic Analysis.

Industry	Final-demand Employment /3/ (number of jobs)
	, , , ,
Specialized design services	12 7/7
Dental Jahoratories	10.9704
Ontical instrument and lens manufacturing	8 1/15
Medical and diagnostic laboratories	7 6012
	7.0913
	6.0018
Custom computer programming services	6.9918
Special tool, die, jig, and lixture manufacturing	6.0074
Other electronic component manufacturing	6.0724
Relay and industrial control manufacturing	5.1523
All other miscellaneous electrical equipment and component manufacturing	4.8381
Printed circuit assembly (electronic assembly) manufacturing	4.5108
Scientific research and development services	4.3489
Wiring device manufacturing	4.3425
Other plastics product manufacturing	4.1208
Paperboard container manufacturing	3.6555
Plastics packaging materials and unlaminated film and sheet manufacturing	3.4834
Motor and generator manufacturing	3.4208
Rail transportation	3.3082
Other basic organic chemical manufacturing	3.0712
Medicinal and botanical manufacturing	3.0573
Pharmaceutical preparation manufacturing	3.0095
Communication and energy wire and cable manufacturing	2.8873
Other basic inorganic chemical manufacturing	0
Plastics material and resin manufacturing	0
Biological product (except diagnostic) manufacturing	0
Semiconductor machinery manufacturing	0
Industrial mold manufacturing	0
Semiconductor and related device manufacturing	0
Electromedical and electrotherapeutic apparatus manufacturing	0
Electricity and signal testing instruments manufacturing	0
Analytical laboratory instrument manufacturing	0
Irradiation apparatus manufacturing	0
Manufacturing and reproducing magnetic and optical media	0
Storage battery manufacturing	0
Primary battery manufacturing	0
Carbon and graphite product manufacturing	0
Surgical and medical instrument manufacturing	0
Dental equipment and supplies manufacturing	0
Ophthalmic goods manufacturing	0
Air transportation	0
Water transportation	0

		Employment [Thousands of workers]		
		Total	Full-time	Ratio of full-
Rank	Industry	employees	employees	time to total
1	Electrical equipment, appliances, and components	381	376	0.98687664
2	Computer and electronic products	1048	1033	0.985687023
3	Plastics and rubber products	702	689	0.981481481
4	Fabricated metal products	1420	1387	0.976760563
5	Primary metals	375	366	0.976
6	Paper products	370	361	0.975675676
7	Printing and related support activities	449	438	0.975501114
8	Computer systems design and related services	1989	1892	0.951231775
9	Rail transportation	189	178	0.941798942
10	Truck transportation	1484	1397	0.941374663
11	Warehousing and storage	928	873	0.940732759
12	Information and data processing services	422	396	0.938388626
13	Publishing industries (includes software)	874	799	0.914187643

Table 21. All MDM-related industries available in BEA's Full-Time and Part-Time Employees by Industry, ranked by ratio of full-time to total employees. Note these are national numbers, as the larger profiles are more reflective of employer-type trends, rather than current employer status within a region.

Employment (left) and Earnings (right) by Industry in Region Nine Counties

600



Blue Earth



Brown



-Government





Le Sueur





----Government

Employment (left) and Earnings (right) by Industry in Region Nine Counties cont.

Martin



Nicollet







Waseca



Employment (left) and Earnings (right) by Industry in Region Nine Counties cont.

Watonwan





Definitions and Acronyms

BEA- Bureau of Economic Analysis, U.S. Department of Commerce
CEDS- Comprehensive Economic Development Strategy
CRS- Congressional Research Service
DEED- Minnesota Department of Employment and Economic Development
DMC- Destination Medical Center
EDA- Economic Development Administration, U.S. Department of Commerce
MDM- Medical Device Manufacturing
MMMP- Minnesota Medical Manufacturing Partnership
MnDOT- Minnesota Department of Transportation
MSA- Metropolitan Statistical Area
NAICS- North American Industry Classification System, U.S. Census Bureau
RIMS-II Regional Input-Output Modeling System, U.S. Bureau of Economic Analysis
RNDC- Region Nine Development Commission
SMIF- Southern Minnesota Initiative Foundation



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