

Knowledge networking to support medical new product development

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Abstract

New product development (NPD) in the pharmaceutical industry is very knowledge intensive. Knowledge generated and used during medical NPD processes is fragmented and distributed across various phases and artifacts. Many challenges in medical NPD can be addressed by the integration of this fragmented knowledge. We propose the creation and use of knowledge networks to address these challenges. Based on a case study conducted in a leading pharmaceutical company, we have developed a knowledge framework that represents knowledge fragments that need to be integrated to support medical NPD. We have also developed a prototype system that supports knowledge integration using knowledge networks. We illustrate the capabilities of the system through scenarios drawn from the case study. Qualitative validation of our approach is also presented.

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1. Introduction

The pharmaceutical industry occupies an important position in developed economies both due to the tremendous impact it has on the daily life as well as its extremely capital intensive nature. In the USA, Food and Drug Administration (FDA) alone regulates over \$1 trillion worth of medical devices, drugs, biologics, and food products [35]. According to Association of the British Pharmaceutical Industry (ABPI), pharmaceuticals are one of Britain's leading manufacturing sectors, bringing in a trade surplus of £3.6 billion with exports valued at £11.9 billion [8].

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As it represents a significant component of the developed economies, any improvements in the management of critical processes in this industry are likely to have enormous economic impact.

Pharmaceutical firms depend heavily upon their ability to rapidly develop and introduce new products into the market. In fact, product development speed directly impacts their financial bottom-line as well as their ability to satisfy unmet medical needs of patients. However, development of new medical products is complex and time-consuming. It takes anywhere between 7 and 17 years and several millions to billions of dollars to launch new medical products [16]. Some of the factors contributing to the length, cost, and uncertainty of this process include:

- The stringent regulatory requirements of governmental entities like the FDA requiring the maintenance of

design history for every medical product to show that the products were developed as per the approved plan and with extensive clinical trials,

- Medical products are used to treat human beings whose well-being and safety are of utmost importance. Failure of the product can have serious consequences.
- Increasing possibilities for therapeutic intervention brought about by newer technologies, and
- Enormous investments required in research and development, and testing.

The regulatory load faced by pharmaceutical new product development (NPD) organizations is increasing to the point of overload. More records of increasing complexity will be under the scrutiny of a number of authorities as emerging markets develop [15]. For example, manufacturers have to satisfy different sets of requirements for the products marketed in the European Union which may be significantly different from those of the FDA. Furthermore, this industry faces very low success rate in NPD; vast majority of investigational products that enter clinical trials fail [16]. As a result of these challenges, medical NPD teams are constantly seeking novel ways to improve development processes, while at the same time ensuring the safety of the products under development. Effective knowledge management offers potential for such improvements in this knowledge intensive industry which draws on a variety of knowledge sources [32]. As the knowledge capital acquired by the firms during the development process is the primary source of competitiveness in this industry, it is critical to capture, communicate, and reuse this knowledge gained from various sources [29]. However, long development time-frames and the distributed nature of the research and development process across organizational and geographical boundaries exacerbate the fragmentation of knowledge generated and used across the different phases of the NPD life cycle [34]. Currently, pharmaceutical product development organizations use commercial document management systems to record NPD design history [9]. These systems place significant restrictions on the type and granularity of knowledge that can be recorded. Also, these systems do not provide adequate support to integrate knowledge that is scattered throughout the various phases and artifacts of the NPD process [9].

Our research is based on the premise that, in order to effectively manage knowledge in the medical NPD process, techniques to integrate fragmented knowledge chunks are essential. A critical problem in facilitating the integration of knowledge to support NPD is that

there has been little attention focused on providing specific guidelines to medical product developers on how to effectively integrate essential knowledge elements so that they are useful throughout the product life cycle [33]. In this research, we address this issue by developing an approach to seamlessly integrate fragmented knowledge using knowledge networks. Semantic knowledge networks provide the ability to describe and follow the life of a physical or conceptual artifact. These have been used as effective solutions to support knowledge integration in knowledge intensive processes in multiple domains [25]. Motivated by their effectiveness in supporting knowledge intensive processes, we propose the creation and use of knowledge networks to facilitate integration of knowledge fragments that are generated and used in medical NPD. The development of a knowledge network should be guided by the unique characteristics of the medical NPD domain. Based on this premise, we address the following key research questions:

- (1) What are the elements of a knowledge network that can facilitate knowledge integration in medical NPD? and
- (2) What functionalities should be provided in a system that supports the creation and use of knowledge networks to facilitate knowledge integration in medical NPD?

The paper is organized as follows: Section 2 provides the background on the process of medical NPD, along with unique issues in this area. We draw from the literature on knowledge integration for supporting medical NPD. We then present knowledge networking as an approach for knowledge integration to support NPD in this domain. This is followed by the description of a case study in Section 3. Based on our case study and literature review, we draw the requirements that must be satisfied by the proposed approach. We then present our knowledge integration framework. Section 4 presents our prototype system. In Section 5, we present the preliminary qualitative evaluation of the usefulness of our approach. Section 6 presents the contributions of our approach and concludes with limitations and future research.

2. Background

2.1. New product development in pharmaceutical industry

Medical NPD typically involves the following phases: (1) Discovery, (2) Feasibility, (3) Optimization,

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