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Incorporating sustainability in decision-making for medical device development

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ABSTRACT

The development and commercialization of contemporary medical devices are inherently multidisciplinary. Consequently, they have to undergo a stringent regulatory compliance procedure in conformity with an ever increasingly fierce and competitive business environment. Throughout the product life cycle, medical devices would significantly consume renewable as well as non-renewable resources and as a result exert a substantial social, economic and environmental impact(s). Sustainability from an overall perspective in terms of social, economic and environmental domains is crucial for decision-making during product development; nevertheless they have rarely been incorporated simultaneously. Both public and private institutions only focused towards economic and environmental sustainability without acknowledging the critical role of social sustainability that needs to be addressed concurrently so as to uphold the other two. Accordingly, it is imperative to consider the criteria of the aforementioned domains of sustainability in the initial phases of product development. The proposed conceptual multifaceted framework comprehensively explores a broader scope of sustainable product development, mainly from the pragmatic standpoint of systems engineering in comparison to the contemporary evaluation and development approaches. The underpinnings of the proposed framework encompass the critical role of a MultiCriteria Hierarchical Model (MCHM), which is in fact an extensive revision of the analytical hierarchy process decision making model. The MCHM mainly functions across the idea screening phase (Stage 2) up to the business and feasibility analysis phase (Stage 4). Moreover, unlike its predecessors, the MultiCriteria Hierarchical Model is less dependent upon numerical scores allotted by expert opinion and apparently broader in its scope of application. Furthermore, the proposed framework elucidates the active participation of the MCHM in product design and development by conjoining with an artificial intelligence based computer system known as expert systems. The principal objective of the proposed conceptual framework is to deliver a thorough assessment and a feasible roadmap for the development of sustainable medical devices.

1. Introduction

The onset of globalization has imposed a tremendous pressure on medical device companies, specifically pertaining to stringent regulatory compliance and accomplishing desired economic goals in a fiercely competitive business atmosphere. Furthermore, similar to other industrial activities,

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the medical device sector is also known to consume significant renewable and finitely available non-renewable resources that are known to intensify socio-economic imbalances (especially health related hazards) across diverse geographical locations, mainly as a result of the alarming environmental consequences [4,30,72,74]. The scenario is further aggravated by the rising healthcare costs, evolving knowledge about existing/new diseases and competitive purchase negotiations put forward by healthcare service providers [53]. Accordingly, these newly identified dynamics have stimulated enormous research in the domain of decision modeling techniques and new product development frameworks, with a holistic perspective so as to overcome the obsolescence of their conventional predecessors. These advanced holistic frameworks are desired by its users to determine and resolve a vast number of conflicts and synergies, by way of translating an equivalent magnitude of stakeholders' requirements into an exhaustive list of considerations comprising of criteria; factors; drivers and their corresponding parameters and specifications. The renowned tool of quality function deployment is a known remarkable example www.qfdi.org. To explain further, let us consider a sophisticated cardiac health monitor that is desired by the market to possess multiple features. These features would be attributed to an equivalent number of corresponding subsystems, thus increasing the weight as well as the environmental impact. The outcome is definitely undesired by both regulatory agencies and ecologically conscious end-users/patients [74]. The translation of stakeholder requirements into product specifications, essentially results from the interactive dynamics between the key stakeholders and various cross-organizational boundaries. These boundaries include but are not limited to environment, socio-economic domains, human resources, end-users, patients, regulatory bodies, suppliers, distributors, manufacturers, development collaborators, shareholders, remote/distant communities, government(s), healthcare institutions and insurance companies [9]. Consequently, acknowledging the necessity of a holistic stakeholder perspective, this research paper briefly discusses the prior research accomplishments and thereby proposes a conceptual, nonetheless a comprehensive as well as pragmatic multifaceted framework that encompasses both decision modeling and product development features. Medical devices, similar to the aerospace, automobile and military engineering counterparts are comprised of diverse interdisciplinary scientific and technological breakthroughs, that encompass electro-mechanical (e.g. wheelchairs), chemical (e.g. gloves and syringes), electronic/software (e.g. cardiac pacemakers) and biological (e.g. stem cells) engineering domains. Consequently, the framework proposed in this paper is applicable to other interdisciplinary areas with suitable alterations.

The objective of the proposed framework is to concurrently account for the three interdependent domains of social, environmental and economic sustainability for medical device development [31]. The interdependency is explained in Ref. [59] latest book titled, The Tropic of Chaos: Climate Change and the New Geography of Violence; wherein the author has closely investigated the compounding impact of ecological crises and climate change onto ongoing socio-political disturbances.

2. Medical devices and sustainability

Medical devices are composed of a diversified spectrum of products and corresponding services, spanning across Class I devices (e.g.: tongue depressor) which are subjected to the least regulatory controls. On the other hand, Class III (e.g.: cardiac pacemaker) requires the most stringent regulatory controls, owing to a higher degree of risk to human health in cases of malfunction or erroneous use (Source: Food and Drug Administration). As discussed previously, any organization committed to sustainability should extend its sustainability commitment beyond environmental compliance and accommodate other crucial social responsibilities pertaining to labor practices; transparency; human rights and fair business practices (Source: Division of Sustainable Development, United Nations). Moreover, for minimizing any negative consequences owing to the product development and commercialization activities, it is obligatory to address the 3 facets of sustainability within the initial stages of product development [30,74,76]. As per the Stage-Gate Process, the pertinent phases addressed by the proposed multifaceted framework commences from the Idea Selection (Stage 2) up to Verification and Validation (Stage 5) [78]. The idea generation stage is excluded so as to avoid stifling of creativity within the Product Development Teams, to be referred as 'Teams' from here onwards [9]. The aforementioned stages must compulsorily account for the overall sustainability (which includes the 3 aforementioned facets of sustainability) throughout each of the product life cycle phases namely, extraction, production, distribution, utilization, disposal and end-of-life [31,76]. Furthermore, the life cycle approach towards sustainability needs to be fortified by the culture and capabilities of the participating organization(s). Since the articulation of the company's interconnected business processes pertaining to life cycle thinking, engineering and management paradigms play a pivotal role for upholding its long term competitive position [21,35]. To re-iterate further, the development phases are for incorporation of the sustainability considerations, while the commercialization phase is the implementation of the defined sustainability objectives. The holistic stakeholder perspective of the proposed framework is aimed at strengthening a medical device company's long term competitive position [84].

3. Decision modeling for sustainability

3.1. The landscape of decision modeling techniques

During decision modeling, the conventional approaches to assign financial numerical values to the envisaged outcomes, such as cost benefit analysis are perceived to have inherent limitations pertaining to both its accuracy and scope [42]. Consequently, in this research paper the authors propose a more qualitative approach known as the multicriteria method towards decision modeling. This decision modeling approach simultaneously considers wide range of criteria ranging which include but not limited to social; economical; environmental; rational and emotional with a substantial degree of consistency [68,69]. The methodology of Multi-Criteria Analysis (MCA) involves the assigning of numerical