ABSTRACT

Medical device industry is highly competitive and fragmented which manufactures devices with highest safety and regulatory compliances. This is accomplished by making use of advanced technologies and sustained investment into research and development leading to manufacturing excellence, thereby making the device safe, reliable and effective for human use. International standards (ISO13485) classify the medical devices into three major categories based on the risk involved; which are high risk e.g. Cardiac Stent, medium risk e.g. Dental Implants and low risk e.g. Catheter. Developing valuable medical devices is a big challenge. This should not only fulfil its intended function safely and effectively but at an affordable cost. India has become a favored destination in medical tourism because of the low cost of treatment and world class care, however, the value added medical device industry has not yet evolved. Value creation in the entire chain can be seen as comprehensive multidisciplinary process. Supply chain of the medical devices is different from other commercial supply chains on many aspects such as product complexity, customization, handling and storage, safety standards & strict regulations.

For the value creation process, various factors are identified from the literature and their causal relationship is analyzed. Based on the causal relationship model, inferences are drawn regarding the significant factors. This proposed model is made generic and the factors considered during this study can comply to any medical device. Such an analysis can also help the decision maker to focus on and improve those factors which have greater significance on creating value for the stakeholders. An attempt has been made to predict the value in the whole system based on numerous associated factors at various nodes of the supply chain. The results were compared through different methods.
Medical device manufacturing requires manufacturing with some of the advanced technologies. Technology incorporation in an organization during the development stage depends upon the failures that can result through the existing manufacturing technologies and its associated risks. The study involves analyzing the capability of the manufacturing processes for manufacturing medical device based on the failure rates for a real-life case. Propositions regarding process improvement were made based on the economic viability of the available alternatives. The issue of affordable manufacturing is tackled through collaborative manufacturing. Decision making related aspects of medical device selection are studied in line with the ‘shared decision making’. Regulatory and traceability aspects of the medical devices were studied and software architecture for an effective traceability is proposed involving all stakeholders.

The study addresses the real-life issues of a medical device supply chain and adds value to regulators, manufacturers, clinicians and patients involving effective decision making. The value addition can be articulated in terms of predicting & quantifying value and thereby validating the model leading to affordable manufacturing through collaboration and a proposed software architecture.