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Latest Medical Devices Site Selection Trends

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Introduction

This article addresses the latest site selection trends displayed by the medical devices industry. Article content embraces: industry definition; revenue and growth; geographic agglomeration; industry informational sources; key location factors; location decision making process; and concluding remarks.

Definition

According to the Food & Drug Administration (FDA) a medical device comprises an instrument, apparatus, implant, invitro reagent, or similar article whose utilization involves diagnosing, preventing, or treating diseases/medical afflictions. A medical device does not achieve its purpose via chemical action within the body: that would constitute a drug or pharmaceutical.

Medical devices cover an array of products varying greatly in complexity. Examples of more straightforward products are tongue depressors, disposable gloves, and thermometers. Among more sophisticated goods are minimally invasive surgical instruments, medical electronics, joint implants, prosthetics, anesthetics equipment, pulmonary devices, magnetic resonating equipment, and pacemakers.

Principal NAICS for the industry are shown below; NAICS Code and Description:

334510 - Electro medical & electrotherapeutic apparatus

334517 - Irradiation apparatus

333314 - Optical instruments and lens

3391 - Surgical & medical instrument including dental and ophthalmic

443450 - Medical supplies/equipment

541711 - Biotech R&D

541712 - Life Sciences R&D

Geographic Agglomeration

In the U.S. there are some 33,500 medical device facilities. Most (about 95 percent) are small-scale operations (under 100 employees.) Total industry employment is nearly one million. Among the major players within the industry are Medtronic, Boston Scientific, St. Jude, Johnson & Johnson, Stryker, Becton Dickinson, Baxter, Cardinal Health, Cook Medical, GE, Covidien, Abbott Labs, Siemens Healthcare, Danaher, and Philips Healthcare.

Geographically, the industry is diverse. Exhibits one and two list the top 20 states measured by actual employment and workforce concentration (ratio of industry to total employment). Among the leading states in both measures are CA, MA, NJ, MN, TN, PA, MD, and UT. Common traits displayed by many states with the highest industry representation are: large population, above average "baby boomer" segment of the population, educated workforce, and superior health infrastructure including medical and engineering schools.

Going forward, the industry will continue to expand throughout the U.S. On balance, companies will be searching for "value" locations. These will be characterized by moderate cost, quality workforce, and reasonable access to medical and engineering education.

Developing countries will also see a wave of fresh capacity. The preponderance of this capital investment will be to gain local market access at a favorable cost level. Among the more active offshore

countries will be China, India, Eastern Europe, Brazil, and Mexico.

There will be some offshoring (sometimes utilizing a contract manufacturer) for cost reduction reasons (i.e. going offshore to serve the U.S. market). Among the more notable destinations will be Mexico, Central America, China, and India. Down the road (most likely latter half of this decade), Africa should witness an influx of medical device manufacturing due to both market potential and cost attractiveness.

The Marketplace

This is a robust industry, growing at an 8 percent annual clip. In 2013, global revenue for the medical device sector was an estimated $280 billion. The U.S. accounts for roughly 45 percent of worldwide revenue.

The impressive growth rate should persist well into the future. Dynamics spurring growth entail the following: (a) continuously aging population in developed countries; (b) improving health care infrastructure in emerging economies; (c) the fact that most consumer spending on health is not discretionary.

R&D is vital for any company's long-term performance. On average medical devices producers spend 9-11 percent of sales on research and development. While R&D centers are not always co-located with manufacturing, the interface between these two functions is critical for bringing new products through clinical trials and into the marketplace.

Despite a sunny forecast there are some clouds on the horizon that could diminish profitability for the industry. These challenges include uncertainty over the U.S. Affordable Health Care Act, a 2.3 percent gross revenue tax likely to be imposed on U.S. based medical device companies (mandated by the Affordable Health Care Act), product recalls, unsuccessful clinical investigations, and tightening FDA regulations.

Concerning regulation, the Center for Devices and Radiological Health (CDRA) is the FDA unit responsible for medical devices. Devices sold in the U.S. are subject to General Controls (including Good Manufacturing Practices), pre-marketing, and post marketing.

Importantly, the FDA will audit most medical device manufacturing plants, including those based overseas but distributing products in the U.S. The inspection is called Good Manufacturing Compliance (GMC) which is similar to ISO 9001:2008. When building a new manufacturing facility, design standards should take into account GMC.

Given the underlying dynamics shaping the industry's future, a significant level of new manufacturing plant construction can be anticipated. The U.S. will see plenty of new location activity. Some 15 percent of this activity will emanate from foreign manufacturers siting new manufacturing capacity in the U.S. Illustrative of new facility investment by medical device producers in the U.S. are Cadence, Becton Dickinson, and Gambro.

Cadence

Becton Dickinson

Gambro

Industry International Sources

There are a fair number of trade associations, shows, and journals that provide opportunities for staying current on medical device industry trends. A sampling appears below:

Associations

- Medical Device Manufacturers Association (MDMA)
- Advanced Medical Technology Association
- Medical Imaging & Technology Alliance
- Association of Medical Device Reprocessors
- Analytical Life Science & Diagnostics Association
- Association of Medical Diagnostics Manufacturers

Shows

- MDMA, Annual Conference
- MD&M (East & West)
- Medical Devices Summit
- Med Tech World Shows
  - + Biomed Device
  - + Medical Design & Manufacturing Executive Summit
  - + Design of Implantable Devices Conference
  - + Wireless Medical Devices
- Orthopedic Manufacturing & Technology Exposition
- International Vision Expo
- FIME International Medical Exposition

Journals and Newsletters

- Medical Electronics Manufacturing Magazine
- Medical Device & Diagnostic News
- Medical Device Daily
- Medical Design Technology
- International Medical Devices Magazine
- Medical Design
- Medical Product Manufacturing News
- Journal of Medical Devices

Predominant Location Factors

Locational determinants for new medical device facilities vary by type of product manufactured. For instance, high volume/commodity oriented goods such as disposable instruments will opt for lower cost locations. Products with heavier engineering content and/or a high degree of customization will need proximity to medical/engineering schools and a highly-skilled workforce.

Wholesalers will site distribution centers close to customer agglomerations. R&D operations will gravitate to areas where there is a critical mass of requisite resources. These embody similar operations (R&D and to a lesser extent manufacturing), medical schools, engineering schools, and specific talent (e.g., biomedical engineers).

For manufacturing plants, the following criteria will often be accorded a status of important or very important.

1. Sufficient availability of experienced talent, e.g.,
    - Precision assembler
    - Instrument technician
    - Clean room technician
    - Quality assurance technician
    - Biomedical engineer
2. Excess supply of qualified entry level workers for the above positions and others such as
    - Packaging machine operator
    - Shipping/receiving clerk
    - Warehouse worker
3. Moderate labor cost (often prefer less than the U.S. average)
4. Educated workforce (above average 12-15 years and for some operations, college educated)
5. Nonunion
6. Proximity to
    - Medical schools
    - Teaching hospitals
    - Engineering schools
7. Community college with programs to support the industry (e.g., regulatory standards, wireless technologies, medical robotics)
8. Frequently a modern, vacant building which might include a Class 1000 or Class 100 clean room
9. Attractive business park with all utilities in place (dual electric power feed from two substations a plus)

10. Reliable electric power
11. Fast track construction
12. Four lane highway access
13. Within 45-60 minutes of a commercial airport
14. Array of motor carriers with local terminals
15. For some companies proximity to a small package processing hub (within 60-90 minutes)
16. Moderate taxation, especially sales and property
17. Stable state/local fiscal status
18. Meaningful incentives package such as payroll tax rebates and refundable capital investment tax credits

The Decision Making Process

Concept

When planning a new production facility for medical devices, a structured/systematic process will help ensure that the ultimate location maximizes the business unit's success potential. Pivotal elements of the multi-phase decision making process follow.

Phase One: Discovery

1. Multi-discipline team assembled
2. Key objectives stated
3. Strategic considerations addressed (e.g., outsource vs. captive manufacturing)
4. Target date for going "live" established
5. Geographic preferences (e.g., region for the initial search territory) delineated
6. Year one and future operating requirements defined
   - Labor
   - Site
   - Building
   - Utilities
   - Transportation
   - Proximities
   - Customer
   - Higher education
   - Health care cluster
   - Operating cost ceilings (e.g., labor)
7. Rules of disclosure/confidentiality agreed upon

Phase Two: Screening

1. A multiple stage process to generate a shortlist (typically three) of promising locations
2. Basic criteria (such as population size, distance to medical school, limited access four lane highway) initially applied to begin whittling the field

3. Utilizing mostly desktop research, more restrictive criteria interjected until a group of semifinalist (longlist) candidates emerges (8-12 areas), e.g.,
- Talent pool size
- Health care industry presence
- Average manufacturing wages
- Airport access
- Small package processing center
- Workforce educational attainment
- Unemployment rate

4. Additional research (e.g., outreach to economic development organizations) conducted on longlisted areas, e.g.,
- Comparable employers
- New/expanding companies
- Downsizing companies
- College graduates (e.g., biomed engineers)
- Available building
- Ready-to-go sites
- Electric power cost/reliability
- Small package pick-up/delivery hours
- Tax practices/rates
- Possible incentives

5. Longlisted areas ranked/scored (utilizing an area rating model)
- Cost factors (e.g., labor)
- Qualitative factors (e.g., talent pool depth)
- Shortlist generated

Phase Three: Selection

1. Shortlist locations subject to field-based due diligence including
- Employer interviews (including medical related)
- Other interviews (e.g., education)
- Site/building tours
- Quality-of-life tours

2. GIS mapping for sites and demographics

3. Preliminary incentives package requested

4. Shortlisted areas compared on primary factors such as:
- Labor market
- Competitive demand (by skillset)
- Availability/applicant flow (by skillset)
- Market wage levels
  + Start
  + Progression
- Future supply/cost stability
- Quality-of-life/cost of living
- National recruiting
- Recent college graduates
- Experienced talent
- Higher education support
- Health industry support
- Sites/buildings
- Characteristics
- Access
- Expansion potential
- Cost
- Utilities (especially electric power)
- Permits (especially building and environmental)
- Transportation
- Surface
- Air
- Multi-year business costs
- One-time
  + Real estate
  + Equipment
  + Human resources
  + Other (e.g., project management)
- Annual
  + Payroll
  + Occupancy
  + Transportation
  + Taxes
  + Incentives offset

5. Best long-range location tentatively selected

6. Best alternate location targeted

7. Project team expanded (e.g., design/construction, corporate affairs, project management)

8. Final real estate/incentives negotiated

9. Final due diligence on other issues conducted (e.g., legal, tax, labor commitments from medical/health care institutions)

Typically the above defined process spans a three to four month period. Another 9-12 months (perhaps longer for a more complex build-to-suit facility) would be required to enter a full production mode.

Concluding Remarks

Medical device manufacturing will continue to display impressive growth and profitability. Underlying forces shaping future buoyancy will also translate into a strong level of new facility investment. This will include both manufacturing and R&D.

The U.S. will retain its locational dominance. However, mainly to increase market share, there will be a notable amount of new production and R&D capacity established outside of the U.S. China, Brazil, and India will be major destinations.

In choosing new locations, either in the U.S. or offshore, it is essential to follow a time-tested process to ensure a favorable outcome. This requires upfront planning both for strategic and tactical parameters.

Depth and quality of workforce will be critical for making sure that a new location maximizes the facility's operational success. Similarly a quality facility/business environment will also be important. Both a building and a manufacturing process that are FDA compliant is essential. Lastly, while incentives are desirable they should be considered "icing on the cake." Operational considerations, especially human resources, will be far more important for successful performance of a company's next medical devices facility.

About the Author

Dennis J. Donovan is a Principal of Wadley Donovan Gutshaw Consulting, based in Bridgewater, (NJ). WDGC specializes in corporate site selection. Clientele have included a variety of medical device manufacturers.