Key Supply Chain Integration Factors for success of Medical Device Startups

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Topic Areas: Healthcare, Strategy, Sourcing

Summary: This research is focused on key supply chain integration factors for success of medical device startups. Sixteen key supply chain integration factors were identified using systematic literature review and interview research methodology. A survey was conducted to a range of industry participants to validate these factors. These supply chain integration factors were further categorized under three major categories namely compliance, cost and collaboration. A medical device startup need to manage simultaneously all supply chain integration factors under these three categories in order to be successful.

Prior to MIT, Sanjay Gupta graduated with Masters in Business Logistics Engineering from The Ohio State University and then worked for Philips Medical Systems for 6 years. Prior to that, he graduated with a Bachelor's degree in Nautical Sciences from Indian Maritime University and served under various capacities as Merchant Marine officer in Maersk Line. Upon graduation from MIT SCM Program, Sanjay will join Philips Healthcare as Procurement Engineering and Supply Chain Manager.

KEY INSIGHTS

1. Medical Device startups will play crucial role in healthcare eco-system to bring innovative products to market place and reduce overall healthcare cost.
2. Quality Management System is most important supply chain integration factor for success of a medical device startup.
3. "Three C" for success of medical device startup: Compliance, Cost, Collaboration

Introduction

Medical device startups play an important role in the medical device industry. Medical innovations and new technologies are generally developed by startup companies in the medical device industry. Typically, a physician and or inventor conceives a solution for unmet challenges, then initiates a patent and builds device prototypes. Further development leads to a startup of a small team who works with advisors to bring from concept to product. According to the study done by International Trade Administration, startups constitute 80% of the medical device industry. Yet, the survival rate of these startups is very low, only 37% of these startups survive.

At the same time, healthcare cost is on the rise. Healthcare spending has reached to $3.3 trillion in 2016, the largest individual contributor to U.S. gross domestic product (GDP). The increasing healthcare cost has forced the industry to shift from a volume-based to a patient outcome-based delivery models. This shift would require innovation and process efficiency in all workflows of healthcare. Government, payers and insurers have turned to healthcare providers, healthcare IT, pharmaceuticals and medical device companies to come up with innovative solutions. Startups in healthcare sector will play a prominent role to achieve this goal.

There can be various contributing factors to the success of these startups such as: market scope, financial support, supply chain integration, patent protection, regulatory compliance, founders experience etc. Notably, supply chain integration has highest correlation to success.

Thus, a high dependency on startups by medical device industry, increasing healthcare

cost and supply chain being key contributing factor for success of medical device startups motivated the research to find key supply chain integration factors for success of a medical device startup.

Methodology

For the purpose of this research Supply Chain Integration Factors (SCIFs) are defined as a firm's cooperation across different levels of the value-chain including suppliers, manufacturing partners, distributors and customers.

Success of a medical device startup is defined as successful exit either by acquisition by another firm or by issuing Initial Public Offering (IPO). However, a startup can also be successful even if it remains private. Private medical device firms are not included in the research as they are low in number and there is not much information and data available in public domain.

SCIFs were identified through interviews with experts in the medical device industry, systematic literature review of academic publications and content review of various reports issued by trade associations, consulting firms and other governmental and non-governmental organizations related to medical device industry.

Further, a survey was conducted to validate these factors using 5-point Likert scale,1 being " Extremely important" to 5 to "Not at all important". Responses of the survey were analyzed using a weighted average method in SAS JMP 14.

Results and Discussion

Sixteen key supply chain integration factors were identified using interviews, systematic literature reviews and industry focused content reviews. (see Figure 1). Clearly, quality related SCIF outnumbered other factors as medical device industry is heavily regulated.

Figure 1 shows weighted average score of all SCIFs. The weighted score of all factors is less than 3 which implies that all 16 factors are at least moderately important to the success of medical device startups. It also shows relative importance to all factors from the perspective of the respondents to the survey.

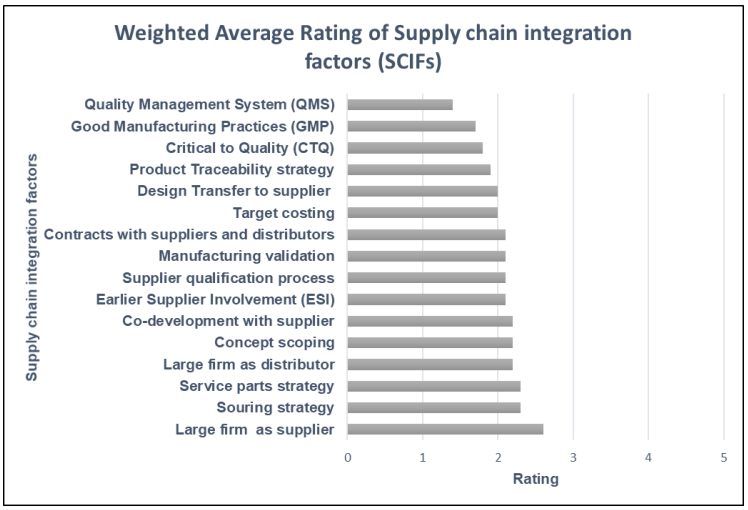

Figure 1. Weighted average ratings of key supply chain integration factors

At the end of the survey, respondents were asked to choose one factor which they feel is most important out of all sixteen factors. More than 56% of respondent selected Quality Management System (QMS) as the most important supply chain integration factor.

As Quality Management System (QMS) is by far most important factor, it is worth mentioning and explaining little bit more about it.
FDA mandates establishment of Quality Management System by manufacturers in U.S. FDA has provided guidelines to startups under their publication "FDA small business Regulatory Education for Industry". FDA Quality System Regulation Part 820, is harmonized with International Standard Organization's ISO13485 guidelines. It essentially states that a manufacturer must develop a quality management system commensurate with risk presented by device, complexity of device and manufacturing process.
A QMS helps a medical device startup in many ways:
First, it provides a structure for development of a product in a compliant manner under a highly regulated environment. Following QMS, a startup produces various important records such as Design History File (DHF), a compilation of product design and, Device Master record (DMR), a compilation of instruction for product production. The DHF and

DMR records maintains traceable records of design and manufacturing instructions.
Second, a well-established QMS assist in regulatory approval of product by FDA. Startups with QMS are more likely to get their product approved early than startups without it.
And at last, healthcare providers (hospitals, clinics, doctors, etc.) perceive higher level of safety and security when they see a medical device manufacturer has developed their product under an established QMS.

Importance of Good Manufacturing Practice (GMP)

The second important SCIF was Good Manufacturing Practice (GMP). GMP provides manufacturing guidelines to produce a safe and quality product. As per these guidelines, a medical device manufacturer is required to establish methods and procedures to procure, produce, distribute, devices under its quality system. Following GMP, a medical device will have a Device History Record (DHR) which contains auditable and verifiable record of production from receiving of raw materials to final assembly and test of medical device. FDA see compliance of GMP during their audit at medical device manufacturers. FDA may deem a product "adulterated" even if it meets all technical specifications but found to be made under settings which contradicts good manufacturing practice (GMP) guidelines.

Simply put, a startup should incorporate GMP guidelines right from concept phase of product so that they do not end up correcting costly and time-consuming mistakes at the later stages. The best time to incorporate GMP guidelines is when a startup is setting up its QMS.

Role SCIFs play in Idea to Market

A medical device is developed and commercialized by following various phases. Figure 2 shows various phases mapped with supply chain integration factors. Phase I to Phase V correspond to the various segments of product development, starting from initial idea or concept of device to final product launch. Post launch phases, Phase VI to Phase VII ensures longevity of device in highly regulated environment. A medical device startup can utilize this table to anticipate and plan various supply chain activities well in advance. A well-developed plan can assist a startup in assigning scared resources for product development. Further, it can assist a startup in obtaining funding and support for subsequent development.

Product lifecycle : Development to Commercialization

	Phase I Product Proposal	Phase II Product Planning	Phase III Design & Development	Phase IV Design Verification	Phase V Validation & Launch	Phase VI Manufacturing & Monitoring	Phase VII Maintenance	Phase VIII End of Production
	Develop Product proposal Develop Business case Capture customer requirements	Define detailed product, system requirements. Prepare detailed project plan including interface with internal and external partners	Design and implement the product. Build prototype. Test on module level	Verify technical specifications	Validate product Validate production process Transfer to production, sales and support.	Product commercial production. Feedback from customer service to development team	Maintain design of the product throughout product lifecycle while retaining form , fit and function	Stop product form production Manage spare parts as per applicable regulations
Supply chain integration factors	- Concept scoping	- Earlier Supplier Involvement (ESI) - Souring strategy - Service parts strategy - Product Traceability strategy - Target costing	- Co-development with supplier - Critical to Quality (CTQ)	- Supplier qualification process	- Manufacturing validation - Contracts with suppliers and distributors - Design Transfer to supplier	- Large firm as supplier - Large firm as distributor - Good Manufacturing Practices (GMP)	- Service parts	- Product Traceability
	Quality Management System (QMS)							

Figure 2. Supply chain integration factors in product life cycle

Key Recommendations to Medical Device Startups

Key supply chain integration factors as discussed in previous sections falls under three main categories which can be called as “Three C” of supply chain integration factors for medical device startups – Compliance, Cost and Collaboration. (see Figure 3)

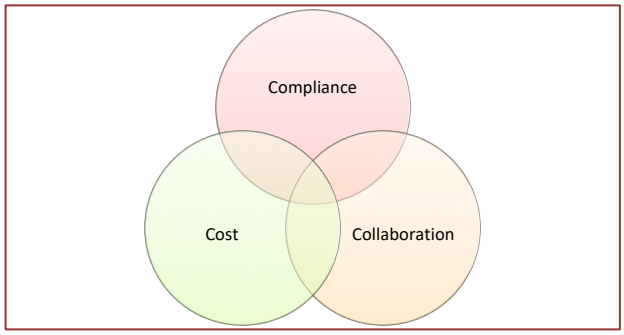

Figure 3. “Three C” of supply chain integration factors for medical device startups

First, ensure compliance of supply chain with regulatory framework mandated by the FDA such as Quality Management System (QMS), Good Manufacturing Practices(GMP), design transfer, supplier qualification, service and traceability.

Second, bring cost effective solution to market to reduce overall healthcare cost by adopting Concept scoping, Sourcing strategy, Target costing, Earlier Supplier Involvement (ESI) Manufacturing validation and effective contracts with suppliers and distributors.

Last, embrace collaboration with large players to take leverage of established distribution channels and reduce supply risk. At the same time, make startup more attractive to investors and potential buyers for a successful exit.

Conclusion

While finding key supply chain integration factors for success of medical device startups, an analysis of healthcare ecosystem, role of medical device industry in disease diagnosis and treatment and unique position of medical device startups was performed. It was found that medical device companies are operating under high pressure to increase efficiency and reduce cost. Medical device industry is also highly concentrated with very few big players and lots of startups. Big player relies heavily on innovation by medical device startups. Medical device industry, being complex technology and highly regulated, Quality Management system (QMS), Good Manufacturing Practice (GMP) and external collaboration with supplier and distributors are by far most important supply chain integration factors for success of medical device startups. At the same time, all supply chain integration factors fall under three major categories namely compliance, cost and collaboration.

A medical device startup need to chart their course by keeping all three categories in mind, navigate through complex healthcare eco system to stay on course and become successful in their venture