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DEVELOPMENT OF SUSTAINABLE MEDICAL DEVICES

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ABSTRACT

The development and commercialization of Medical Devices exerts a significant Social, Economic and Environmental impact, throughout its Life Cycle. Therefore, it is imperative to consider the criteria of the aforementioned domains of Sustainability in the early developmental phases. The proposed conceptual multifaceted framework, consists of a Systems Engineering based Design Structure Matrix, which addresses the interdependencies between various interdisciplinary systems and sub-systems. The matrix is capable of accounting for any unforeseen modifications caused by a fierce and dynamically changing environment, namely at the frontiers of technology, sustainability, regulatory compliance and business performance. Moreover, the contribution of each developmental process towards these frontiers is assessed through the facet of Value Engineering Analysis. The matrix in accordance with a priority based decision making model (Analytical Hierarchy Process), resolves potential conflicts between diverse requirements and specifications in order to shorten the development cycle. The objective of the conceptual framework is to deliver a thorough assessment and a robust sustainable development plan for developing Medical Devices.

INTRODUCTION

The interrelated Sustainability of the Social, Economic and Environmental dimensions are significantly affected by the consumption of non-renewable resources by Medical Devices (mainly single-use devices) throughout each of its life cycle stages namely; extraction; production; distribution; utilization; disposal and end-of-life (Hauschild et al. 2005; Hanson and Hitchcock 2009). The inclusion of sustainability criteria, in the initial design and development phases, is known to minimize negative consequences at the downstream segment of commercialization and promote the long term strategic business goals of the enterprise (Hauschild et al. 2005). Previously, developed approaches for Sustainable Medical Device Development, proved to be exhaustive and are deprived of a holistic understanding towards Social Sustainability. The proposed framework, under discussion, is a collaborative structure consisting of product development process planning, value engineering analysis of the developmental processes and a priority based decision making tool. This work explores the applicability of the proposed multifaceted framework, towards the development of sustainable medical devices.

FRAMEWORK

a) The exhaustive list of product requirements which is composed of regulatory, business performance and sustainability criteria, is identified to be overwhelming pertaining to its inherent in-between conflicts and the limitations posed by the availability of time, managerial capacity and resources (namely Software, Machinery and Instrumentation). Therefore, a decision making model, with the appropriate criteria is essential to resolve any arising conflicts and synergies. Compared to various other multicriteria analysis tools, Analytical Hierarchy Process (AHP) (Saaty 2008) is simple to use, wherein the criteria are systematically arranged in a multilevel hierarchy with priorities (or ranks) assigned at each level. The decision model (Figure 1) incorporates 2 major criteria namely, Regulatory Compliance and Business Performance. The model is further divided into 3 tiers on the basis of their priority (or ranking), wherein sub-criteria in Tier 1 are critical and are non-negotiable, without which sub-criteria of the other 2 tiers cannot be considered.

b) Medical Devices are a manifestation of multiple processes (project management and engineering) and sound decision making at each of its developmental stages (Hanson and Hitchcock 2009). Accordingly, each developmental process should incorporate the criteria for product functionality, business performance,

A. Regulatory Compliance
TIER 1 (Non-Negotiable)
(Stakeholders: Supply Chain, Personnel, Patients, End-users)
i) Medical Device Regulations (Eg: FDA, ISO):
Function, Reliability, Clinical Evaluation, Human Factors Eng.
ii) Environment (RoHS, REACH, WEEE): Minimize waste & emissions.
iii) Social Factors: Health and Safety of Stakeholders
TIER 2
i) Environment: (End-Of-Life) Remanufacturing, Reuse and Recycle.
ii) Social: Employment and Growth in Income Distribution.
TIER 3: Social: Employee Housing and Community Welfare.

B. Economic & Business Performance
TIER 1 (Non-Negotiable)
i) Competitive Edge and Knowledge Curve.
ii) Market Acceptance and Stakeholder Satisfaction.
iii) Payment and Reimbursement (Government/Insurance).
iv.) Competitive Shorter Time to Market.
v) Return on Investment:
(1) Adequate profit for a 3 year no-growth period [or]
(2) 2 year growth period of 2%.
TIER 2: Growth in Market Share/ (~2-5%)
TIER 3: Corporate Expansion.

Figure 1: Priority Based Decision Model (Analytical Hierarchy Process)

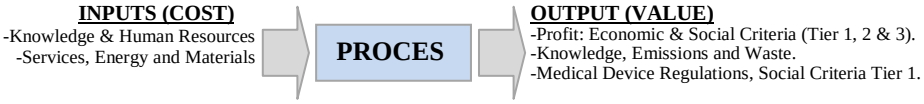

Figure 2: Value Engineering Analysis

regulatory compliance and sustainability. Value Engineering Analysis (SAVE International) illustrated in Figure 2, enables product development teams to optimize the consumption of resources, generation of waste/ emissions and include a suitable End-Of-Life option (Hauschild et al. 2005). Moreover, the social criteria such as Employee Housing are attainable through investment of monetary resources, unlike environmental criteria such as emissions, that are addressed using computational design and environmental life cycle impact analysis tools (Hanson and Hitchcock 2009).

c) High-end Medical Devices are composed of multiple systems and sub-systems that are based on the principles of Systems Engineering and therefore are interconnected/interdependent upon each other for their functionality (International Council on Systems Engineering). Consequently, the development of one sub-system influences the development of another sub-system(s), mainly pertaining to sustainability, functionality, regulatory compliance and business performance. The Design Structure Matrix (DSM) (DSMWeb.org), illustrated in Figure 3, is able to detail the knowledge and information for the sub-system development and also evaluate its interdependencies. Therefore, DSM is capable of process planning and addressing any modifications arising out of unforeseen changes in a dynamically changing business and regulatory environment.

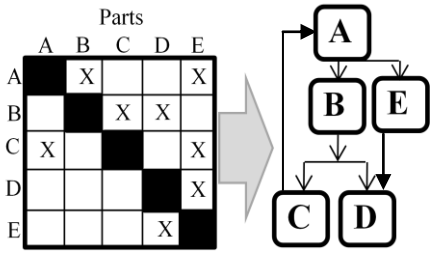

Figure 3: Design Structure Matrix

CONCLUSION

The multifaceted framework is able to explicitly illustrate the co-relation between various design & development processes and its corresponding contribution towards sustainability, functionality, regulatory compliance and business performance. The Framework can also be considered as a decision making aid, throughout the Stage Gate Process of Product Development.

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