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Review Article

Operations Management, and Quality Control in the U.S. Medical Device Industry

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Abstract: This abstract discusses various aspects of the medical device industry, including the need for efficient supply chain management, the importance of partnerships between suppliers and manufacturers, and the critical role of specific parts and electronic boards in the design of medical devices. The paper also addresses the concept of outsourcing in the medical device electronics industry, highlighting the hesitation of industry leaders to trust outside firms with the production of proprietary products. It emphasizes that trust is at the core of outsourcing decisions and that companies in the medical device business have the opportunity to create a business model that deserves trust. The research paper highlights the need for development firms to have confidence that quality and delivery needs are being met, and that regulatory procedures with agencies such as the Food and Drug Administration are efficiently managed.

Keywords: medical device industry, electronic boards, Food and Drug Administration

INTRODUCTION

The demand for medical devices is being impacted by the growth of the patient population, efforts to control healthcare costs and the worldwide adoption of preventative treatments.

A "medical device" is a broad term that includes a wide range of equipment, consumable and disposable items used in diagnostic imaging, clinical laboratory, critical and routine patient care, patient monitoring, and surgical procedures. It also includes equipment used for assistance in cardiovascular, orthopedic, respiratory, ophthalmic, auditory, neurology, urinary, etc. disorders, and self-care equipment. It is defined as an article, instrument, device, or machine that's used to prevent, diagnose or treat disease, or to detect, measure, restore, correct, or modify the structure or function of the body for a health purpose. Its primary mode of action is not based on pharmacological, metabolic, or immune processes. (Medical Device Product Innovation Choices in Asia: An Empirical Analysis Based on Product Space, 2022).

Operations management in a medical device company focuses on carefully managing the processes to produce and distribute medical products.

Operations management encompasses all aspects of an organization's operations, including managing purchases, inventory, quality control, storage, logistics, and evaluations. The main focus is on improving the efficiency and effectiveness of

processes, which often involves extensive measurement and analysis. The approach taken to operations management within an organization is largely dependent on the type of medical device produced by that organization.

Globalization

The US remains the largest medical device market and is a global leader in cutting-edge medical technology. Despite its dominance in the world market, its share has decreased over the past few decades, from 75% in the 1980s to 43% today.

The President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry (1998: 21) notes that "today, in America, there is no guarantee that any individual will receive high-quality care for any particular health problem." (Challenges Facing the Health System and Implications for Educational Reform, n.d.).

Western Europe is the second largest market and accounts for nearly 25 percent of the global medical device industry. In Asia, the Japanese market has the highest level of advanced medical technologies and economic development. According to IBM statistics, Japan accounts for 73% of total IT spending in the Asia Pacific region. This makes it IBM's largest healthcare market in the region, as noted by Jozef Wysen, IBM Asia Pacific Healthcare's marketing manager in Brisbane, Australia. (Payoff in the Pacific, 2011).

Countries with large populations and developing healthcare systems, such as China and India, are expected to have the highest growth potential in the medical device market. Other countries like Singapore, Malaysia, Brazil, Mexico, Chile, and Korea are also expected to experience significant growth in the market for medical disposables and equipment due to improvements in their economies and healthcare systems.

In the global economy, it is widely recognized that there is a connection between a company's competitiveness in the international market and its local roots, even if local manufacturing systems no longer play as significant a role. Nonetheless, as noted by IBM's Wysen, "the level of IT maturity varies across countries, but the issues and challenges faced by organizations are still very similar to those in the US." (Payoff in the Pacific, 2011).

Opportunities arising from new technologies and the global economy seem to favor better-equipped and large-sized enterprises rather than small suppliers (, 2022).

Competitiveness

The U.S. medical device industry has been a bright spot in an otherwise gloomy economy. The industry is marking considerable recent growth due to the aged population and product innovation.

Global demand for medical devices is growing rapidly as well. U.S. device manufacturers, with their R&D strength and high-tech devices, are well-positioned to exploit international markets. The U.S. medical device industry has blossomed into a lucrative international business and is poised for sustained long-term growth. According to a report from Mentor Corporation, a leading supplier of medical products, the medical device industry has great potential for sustained long-term growth in the coming years (2008 Johnson & Johnson Annual Report, 2009). This growth is driven by increasing demand for medical products, innovations in technology, and advances in healthcare delivery. With the advent of new technologies, such as 3D printing, the medical device industry is becoming more accessible and cost-effective, making it an attractive option for those looking for reliable, long-term investments.

The medical device industry's structure is changing due to the rise in mergers and acquisitions. Global multinational companies are joining forces to strengthen their worldwide presence.

Mergers & acquisitions have helped companies to offer end-to-end solutions in their core area of operations. The customer gets better products resulting from the consolidation of R&D spending with the option of a "one-stop shop". Additionally, the company can concentrate on value-added functions like understanding customer satisfaction, factors influencing their purchase decisions, and product development rather than doing a simple sales function (Home, n.d.).

To succeed in a constantly evolving and competitive market, players must have a clear understanding of the market environment. This includes knowledge of consumer purchasing behavior, profile, purchase decision factors, spending habits, and payment options.

Proper utilization of these tools can aid in product positioning and increase customer loyalty, especially in the aftermath of consolidation.

FDA

The food and Drug Administration is a federal agency that regulates products of food, medical device, cosmetics (such as safety and labeling), biologics (such as vaccines and blood products), Radiation-Emitting Products (such as cell

phones, microwaves, and laser) and Animal feed and drug (such as livestock and pets). Its customers and key stakeholders include American patients and consumers; healthcare professionals; regulated industry; academia; and, state, local, federal, and international governmental agencies (FDA Fiscal Year 2021 Justification of Estimates for Appropriations Committees, n.d.).

The FDA's Center for Devices and Radiological Health (CDRH) oversees the regulation of medical device companies that produce, repackage, relabel, and import medical devices sold in the US. It also regulates electronic products that emit radiation, both medical and non-medical, such as lasers, x-ray systems, ultrasound machines, microwave ovens, and color TVs.

A brief examination of FDA inspections of medical devices highlights the significant impact the FDA has on the medical device industry (FDA, n.d.):

- FDA may conduct administrative inspections.
- It may inspect facilities where food, drugs, devices, biologics, or cosmetics are manufactured, processed, packed, or held before or after introduction into interstate commerce.
- Establishments are usually subject to inspection at least once every two years unless there is a reason to inspect them earlier.
- Inspections may include records, files, papers, processes, controls, and facilities.
- This may extend beyond U.S. territories if products are imported into the U.S.

Failing to meet the FDA regulations, FDA can enforce the following actions:

- Recalls.
- Seizures – FDA may seize products with assistance from the U.S. Marshal and U.S. Attorney; a company cannot block a seizure once it is initiated.
- Injunctions.
- Civil Money Penalties.
- Criminal Charges

Forecasting

There are two main approaches to forecasting. The first approach is based primarily on customer feedback, which is seen as a fair and reasonable method. According to Kiely (1999), "The first type of customer-supplied information is demand forecasts."

The second school of thought in forecasting follows the "Here it is, comes and gets it" philosophy, meaning that the approach is more passive and relies on customers to make use of the forecasts without providing input or feedback. According to Ulwick (2002), customers should not be relied on to provide solutions in the innovation process as they may not have the expertise or information required. The responsibility for this falls on the R&D team. This approach is centered on the idea that forecasts should be made available for customers to use, but their input is not actively sought or incorporated into the forecasting process.

Customers presented by healthcare professionals or ordinary end users wait for innovators to lead the industry into better technology. By engaging with customers and listening to their needs and experiences, healthcare professionals and innovators can gain a better understanding of how to improve device performance and create better products. According to an article by Harvard Business Review, “disruptive innovations don’t catch on with mainstream customers until quality catches up to their standards” (Christensen, n.d.)

I generally concur with Chase Jr.'s (1997) statement that all forecasting methods, whether they be judgmental, time series, or causal, rely on the idea that the past can be used to predict the future. However, in today's rapidly changing market environment, relying solely on historical data is no longer sufficient. The constant influx of news from scientists, regulatory agencies like the FDA, and competitors means that the market is in a constant state of flux. To accurately monitor the market's movements, it is necessary to take these developments into account, in addition to historical data.

Forecasting the medical device market is typically a routine process, but there are two exceptions. The first exception is when a new product is being introduced to the market for the first time. In this case, predicting customer response can be extremely difficult due to the lack of historical data and information. This uncertainty can make it challenging to accurately forecast demand and market reception of the new product.

Bringing new products to market under the conditions of the early 21st Century means that medical device companies will have to demonstrate credible value for their products if they are to win in the marketplace. There are many aspects to this effort and each step in the process must be executed well if pitfalls downstream are to be avoided.

The second exception to routine market forecasting in the medical device industry is when a surprising acquisition by a competitor occurs. Such

acquisitions can often result in a shift in market share, which can have a significant impact on the market. Business analysts must be able to quickly analyze and respond to these changes, making accurate forecasting even more challenging in these situations.

Manufacture Layout

Facility layout refers to the arrangement of machines, departments, workstations, storage areas, aisles, and common areas within an existing or proposed facility. The layout has far-reaching implications for the quality, productivity, and competitiveness of a firm (Chapter 7 Facility Layout, n.d.).

Layout decisions significantly affect how efficiently workers can do their jobs, how fast goods can be produced, how difficult it is to automate a system, and how responsive the system can be to changes in product or service design, product mix, and demand volume.

The basic objective of the layout decision is to ensure a smooth flow of work, material, people, and information through the system (Facility Layout and Design Inc.com, 2020).

Effective layouts also:

1. Minimize materials handling costs
2. Utilize space efficiently
3. Utilize labor efficiently
4. Eliminate bottlenecks
5. Facilitate communication and interaction between workers, between workers and their supervisors, or between workers and customers.
6. Reduce manufacturing cycle time or customer service time
7. Eliminate wasted or redundant movement
8. Facilitate the entry, exit, and placement of the material, product, or people
9. Incorporate safety and security measures
10. Promote product and service quality
11. Encourage proper maintenance activities
12. Provide a visual control of operations or activities
13. Provide flexibility to adapt to changing conditions

Since a medical device is built from parts that come in the form of blocks, either assembled in or outside the factory, the most two famous layouts in medical device manufacturers are process layout and fixed-position layout, depending mainly on the size of the medical device, a layout is chosen.

Process layouts, also known as functional layouts, group similar activities together in departments or work centers according to the process or function they perform. A process layout is characteristic of intermittent operations, job shops, or batch production, which serve different customers with different needs. The volume of each customer's order is low, and the sequence of operations required to complete can vary considerably.

The equipment in a process layout is a general purpose, and the workers are skilled at operating the equipment in their particular department. The advantage of this layout is flexibility. Additionally, improving process layouts involves the minimization of transportation cost, distance, or time (Layout - System, Examples, Advantages, Type, Disadvantages, System, Process Layout, n.d.).

The disadvantages of inefficiency are jobs do not flow through the system in an orderly manner, backtracking is common, movement from department to department can take a considerable amount of time, and queues tend to develop. (Chapter 7 Facility Layout Basic Layouts, n.d.).

In addition, each new job arrival at the work center may require that the machine be set up differently for its particular processing requirements. Although workers can operate several machines in a single department, their workload often fluctuates - from queues of jobs waiting to be processed to idle time between jobs.

Equipment for process layouts needs to be adaptable and capable of maneuvering along various routes and in any direction. This layout is suitable for facilities that handle small to medium-sized devices, such as monitoring systems, laboratory and emergency room equipment, and clinic devices.

The fixed-position layout is utilized for projects where the product stays in a fixed location throughout the manufacturing process. Instead of moving the product, workers, equipment, materials, and other resources are brought to the product's location for production. The fixed-position layout is also common for on-site services such as housecleaning services, pest control, and landscaping (Facility Location and Layout Introduction to Business, n.d.).

The use of a fixed-position layout in a factory might seem unusual, but it is necessary for certain large and heavy items that cannot be moved, such as a linear accelerator used in radiotherapy treatments. These devices can reach a height of 9 feet, a length of nearly 15 feet, and weigh as much as

18,700 pounds, making it impossible for workers to relocate them.

In such cases, a combination of process and fixed-position layouts is used also referred to as a hybrid layout (Hybrid Layouts: Cellular, Flexible Manufacturing & Mixed-Model Assembly - Video & Lesson Transcript, 2021).

The unit is moved for testing and disassembled for shipping, with minimal changes to the layout. Many medical devices, such as x-ray machines, fall into this category. Specialized workers are called upon to perform specific tasks as needed.

TOM (Total Quality Management)

Definitions of TQM vary widely, in general, TQM refers to any emphasis on quality that encompasses the whole organization, from supplier to customer. In a TQM effort, all members of an organization participate in improving processes, products, services, and the culture in which they work (Total Quality Management (TQM): What Is TQM? n.d.).

Despite the lack of a universally agreed-upon definition of total quality management (TQM), there have been several attempts to define the concept. Some examples of these definitions are:

- A comprehensive methodology aims to improve competitiveness and enhance flexibility through planning, organizing, and understanding each activity, and all personnel at all levels are involved in this system. TQM ensures that the management adopts a strategic overview of quality and focuses on prevention rather than inspection (Oakland, 2014).
- TQM is the cooperation between all organization's staff and the associated business processes to produce products or services which fulfill or exceed customers' needs and expectations (Dale, 2003).
- What makes TQM different from other management processes is the concentrated focus on continuous improvement for individuals, groups, and whole organizations processes (Kanji, 2010).
- An integrated approach to achieve and sustain high-quality output which leads to defect prevention by focusing on the maintenance and continuous improvement of processes at all levels and in all functions of the organization, to meet or exceed customers' expectations (Flynn *et al*., 1994).
- Total quality management is a set of management practices aimed at instilling an awareness of quality principles throughout the organization and ensuring that customer requirements are consistently met or exceeded (Montgomery *et al*., 1996).

It can be inferred from the definitions that TQM is a philosophy aimed at enhancing quality, productivity, and services, and improving all aspects of an organization's operations. The emphasis is on satisfying the current and future needs of consumers. As a result, the researcher considers TQM to be a comprehensive philosophy, which adopts a strategic overview of quality, creating an organizational culture committed to the continuous improvement process in every aspect of an organization's activities.

This is achieved through top management commitment, the participation of employees, providing products and services of high quality to improve the competitiveness of the organization, and consistently meeting the needs and expectations of customers to achieve customer satisfaction. TQM is a management approach that involves the use of strategies, tools, and relevant factors for implementation through ongoing improvement of an organization's operations. This is achieved through the involvement of all employees to ensure customer satisfaction.

Production with fewer defects, reduction in rework, lead times and cost, improved business competitiveness, increases in market share and profitability, increased flexibility, and enhanced employee and customer satisfaction are examples of TQM implementation benefits (Youssef *et al*., 2010).

Effective quality management systems are recognized as a key regulatory consideration for allowing medical device manufacturers to market their products around the world. It helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency continuously (What Is a Quality Management System (QMS)? n.d.). The level of quality management system registration required will vary from market to market and be dependent on the risks and hazards associated with the devices.

Medical device makers need to comply with the most recent global regulations governing their products. The most well-known quality standards applied on the international level are:

- ISO 9001, ISO 9002 & ISO 9003 - The general quality management standards that are recognized around the world.
- EN 46001, EN 46002 & EN 46003 - The European quality management standards focus on the requirements of medical device manufacturers. Widely used

as the basis of CE Marking certifications, EN 46001 & EN 46003 are now being replaced by EN ISO 13485 & EN ISO 13488

- ISO 13485 & ISO 13488 - The international quality management standards focus on the requirements for medical device manufacturers, the basis for USA FDA requirements, and are required by Canada under their CMDCAS program. These international standards have been adopted by Europe as EN ISO 13485 & EN ISO 13488 European standards for CE Marking, replacing EN 46001 and EN 46002.

Discussions continue to standardize U.S. and European medical device standards to avoid duplicate regulatory laws. However, both sides have vastly different guidelines that will pre-empt a settlement shortly. European regulations require that devices perform according to product specifications. For instance, an EU declaration of conformity (DoC) is a mandatory document that the manufacturer or an authorized representative needs to sign to declare that the products comply with the EU requirements (Technical Documentation and EU Declaration of Conformity - Your Europe, 2022).

Similarly, the U.S. Food and Drug Administration insists on documentation that proves that products can improve the health of the patient. The medical device and supplies industry is overseen by the U.S. Food and Drug Administration (FDA), which regulates the performance and functionality of these products. Additionally, the industry is subject to consumer product safety legislation, creating a need for systems that are flexible and capable of adapting to changes.

Medical device manufacturers must consistently produce devices that are safe and effective. There are three nationally recognized standards relevant for their consideration in registration: ISO 13485:1996, ISO 13485:2003, and ISO 13488:1996. These ISO standards for medical devices are written and approved by the FDA.

Inventory

According to EIM, (Effective Inventory Management, Inc) Inventory is usually an organization's largest asset. However, many are not satisfied with the contribution inventory makes toward the overall success of their business:

- The wrong quantities of the wrong items are often found on warehouse shelves. Even though there may be a lot of surplus inventory and dead stock in their warehouse(s), backorders and customer-lost sales are common. The material a distributor has committed to stock isn't available when customers request it.
- Computer inventory records are not accurate.
  Inventory balance information in the expensive computer system does not accurately reflect what is available for sale in the warehouse.
- The return on investment is not satisfactory. The organization's profits, considering its substantial investment in inventory, are far less than what could be earned if the money were invested elsewhere (About EIM, n.d.)

I cannot agree more with Spear (2002) "Many scholars have argued that complex social systems must be studied closely by observation and participation as a prerequisite to building inductive theories of how processes truly operate".

Amazingly, by studying the healthcare and medical industry, we will find that the dimension of urgency is always in the bottom mind of workers. Moreover, a survey reveals that the pandemic has raised the importance of healthcare organizations actively choosing, evolving, accelerating, and extending their innovation efforts. One healthcare leader stated "There is so much chaos, it's like a constantly changing game board. We need even more discipline to make sure we don't miss something or get overly enamored of shiny new things" (Cohen *et al*., 2021).

While cutting costs through a good inventory system in the medical device industry is a priority, meeting customers' delivery schedules gets a higher priority. It might sound very familiar to this industry's manufacturers that the waste of materials is not an issue as long as the quality product has been met.

Kanban is a common method used for the seamless transfer of components in medical device manufacturing. It is an agile method focused on process improvement, based on lean values and lean thinking. Simply put, it's a set of principles and practices for managing workflow efficiently and reducing the lead time for new ideas or features from ideation to customer delivery (Petrova, 2022).

Supply Chain

The present global economic scenario has created challenging trade circumstances. This, combined with a hectic phase of industry mergers and acquisitions, has emphasized the vital importance of efficient supply chain management. Never before has the call to cut costs while still providing superior customer service been more important than it is right now. At the same time,

customers' service level expectations are becoming more demanding. After all, research shows that when an individual doesn't receive excellent customer service, they're likely to ditch those businesses for ones that provide truly memorable interactions (Kitson, 2016).

Finding the optimal balance requires more than just streamlining an inventory; top-performing companies are consistently showing how innovative supply chain solutions can help to achieve levels of efficiency that were previously believed impossible. By bringing all sources of information into one place, implementing agile technology, and prioritizing cross-team collaboration, organizations can increase supply chain efficiency (, 2022).

For a medical device manufacturer, the ideal supply chain model should aim to meet two objectives. The first is to deliver the desired product to the appropriate location at the appropriate time while minimizing total cost. Total cost is significant as it encompasses not only the expenses that the customer is aware of but also those that are incurred by the manufacturer.

The second goal is that a supply chain must deliver the highest possible quality assurance and the lowest possible risk. According to Bragg and Kumar (2003), "Effective supplier management facilitates building strategic partnerships with suppliers, which is vital to a successful supply chain. It allows companies to integrate with their critical suppliers to streamline order management, replenishment, and fulfillment; inventory management; and engineering change management."

In the medical field, the relationship between suppliers and manufacturers extends beyond the advantages of high quality, low cost, and timely delivery. It encompasses sharing of risks and rewards during the introduction of a medical product to the market, reflecting the unique nature of the industry. According to Gallup, "A relationship based on price is not enough to mitigate or overcome serious supply chain risks. Though price will always be a major consideration in any buyer-seller relationship, an effective, profitable, and successful partnership requires more than that" (Goodman & Jones, 2013) n Medical device manufacturing, it is common to have certain parts or electronic boards made from raw materials in a secure section within the factory, as they are the most critical components in the product design.

If these parts are manufactured externally, the manufacturer must have a strong relationship with the supplier and transfer their patents to the supplier's location for production. Several assurance documents must be signed and the supplier's location must be regularly inspected without prior notice. Part of the FDA's evaluation of the safety and effectiveness of a device involves a premarket review of information about the materials used in the device (Safety of Metals and Other Materials Used in Medical Devices, 2022). The FDA considers the specific properties of the material, the intended use of the device, and the function of the device when evaluating the safety of the device materials.

Outsourcing

The practice of outsourcing is not novel in business, companies have been relying on consulting firms for advertising, public relations, and consumer research for decades. In certain industries, especially consumer electronics, manufacturing outsourcing has become widespread and is experiencing significant growth.

Outsourcing can bring big benefits, but risks and challenges abound when negotiating and managing outsourcing relationships (Overby, 2022). However, outsourcing has yet to have a significant impact on the highly specialized medical device electronics industry, as industry leaders are yet to witness its success in a low-volume, highly regulated sector. These executives may also be hesitant to entrust an external firm with the production of their proprietary product. Farming out work to an external service provider can have many unintended results, including inconsistencies in standards of care; harmful medical errors; declines in patient and employee satisfaction; and damage to clinicians' morale and income, as well as to the organization's culture, reputation, and long-term financial performance. (Berry, Letchuman, Ramani, & Barach, n.d.).

Certainly, trust is the fundamental factor in outsourcing decisions. Development companies must have confidence that their quality and delivery requirements are met and that regulatory procedures with the FDA and other organizations are efficiently managed.

As stated in an article, "trust is the glue that binds society, community, the economy, critical infrastructure, business, and government. In today's digital ecosystem, trust has become a critical business asset that's essential to long-term success and growth (Trust Is Key in Utilizing Outsourced or Managed Services, 2021).

Companies in the medical device industry have a rare chance to establish a business model that deserves trust.

CONCLUSION

In conclusion, the medical device industry is facing a range of challenges, from political and regulatory pressures to changing consumer expectations, which require them to be more effective and responsive in their operations management. To stay ahead of the competition, companies are developing core competencies, expanding through strategic partnerships, and leveraging technology to cater to a diverse and sophisticated customer base.

However, the ultimate goal of these companies should not be just about business success, but also about making a positive impact on people's lives by providing innovative solutions to alleviate suffering and improve health outcomes. By fostering a sense of purpose and mission, medical device companies can inspire their employees and gain a competitive advantage in the industry.

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