A Reference Model for the Pharmaceutical PDP Management – an architecture

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Abstract. The purpose of this article is to introduce the reference model architeture used in the development of a reference model for pharmaceutical Product Development Process. The model was created founded on renowned methods as Concurrent Engineering, Stage Gates and Product Based Business. It was developed using legislation and information from interviews with professionals of Brazilian pharmaceutical companies and information from Project Management. This architeture supported the development of a reference model for the pharmaceutical PDP management, which is adjusted to the Brazilian companies' reality and demand.

Keywords. Reference Model, Concurrent Engineering, Pharmaceutical Product Development Process (PDP)

1 Introduction

Since the 1990's product development has been considered under a broader standpoint, in which the idea of development centered in technical activities was substituted by the concept of business supported by product development. This new concept has been called, afterwards, Product Development Process (PDP) [5-9, 19]. Along the last twenty five years several product development approaches were proposed, supported by methods and tools [6]. Each of them has particularly contributed to the evolution of this knowledge area. Among the development approaches, outstands those that are considered under the expression *Integrated Product Development* (IPD) as *Concurrent Engineering* (CE) [22]; *Stage Gates methodology* (SG) [6,7]; *Product Based Business* (PBB) [9,19]; and more recently the *Lean* (L); *Design for Six Sigma* (DfSS) and *Maturity Models* (MM) considered as new IPD approaches [23]. Some authors [1,16] discuss IPD as a separate methodology, but Rozenfeld et al. [23] group CE, SG and PBB as being Integrated Product Development expressions.

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Historically speaking, in the same decade (1960), NASA (National Aeronautics and Space Administration) and the US Department of Defense (DoD) have developed tools to improve Project Management (PM) activities and to enhance project success. They were compiled, afterwards, by PMI (Project Management Institute) in the renowned PMBoK (Project Management Body of Knowledge) [15,21,24]. Accordingly to Kerzner [15], the tools mentioned in PMBoK have influenced the Product Development area and, inversely, the Product Development methodologies have influenced and supported the PM subject growth.

Global pharmaceutical corporations, even dominating large markets and presenting a typical very long lasting product development process, have adhered, in the 1990's decade, to the product speed development concept. The two approaches adopted by them include new PDP management practices [3,10,14] and special technology development, directed to new drug discovery, identification and analysis [2,4,11,13,18,26]. The changes in the pharmaceutical field may be attributed to the expiration of many drug patents in the 1980's what boosted the 'generic product' development by competitors, a medicine that presents the same properties of the reference product, and therefore may be interchanged with it, but which presents lower prices. The generic medicine production in Brazil has been encouraged by the government in year 2000, mainly viewing the AIDS drug cocktail price reduction.

In this context, the development and launching of generic products in a fast pace is decisive for competition. Some Brazilian companies observed that the existence of a formal product development process may reinforce product development success. To formalize companies' PDP practices is a global tendency and product development reference models, in addition to PDP methodologies and PM tools, play an important role in such formalization. For this reason, the main objective of this paper is to introduce and discuss the architecture which has lead to the development of a reference model for the pharmaceutical product development process, focused in generic products, a Brazilian pharmaceutical companies' demand.

2 Reference Models

A reference model serves as a description of how a product development process progress, providing a common language, a minimum global vision of the project development or a perception of the expected contribution that project will bring to the company. The reference model may assume several formats. Some of them represent only the activities that must be performed in product development; other models detail what procedures and methods are supposed to be adopted; they may include an evaluation criteria and may mention what literature has to be consulted in order to accomplish a specific activity. The model may be a manuscript, manual or even a graphical representation available in intranet [23]. They may be classified as generic models which may be adopted by different production companies or specific models, that describe a particular type of product development, as the model proposed in this paper.

3 Description of the pharmaceutical reference model architecture

The reference model for pharmaceutical product development architecture was based and is supported by: (*i*) the Brazilian pharmaceutical companies' professionals experience and legislation; (*ii*) the best product development practices from literature, and (*iii*) information from project management.

3.1 The Brazilian pharmaceutical companies' professionals experience and legislation

The qualitative approach was used for data collection and it was performed in two interview blocks. The objective in the first interview block was gathering information for construction of the reference model. The objective in the second interview block was the reference model validation. The latest was performed by submitting the reference model to pharmaceutical professional analysis of performance and applicability in the field.

Five national companies' professionals were interviewed in first block, from two large and two medium size companies, from the medicine and cosmetic fields. The interviewed professional areas were those considered important for product development and it was respected the company development team or professional interview availability. The areas included: marketing, and Sales, R&D, Quality assurance, Production planning and control, Medicine registration, Finances, Information Technology and High Administratrion. A referee for generic product registration from ANVISA (Agência Nacional de Vigilância Sanitária), the Brazilian medicine registration body from the Government Health Ministry, was also interviewed for the reference model construction. Only one referee was interviewed at ANVISA, since the legislation information is of deterministic nature. Concerning validation, the reference model was analyzed by professionals from seven companies, three large and four medium sizes (medicine, veterinary and cosmetic fields). The analysis was conducted in a collective approach inside each company, where the interviewed group exchanged ideas and impressions about the model. The interviews lengths were two hours in average, in both blocks, and semi-structured questionnaires were used.

All interviews were recorded and, afterwards, transcript. The First block interviews were analyzed through internal comparison: between companies' information, and between the latest and the ANVISA referee information. The data gathered were important for construction of the reference model macro-phases and activities. The Second block interviews were analyzed through consensus ordination and importance ordination. Thus, the elements mentioned by the interviewed professionals about which they agreed or disagreed were identified; as well as the model elements considered by them as interesting or object of concern. The elements mentioned by interviewed professionals from one company were compared with the opinion of interviewed professionals from other companies, characterizing the internal comparison in Second block either. The data gathered in validation block interviews were important for

changing, excluding or including phases and activities in the reference model, or for reinforcing its value as a reference for generic product development in pharmaceutical companies.

3.2 The best product development practices from literature

The product development methods that support the reference model are Concurrent Engineering, Stage Gates and Product Based Business.

Concurrent Engineering (CE) focuses in multidisciplinary teams, co-localized and simultaneous activities performance, mainly those which are independent. The physical co-localization of teams and multidisciplinarity will depend on company's culture, but the latest element is mandatory to development efficiency. Much rework may take place when the project of a new product is not simultaneously, but sequentially analyzed by organizational sector specialists. The application of tools and methods is important as IT (Information Technology); DfM (Design for Manufacturability among other methods and tools [12,16,23].

Stage Gates (SG) is a methodology which focuses in two aspects: business character of product development and product development process managerial control. The first aspect is guaranteed by the 'portfolio management methodology' that analyses what business-products are the companies investing in. It is normally performed along Corporate Strategic Planning (CSP) implementation. The process control aspect of SG is the phase transition evaluation/control which is systematically performed via process interruptions named 'gates'. The gates are generally located between important transition phases and they present a decision nature of process abortion; process modification or process maintenance. The gates may include control check lists that confirm the conclusion of the most important activities of that phase; although the document central managerial question is 'will the product development be continued in the next phase, changed or aborted?' The number of gates is a function of the risk level implicated in the product development process, but Cooper suggests six gates in his paper [6,7,23].

Product Based Business (PBB) is a methodology which reinforces the innovation mechanism, represented by two elements: the pair 'portfolio analysis-Corporate Strategic Planning' (from the strategic level) and by the activities of 'identification, selection and development of opportunities that were identified in the market' (from the tactical level). The business/company growth is a result of innovation in products or services since they must provide both, income and profit. The incomes from mature and new products maintain the innovation mechanism, since they may finance new market evaluation and technology acquisition. In this sense, a feedback mechanism is generated in terms of cash and information. The products must be followed after launch for all their lives (product life cycle management), and their performance in market must be measured. The information gathered from products feedbacks the development process for a new 'portfolio analysis-Corporate Strategic Planning' and the improvement cycle is maintained [9,19].

Summarizing, the IPD methodologies have in common: (i) a strong market orientation, based in the knowledge of clients demand; (ii) the practice of business opportunities screening, competitors benchmarking and portfolio management as support for decision in 'what projects to invest'; (iii) the practice of former technical, financial and economical analysis of projects, before product development; (iv) the continuous analysis of products after launching, providing the feedback character of the PDP. The grouped practices (i) to (iii) form the Pre-Development Stage from product development process and the practice number (iv) outlines the Post Development Stage (see Table 2).

3.3 Information from project management

The first effort in organizing a project is the thoroughly description of its scope. Most authors in PM indicate the use of WBS (Work Breakdown Structure) as an efficient tool for scope definition [15,21,24]. WBS is a hierarchical decomposition (top down flow chart) oriented to the project deliverables, including internal and external project products, aiming to reach project goals. This tool organizes the project global scope by its division in work packages that are decomposed in activities. Therefore, WBS is the first step of project planning, since it provides the base from which the project scope, time, human resources, cost, quality, risk and other plans derive. WBS may be presented as an indented list or in a graphic manner as it may be seen in figure 1.

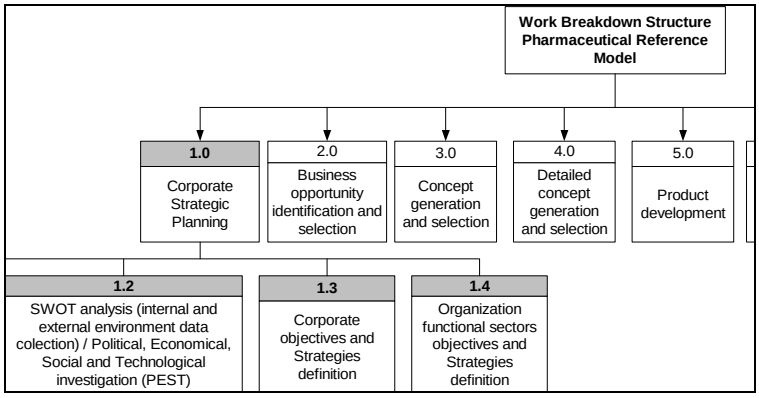

Figure 1. Part view of WBS from the pharmaceutical PDP reference model [20]

Besides WBS, project management methodologies recommend the use of matrices for human resources planning, in which the responsibilities for the project activities are established.

Aiming to control the PDP process, check lists were elaborated for phase transition as recommended in Stage Gates and in PM. Other tools from PM will not be discussed in this paper, although they may facilitate PDP implementation and management (see Table 2).

3.4 General view from the reference model architeture

The final reference model architecture is summarized in table 2. The control documents will not be described in this paper, nor will be detailed the activities. The final reference model graphical representation will be constructed using the architecture from table 2. It will contemplate three macro stages and seven phases, embracing from business opportunity recognition to product market launching. Macro stages and phases names are as prescribed in product development literature mentioned before.

Table 2. General view frome the reference model architeture [20]

Macro Stage	Phase	Gate	Control documents
Pre Development	Business opportunity identification and selection	**1**	Check list
			Product Innovation Charter PIC
			PIC archive
Development	Concept identification and selection	**2**	Check list
			Product Protocol
	Detailed concept identification and selection	**3**	Check list
			Detailed Product Protocol
			Project Plan
			Project Chronogram
			Activity x responsibility matrix
	Product and process development	**4**	Check list
			Phase Register Dossier reports
	Production and marketing plan performance	**5**	Check list
			Phase Register Dossier reports
			Product/Process master file
	PDP conclusion and product registration	**6**	Check list
			Register Dossier
Post Development	Product launching and marketing evaluation	**PDP Feed back**	Check list
			PDP history and project lessons
			Marketing and technical information

4. Conclusion

The qualitative approach adopted in the construction of the reference model proved to be efficient, since it permitted to gather information from professionals in a deeper manner. The choice of companies from medium and large sizes was adequate, since their development processes and relationship with ANVISA presented particularities, and the different types of business these companies develop brought robustness to the final reference model architecture. The same differences would not be so clear if the interviews included small companies; moreover the smaller companies hardly ever produce generic medicines.

The interview with the ANVISA referee was important for the delineation of legislation related activities in all macro-stages and phases. Such details are not represented in this paper.

The interviews in the construction phase were important for the reference model configuration, since each company PDP was modeled in block 1 interviews. Besides that, professionals from seven pharmaceutical companies, totalizing 40 people with large experience in pharmaceutical product development, expressed their impressions about the reference model final graphical representation in block 2 interviews. All the interviewed experts recognized the importance of PDP management, although some of the companies still present a product development not fully formalized. More details from the final graphical reference model are not part of this paper.

The professionals in general appreciated the Pre-Development, concept identification and detailing descriptions in the model, since there is no parallel in pharmaceutical literature. They also valued the control documents suggested in the model. The generality of the model was considered large, since it was analyzed and approved by experts from companies that produce human/veterinary medicines and cosmetics. The macro-stages and phases are independent on the product under development, but the work packages and activities, specially the latest, have to be defined product to product, when adopting the model. Such activities detailing is not part of this paper.

The managerial aspects of the reference model were attributed to: the broad scope description guaranteed by the WBS; the process segmentation, that facilitates risk management, process execution and control, since its complexity is crescent from the begin to the end; the clear indication of organizational function sector activities and work packages in the graphic representation; the decision making and quality control gates, with their check lists and process documentation; the model feedback activity which stimulates the process cyclic quality improvement.

The combination between literature information and companies' professional experience (tacit knowledge from interviews) proved to be an efficient architecture for the reference model construction. The validation of the model structure by interviews with professionals was decisive for the reference model graphical final configuration (not presented in this paper) since it provided the model fine tuning in relation to the Brazilian companies demand for product development.

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