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AN INITIAL PROPOSAL FOR PDP OF SMES DEVELOPING HOSPITAL FURNITURE

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Abstract. *A large percentage of the industrial SMEs has an organizational structure for product development too far from the adequate practices and models, elaborated by renowned authors with expertise in the theme of product development. On the other hand, the authors state that SMEs obtain considerable advantages by adopting a model of Product Development Process (PDP) management. Health is one of the most innovative sectors in the world, and countries like Brazil and Colombia are transitioning from a system that cares for contagious infectious diseases – where the drug product is the main form of treatment – to a system that cares for chronic degenerative conditions – where the equipment, including hospital furniture, has more relevance to the treatment. This change is offering better opportunities of specialized markets to hospital furniture SMEs that adopt an adequate PDP model. The present study proposes a first outline of a model of PDP management for industrial metal-mechanical SMEs that develop and manufacture hospital furniture, from a review of models proposed for great mechanical area.*

Keywords: *Hospital furniture, Industrial SMEs Brazil and Colombia, Product development, Industrial SMEs.*

1. INTRODUCTION

According to several studies, (Echeveste and Ribeiro 2010) among others, SMEs that develop products present low success levels when launching new products. In many occasions, SMEs have no formal procedures for development, or these procedures are too far from the adequate practices and models, elaborated by renowned authors as product development (Mendes and Toledo 2012), (Kaminski, Oliveira and Marques 2008). This, in turn, has a negative impact on competitiveness levels of these companies.

One of the main strategies proposed to improve the competitiveness in the SMEs is to strengthen their innovation ability. This innovation can be related to product, process, marketing or business, according to Tidd, Bessant and Pavitt (2005). Product innovation ranges from capturing ideas up to launching a product and obtain profits from it. The way of transforming an idea into a product is named Product Development Process (PDP), which has been the working theme of distinguished authors. They have proposed models, which basically comprehend the main phases, these phases' activities in a well-defined manner, how people interact and resources administration (Echeveste and Ribeiro 2010).

PDP, like other company processes, is organized from the organization's needs and abilities. In the case of SMEs, it is influenced by internal factors, such as the organizational culture, or external ones, such as the socio-economic context. The present study focuses on industrial SMEs, whose product is basically a metal-mechanical one, specifically of hospital furniture sector. These SMEs are hereinafter named hospital furniture SMEs.

Considering that approximately 75% of product costs and the main quality characteristics are defined in the product design, and that an adequate process management allows obtaining a product in less time (Dieter and Schmidt 2009), this matter has no lower importance for SMEs. However, proposals adjusted to this type of companies are required to more easily implement an adequate PDP to their particular needs (Echeveste and Ribeiro 2010).

In Latin America's countries, SMEs and micro-companies represent 99% of the companies and 67% of total positions, according to Naciones unidas CEPAL (2013). Therefore, these companies are very important from a social point of view. In spite of it, they present low productivity levels compared to large companies. Moreover, the smaller the company, the more representative is this feature. However, the difference in the productivity among SMEs and large companies is more critical in SMEs in Latin America than in Europe. The differences between Latin America and Europe in terms of productivity levels are as follows: 10% in micro-companies, 30% in small companies and 50% in medium enterprises in Latin America and 59% in micro-companies, 72% in small companies and 83% in medium enterprises in Europe, according to Naciones unidas CEPAL (2013, pag 10, 21).

In order to reduce the productivity gap of the SMEs, CEPAL study recommends working in four axes i) innovation to strengthen productive and managing abilities; ii) access to markets; iii) productive articulation and enterprise cooperation, and iv) access to funding. The present study focuses on number i) innovation to strengthen productive and managing abilities, according to CEPAL recommendations.

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Hospital furniture and equipment sector is considered as presenting from medium to high technological complexity according to the results from the investigation on technological innovation PINTEC 2008 (Instituto Brasileiro de Geografia e Estatística IBGE 2008). Hospital furniture subsector presents medium complexity, due to the involved technology and the users' diversity. Therefore, the outcomes obtained can be extrapolated to another type of sectors with aggregated value.

This study aims to propose an initial model of PDP suited to metal-mechanical SMEs developing hospital furniture. The model is conceived through literature review specific to great mechanical area of PDP in addition to review of regulations and guidelines of medical devices. Therefore a model was established concerning both good practices for the product development proposals from the 1980s and specific medical device requirements.

2. HOSPITAL FURNITURE

Hospital furniture is defined as artifacts used to facilitate or help people during regular work of a hospital. This work is related to its main role, i.e., to preserve or improve people's health, but with no active or invasive function in the patient. There is not a universal classification, but hospital furniture can be grouped by function. Basic groups are: beds, stretchers, examination tables, surgical table, cars and several complements.

Basic functions of hospital furniture are the following: accommodate the patient during his/her procedure and recovery; transport the patient; move, support or preserve teams, medications or supplies; help the medical team in their roles, such as to meet patient's needs, to perform diagnoses and procedures. Main users are: health professionals (assistants, physicians or specialists), servicing personnel (cleaning or maintenance), patients and their companions, practitioners or students, people with special needs, investigators and engineers (Santos, Gazelle, et al. 2010).

Traditionally, hospital furniture was distinguished from medical devices. However, classifications used in the last years in Brazil name them as medical equipment and in Colombia, as medical device. Medical devices or equipment comprise a large range of technologies and applications, from manual tools to computerized equipment for surgeries, or implant screw for artificial organ, (Alexander and Clarkson 2000), (Santos, Gazelle, et al. 2012). Basically, these devices are used in i) procedure or treatment and are in close contact with the patient, whether invasive or through contact with prosthesis, implants; ii) diagnosis (X-ray equipment, electrocardiograph); iii) treatment or attenuation of disease (surgical instruments, dosing pumps, defibrillator, ventilator); iv) prevention or control (monitoring vital signs). However, some legal requirements may present variations or may change along the time. The importance of classifications is as follows: depending on the classification and the potential risk for the patient, they have different requirements for the development, manufacturing or distribution chain.

The evolution of hospital furniture has close relation to the evolution of medical treatments. For instance, new diagnosis equipment requires the development of new furniture able to accommodate the patient according to the device's requirements. In recent years, however, there has been a trend of hospital furniture to integrate the Information and Communication Technology (TIC). There are even proposals to integrate them to the hospital's systems.

Mainly metal and plastic materials are used for manufacturing hospital furniture. Likewise, the technology used in its operation is a manual, electrical and hydraulic one. Technological trend is towards the manufacture using plastic materials, as these are more aseptic and molding production processes can be used. Operation technology aims to be more user-friendly, by adopting electrical systems combined to electronic controls.

Medical devices or equipment are classified according to the risk. Both Brazil and Colombia use the European ranking scale. In Brazil, the Agência Nacional de Vigilância Sanitária (ANVISA) is the institution in charge of the classification, ranking the equipment in: Class I, low risk; Class II, medium risk; Class III, high risk; and Class IV, maximum risk. Generally, hospital furniture are class I. In Colombia, the classification is performed by the *Instituto Nacional de Vigilancia de Medicamentos y Alimentos* (INVIMA) as: i) class I, low risk; ii) class IIa, moderate risk; iii) class IIb, high risk; iv) and class III, very high risk. Electric beds are ranked as category I. Depending on the risk level, manufacturers and dealers must meet different requirements in order to commercialize their products.

3. LITERATURE REVIEW OF PDP

PDP models in the middle of 20th century focused on technical subjects, based on sequential activities or sequential engineering. Activities are performed in specialized departments, where an activity only started after finishing the previous one. This has soon evolved to simultaneous models or concurrent engineering, where the tasks are performed in a collaborative form among the different areas, mainly technical ones. Some of the tasks are carried out in parallel or transposed form. Over the past years, PDP presents activities or phases from the market analysis, and verification of product's adequacy for the company up to the product's discontinuation in the market. In consequence, PDP has evolved from a merely technical process to a business process comprising almost all areas in the company (Kaminski 2000).

One of the first authors who organized PDP as a sequence of activities was Morris Asimow, in the beginning of the 1960s. In the book ¨Introduction to design¨ (Asimow 1962), Asimov establishes a development process divided in seven phases: the first three ones are the primary or design phases i) feasibility study; ii) preliminary design; iii) detailed

ISSN 2176-5480

design; the next four phases are the production and consumption cycle phases iv) production plan; v) distribution plan; vi) consumption plan; and vii) plan for retirement of the product. Figure 1 indicates the phases of the model proposed by *Asimow* and a general structure of the design's philosophy. As the process starts from a market's need, the feasibility study firstly explores the validity of the potential need and strong evidence of its existence is sought. Furtherly, possible solutions to the design are explored and finally the design feasibility is determined.

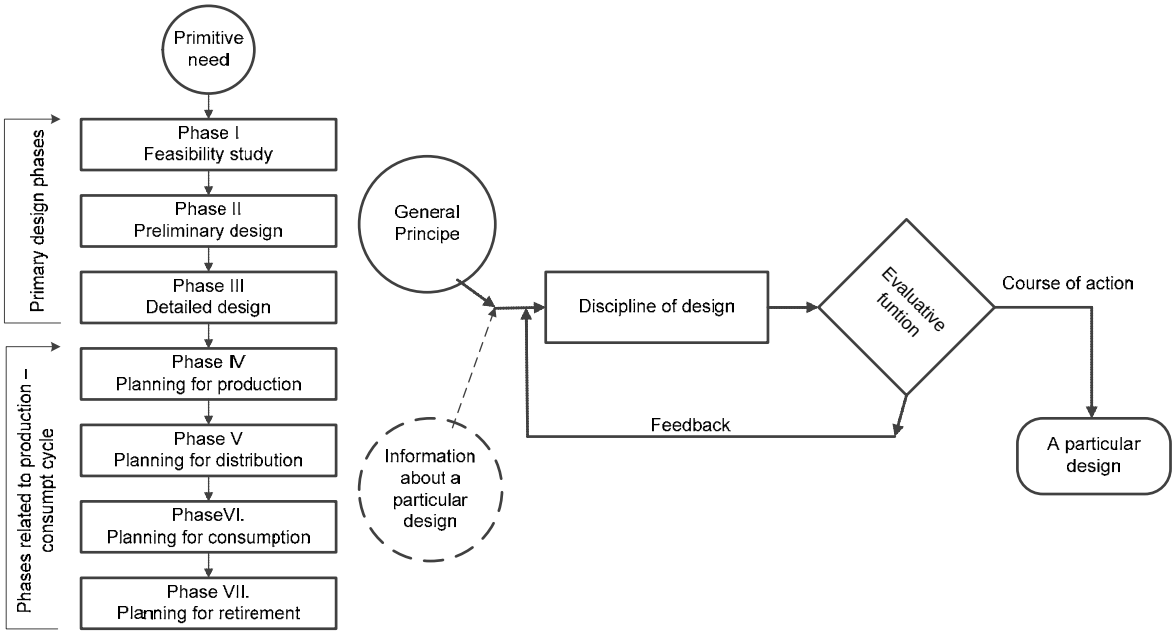

Figure 1. General structure of the process according to Asimow. Source: (Asimow 1962).

The model proposed by Asimow more than 50 years ago considers the development, supported on the need and presents design as a solution. Currently, this is a fact that is not adequately understood by the SMEs, as evidenced in distinguished studies (Kaminski, Oliveira and Marques 2008), (Millward and Lewis 2005), (Echeveste and Duarte Ribeiro 2010), (Mendes and Toledo 2012). In addition, the phases from production to retirement of the product are taken into consideration. Although the model is based on sequential engineering, the author indicates the possibility that once concluded the primary phases, and moving to the production plan, the initial team can follow up the next steps.

During the '80s and '90s in the 20th century, several authors planned PDP proposals. This study does not intend to make a full review, but a compilation to be an element of discussion, in order to establish the model in hospital furniture SMEs. It can be pointed out that i) the models evolved to concurrent engineering and integration of different knowledge areas, not only the technical ones; ii) the market constitutes a relevant force, not only from the initial need, if not the center the PDP orbits around; product's success is identified through satisfaction of the market's needs; iii) an implementation not only of technical reviews – that we could call operative ones – in the process, but also reviews in a more strategic level, where it is determined whether the design continues. This implementation uses criteria to evaluate the adequacy for the company in terms of continuing the design due to changes in external or internal conditions.

The proposal of Clark and Wheelwright in the book ¨*Managing New Product and Process Development*¨ (Clark and Wheelwright 1993) of the product development funnel would later lead to innovation funnel. Product Development Process starts with an idea and ends with the product specifications that meet the market's needs and are also economical and manufacturable. The funnel shows a process where many ideas are identified, selecting the more promising for development, considering the market and the available resources. The authors propose a model of easy understanding and focused on the automotive industry.

Robert Cooper proposes the Stage-Gate, which is based on the concept that PDP has phases (state) and gates. Phases are the design's macro-divisions. In the gates, the design is evaluated and continuation or not continuation is defined. Each phase has activities and deliverables and Figure 2 depicts the structure of State Gate. The author (Cooper 2008) proposes a scalable model according to the design complexity: i) five phases for more complex designs; ii) three phases for designs of moderate risk; and iii) for small designs, such as for customized products. Cooper suggests evaluating with the following structure: i) deliverables of each phase are determined before beginning the phase ii) previously defined evaluation criteria iii) decisions, the design goes, is killed, hold or recycled.

ISSN 2176-5480

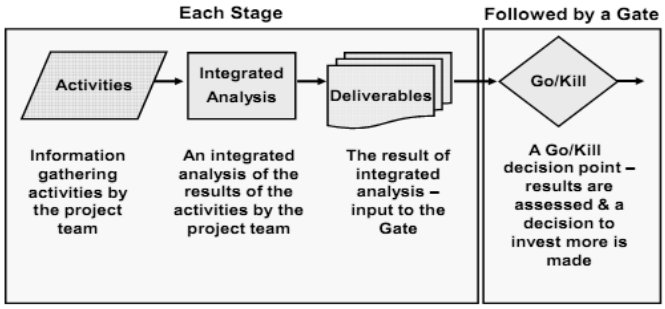

Figure 2. Structure of Stage Gate. Source (Cooper 2008)

Finally, personnel independent of the development team perform an evaluation. It may be difficult for a SME, considering the varied structures in the SMEs. Sometimes, the owner or manager is in charge of the development, or the head in production section is also in the development one. These examples, among other varied structures, make difficult to have an independent evaluation team. Another common situation in SMEs is that technical reviews tend to be confounded with strategic-type gates reviews. In other words, according to Echeveste and Duarte Ribeiro (2010), technical personnel make strategic decisions, with no follow-up from management areas, as their general concept is viewing the PDP as a technical process. These situations indicate risk for the SME.

Recently, there have been some models that integrate many elements proposed by previous authors. We highlight the proposals of Ulrich and Eppinger (2004), who propose a model composed by six phases, as shown in Figure 3. This model starts with a phase zero that comprises activities before starting the design. Then, basically design portfolio is defined and the extent of the product to be developed is established. The design ends with the launch of the product in the market.

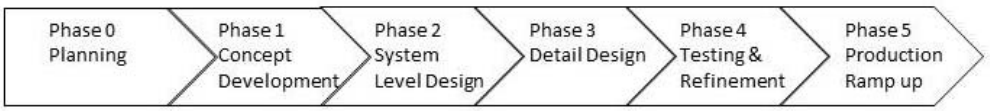

Figure 3. Model of Ulrich and Eppinger. Source: (Ulrich and Eppinger 2004).

Rozenfeld, et al. (2006) formulated a unified general model, which takes into consideration from the company's strategic planning until the discontinuation of the product. The process is divided in three macro-phases: pre-development, development and post-development, as indicated in Figure 4. The two models use main phases, each one having previously established deliverables, as well evacuation parameters.

Although the phases are graphically depicted in sequence, the nature of product development is iterative and one phase can start before finishing the previous one, depending on the relation among the activities. It changes from one company to another and also in different designs developed in the same company. Both models use the logic of State Gate. It is important to point out that the phases are not of one department, there is neither marketing nor product engineering phase, the philosophy of these models is integrative, i.e., the executive team must have members from different functional departments of the company, mainly: marketing, product and production engineering (Ulrich and Eppinger 2004), (Rozenfeld, et al. 2006).

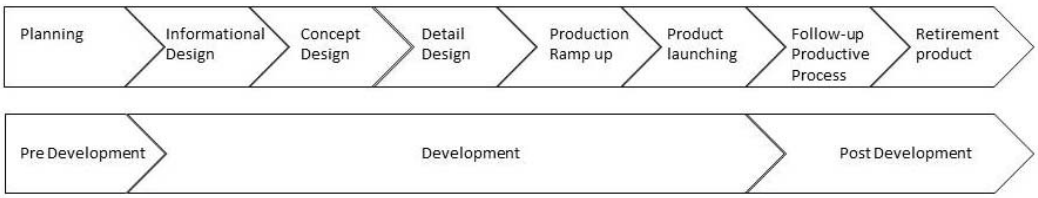

Figure 4. Model of Rozenfeld et al. Source: adapted from (Rozenfeld, et al. 2006).

PDP models mentioned are general ones. Therefore, it is necessary to adapt them to specific situations, to the economic sector, company size, regional aspects, macro-economic characteristics and organizational culture. Therefore, a company determines its specific PDP by meeting its particularities. The product, as we shall further discuss, has large influence in the determination and organization of PDP.

Kaminski (2000) suggests the concept of design spiral, based on the fact that the phases have no linear sequence, i.e., one phase does not end completely before moving to the next one. The spiral consists in each phase being one turn

ISSN 2176-5480

passing by required items or areas. The first turn roughly defines the design, and in each subsequent turn the design becomes closer to the desired outcome, as shown in the Figure 5. Each turn of the spiral only passes by the required areas and corresponds to one phase of the design. The author proposes seven phases: i) feasibility study; ii) basic design; iii) executive design; iv) production planning; v) planning of availability for the client; vi) planning of consumption or use of the product, and vii) planning of retirement of the product.

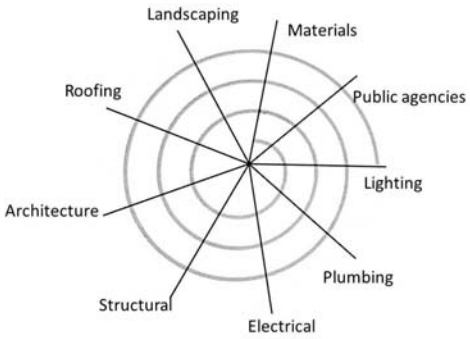

Figure 5. Design spiral from Kaminski. Source: (Kaminski 2000)

Unger and Eppinger (2010) indicate that although phase models have cycles, they generally are rigid, since: i) specifications defined in the beginning of the design are frozen; and ii) reviews or Gates are determined in advance. According to the authors, the phases process is more adequate for products with more stable cycles and better known technologies, requiring less or shorter iterations, as in the case of product update. In addition, phases model basically has two problems: changes in the market can lead to risks, due to the definition and freezing of initial specifications, and difficulties to perform parallel activities can occur. (Cooper and Edgett 2008, apud Unger and Eppinger 2010) state that state gate model's great competitor is the design spiral model, due to its flexibility. However, there are disadvantages: i) administration's attention is required due to the complexity; and ii) lack of rigid specifications can maximize delays in the development of complex systems. According to the author, spiral model is better indicated for designs where technologies are not well known and more and longer iterations are required. Figure 6 shows two proposals for design spiral model. The general proposal on the left side and the model used by Xerox on the right side. Model phases are the proposals in the general phases models. When the design has a few iterations, spiral model tends to the phases model. Phases model has more manageability and is more focused on the technical risks while the spiral model is more focused on the market-type risks.

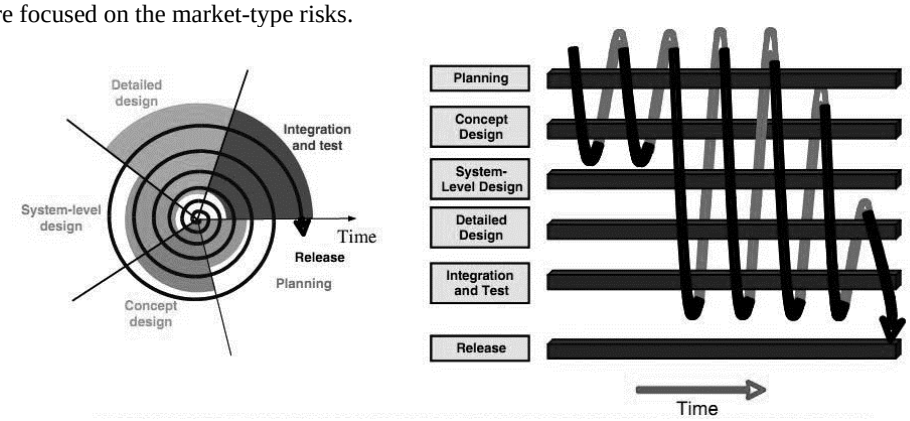

Figure 6. Model of design spiral. Source: (Unger and Eppinger 2010)

Regarding the above mentioned, proposals from authors related to great mechanical area of PDP have some basic elements: i) main design phases are defined, with previously determined entries and exits; ii) the model proposes decision marks or Gates, both strategic and technical, determining the product convenience for the company and related to design operational condition, respectively; iii) PDP is proposed as a business process, not just an engineering procedure. Therefore, integration of different areas of knowledge is essential for the development team. Likewise, higher management levels play an important participative and evaluating role in the early phases of product and process design; iv) there is a trend to enhance initial phases of "fuzzy front end" design considering market and technology features and the company's goals, strategy and abilities; v) scope of PDP, while bearing differences according to the proposal, has a trend to involve from the identification of a market opportunity to the product discontinuation. Product design is the basis for PDP, however, what occurs before and after is also a integral part of the process; vi) designs are

ISSN 2176-5480

performed highlighting a collaborative characteristic (among departments or companies); some activities can be performed concurrently and iterations in a design phase or between phases are part of the models; vii) clear definition of responsibilities of functional areas of the company; viii) the model considers both the phases and organization and communication among team members; ix) the models are adapted to the sector and design of a specific product.

Hospital furniture is developed from technologies and materials previously invented and applied in medical devices or another sector. In order to develop these products, the SME can both use technologies normally employed and master – like the case of metal-mechanical processes and transformation of plastics – and take advantage of technologies that are new for the company, but already existing and used by other companies of the sector or in other domains. The classification that gathers the different groups of designs is performed from classification by authors cited in the present chapter, which is shown in Table 1. In addition, there are proposals of classification of the design types more usual in the hospital furniture SMEs. However, there might be differences between what is proposed by the authors and our definitions.

Designs of the hospital furniture SMEs are basically: i) platform is used in this type of design, when a new concept is developed, intending to satisfy the clients' needs and the time that constitute a family of products, the products are normally modularized. In order to change the provisions, by adding or altering the modules, technologies in SME domain are used, as well as technologies outside the domain, but already developed; ii) new concept: designs where the product is basically new for the company and, like the platform designs, technology non-mastered by the company can be required. The radical difference resides in the fact that there is not a family of products and it is not normally modular either; iii) evolving development, when a product is defined from products existing in the SME. Within this category are included the development of modules, in order to vary the provisions of platform products, or products redesign aiming to perform changes requested by the client, to improve processes or reduce costs; and iv) customized products, which are designs preformed for particular needs of a client, who provides the specifications or needs.

Table 1. Product classification. Source: authors based on: (Dieter and Schmidt 2009), (Kaminski 2000), (Pahl and Beitz 2001), (Rozenfeld, et al. 2006), (Ulrich and Eppinger 2004).

Ulrich and Eppinger	**Pahl and Beitz**	**Rozenfeld et al**	**Kaminski**	**Dieter and Schmidt**	Hospital Furniture
Market Pull	Mass production				x
Technology push		Radical Design	Innovative Project	Original design	x
Plataform Products		Plataform Design			Plataform Products
			Evolutionary Development	Adaptative design	New concept
Process-Intensive Product					x
Costumized Product	Costumized Product				Costumized Product
High- Risk Product					x
Quick-Build Products					x
Complex Products					x
		Incremental Design	Evolutionary Development	Redesign	Evolutionary Development
				Selection design	x
				Industrial design	x
	Part of a sub product				x

From one analysis performed from different studies focused on SMEs, preferably industrial, on the key factors for success or failure in the product development. The following papers were dealt with: (Turner, Ledwith and Kelly (2010), (Millward and Lewis 2005), (Mendes and Toledo 2012), (Kaminski, Oliveira and Marques 2008), (Echeveste and Ribeiro 2010), and (Cheng 2000). The studies have diagnosed industrial SMEs in different economic and geographic sectors and supported the statement that SMEs generally do not have an adequate PDP that allows the development of products. The study of Mendes & Toledo focuses on SMEs in the hospital equipment sector in São Paulo area, which is our target.

Key factors for success in the development of new products, in the context of industrial metal-mechanical SMEs were, in strategic terms, i) focus on the business linking the products to the company's general strategy; ii) presence of senior management in the planning phases; iii) policy of portfolio management and iv) correct evaluation of the market potential. These key factors have higher influence in the beginning or before the design, what we call pre-development, as it allows support the operational process of the product development.

Key factors in the operational level are basically: i) definition of the product development as a sequence of steps and activities, adequate to the objectives and organizational structure; ii) human resources appropriated for the required

ISSN 2176-5480

activities; iii) abilities of product design leader; technical, management abilities, vision, relationship and motivation; iv) functional integration among the departments, mainly marketing, production and design and product engineering; and v) a clear definition of the user's needs, concept of product and its success criteria.

4. SPECIFIC LITERATURE REVIEW FOR MEDICAL DEVICES AREA

United States' Food and Drug Administration (FDA) issued a manual for development control of medical devices (FDA 1997), where they propose a development control from the design, manufacture, distribution, use, maintenance until obsolescence. FDA suggests the waterfall model, which emphasizes the need for reviews of each phase, of technical order; the verifications of design outcomes against the users' needs, which have a more strategic level; and the product validation before transferring the product to the production. Figure 7 represents the model.

FDA highlights the management of device's risk. The development process must integrate one evaluation system in order to identify unacceptable risks, during initial phases of the design, and procedures for risk analysis, control and monitoring. Risk type depends on the nature of the product. FDA classifies medical devices in three categories, depending on the risk level. Category 1 is the lowest one, moderate risk. The manual establishes neither the model nor the procedures; it consists of guidelines to ensure the safety of the users and the companies. In addition, it points out the need for a control of changes and documentation during the product's life.

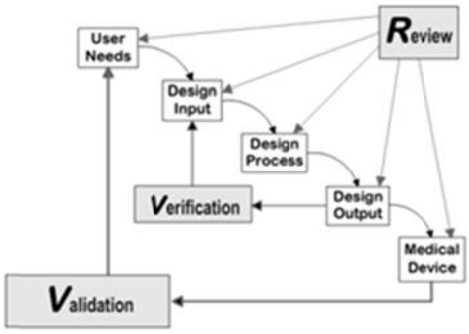

Figure 7. FDA's waterfall model. Source: (FDA 1997)

FDA's main points are: i) review design's inputs. Functional: function's own requirements; performance: requirement of values such as precision, speed, time, among other; and interface: requirement of compatibility with external systems; ii) development control in every steps from the beginning of the design until discontinuation; iii) development steps or phases that are defined and logical; iv) risk management: process that ensures the identification, analysis, control and monitoring of potential risks; v) have one review of process steps, verification of design outcomes against the specifications, and design validation; vi) control of changes in the product; vii) documentation control; viii) define the interphases among the groups; ix) communication policies and procedures for team members; and x) identify responsibilities

ISO 13485 standard, ¨Medical devices Quality, management systems, Requirements for regulatory purposes¨. (International Standard , 2003) proposes a series of measures that the organization developing hospital devices can implement to ensure the quality of the products. The standard establishes the general conditions of product design: i) design planning; ii) procedure documented, with its phases and activities; iii) have one review of process steps, verification of design outcomes against the specifications, and design validation; iv) define the interphases among the groups; v) identify responsibilities; vi) ensure effective communication; vii) human resources with knowledge and skills required for the tasks, have evacuation and training plans; and viii) risk management. Planning exits must be documented and updated according to the case, as the conception and development proceed. Generally, the standard is centered in the PDP, not in a determined specific methodology.

ISO 14971 standard ¨*Medical devices, application of risk, management to medical devices*¨ (International Standard, 2000) establishes procedures for the analysis and risk management in the development of medical devices. Risk, according to the standard, is the situations that might endanger the different users of medical devices. It basically comprises the risk identification, evaluation, control and reduction, in addition to further monitoring. **¡Error! No se encuentra el origen de la referencia.** depicts the diagram of risk control process. Hospital furniture can be classified as class I medical devices, i.e., low risk. For some furniture types, such as surgery tables or ICU beds, establishing the risks for the different users is required.

Other important standards for hospital furniture are IEC 60601-1, which is a European standard for safety of electrical devices and IEC 60601-2-38, which is specific for electrical hospital beds. These standards propose values and types of electrical and mechanical tests, even as outlines regarding tolerances in the mechanisms that may present interaction with the users. Therefore, these standards provide elements for initial specifications and regarding the tests,

ISSN 2176-5480

forms of reviewing the users' safety. The present study does not intend to establish the specific conditions proposed by each of the standards consulted, but show how they can influence the PDP.

Regulations and guidelines provide the following elements, which support the proposal in this study: i) importance of definition of clinical requirements; ii) risk management in PDP, an important feature following the product process step, as well as during the whole process; iii) checking the product developed; vi) clinical validation of the product during use; v) product surveillance and control in the market; vi) starting in the initial phases: product classification according to objective market regulations, regulations and requirements checking for a particular device and validation method planning; vii) documentary control of the medical device during the whole life cycle, including the control of changes; viii) define intephases among working groups, in order to assure the transference of phase deliverables; ix) have a communication strategy among the departments involved in the development; and x) clear definition of responsibilities. These two last items are from both FDA and ISO 13485 standard.

5. PROPOSAL OF A PDP MODEL

Industrial SMEs of the hospital furniture sector are very heterogeneous regarding the size, organizational structure and organizational culture, among others. These internal factors of the SMEs, as well as the external elements, determine the way of implementing and executing the PDP. However, the type of organization in terms of the number of people involved in the product development and the way how it is organized in the company determine the manner of performing the phases and tasks, the communication among departments and the evaluation of the phases. PDP tasks to be performed depend on the need for the correct product development and the company's ability to execute the task (Rozenfeld, et al. 2006).

As we indicated previously, the SMEs have diverse structures and the PDP must fit in the organization's structure and culture in order to be accepted by people in the company. The assignment of responsibilities to the departments depends on the company's own configuration. In the SMEs, the concept of department can be different and presents structures where processes like product development depend on the production or sales. As was identified by distinguished studies, the owner, who is the original entrepreneur in some occasions, has large knowledge about the business regarding the market and/or technology. His/her influence can be large in determining the designs to be executed or included in the product specifications. Although the industrial SMEs – and for our purpose, the hospital furniture SMEs – have these several structures, it is possible to implement a PDP model.

As established, more usual types of design in the hospital furniture SMEs are: i) platform; ii) new concept; iii) evolving development; and iv) customized products. Designs type i and ii correspond to the more complex designs for this type of SMEs by level economical and market risk. It is important for the SMEs to develop this type of design, since the new platform or concept normally is applicable to type iii and iv designs, which are the most usual. With these latter one, products are developed for the market from already developed products, with type i and ii designs. The SME designs products incorporating new trends, as the TICs in these products. The phases for the types of design are distinct due to the differences regarding the complexity, iterations and risk for the company.

PDP model proposed for hospital furniture must meet: general requirements of PDP proposals of mechanical area; general requirements of regulations, guidelines and specific features of SMEs. Critical factors discussed and product types developed by the company are taken in consideration, as they provide key aspects of PDP. Phases considered as required for the model are: i) **strategic planning,** aiming to align the product design to the company's strategic plan. ii) **design planning**, in order to identify users' needs, ascertaining whether there is a market for the future product. This phase ends with the design general plan and product classification according to objective market regulations and product requirements; iii) **establish product specifications**, product target specifications and preliminary assessment of potential risks for users are determined based on users' needs, yielding a detailed plan; iv) **design concept**, final product concept is obtained from the initially tested concepts, taking market characteristics into account; v) **system design**, product' architecture is defined, main aspects, such as material key components, major manufacturing processes, cost estimates are described in more detailed and defined, and risks for product's users are once more considered in this step; vi) **detail design**, the phase ends with a completely defined product, in terms of constructive details. Suppliers and manufacturing processes are also defined and the product is checked against the initial requirements; vii) **trials and tests**, the product and the manufacturing process are tested during this phase. Additionally, the product is validated during use; viii) **homologation and clearance for manufacturing**, required regulatory procedures are performed. This phase begins with classification and checking of requirements in the objective market (phase ii). It ends with the product marketing clearance ix) **manufacturing preparation**, small batches are manufactured. Manufacturing area staff is trained, quality procedures are determined and manufacturing procedure final validation is performed ; x) **follow-up of manufacturing process**, this is a key phase, as both FDA and ISO14971 standard require the definition of interphases among the groups and transfer to manufacturing. This transfer is deemed critical and the phase starts with preparation for manufacturing and has no determined end; xi) **product release**, related to marketing plan and product distribution, determination of shipment and packaging conditions, sales and technical services staff training; xii**) performance monitoring**, this step has two approaches: a pro-active follow-up step of the new product in the market,

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checking its correct performance and possible improvements and a reactive step, i.e, monitoring of adverse occurrences, comprised by damage or personal injury caused by product failure; and xiii) **product discontinuation**.

Therefore, we have a proposal of PDP with thirteen phases, which can be joined to the proposal of Rozenfeld, et al. (2006) in three macro-steps of pre-development, development and post-development**¡Error! No se encuentra el origen de la referencia.**. Regarding the strategic type Gates, these are determined for each phase, but some phases present relevance, in our judgment: i) strategic planning: one evaluation must be performed by the senior management about the adequacy of the design, degree of inversion required, target-market, the SME. By preventing the pet design, as we indicated in advance for one SME, the evaluations of strategic type can be difficult, but they are not less required and the SME needs to have a team evaluating the phases independently of the development team. This is more relevant for platform-type designs, by type of decisions.

The phase iv concept of the design: the technology to be used and the general conception of the product are determined in this phase. Therefore, this is one of the more strategic phases, and it is not convenient that such decision be made by the technical team, as occur in some occasions according to the studies consulted.

The phases: ix preparation for production and xi launch of the product correspond to the phases where the decision concerning high investments in tooling and other productive processes is made. In addition, the production process is started, implying in risks if there is no certainty in the decisions. Therefore, the senior management must be very close to the staff in these Gates.

According to the authors' proposals, there are basically two forms of model, regarding the conception: phases model and spiral model. Unger and Eppinger (2010) indicate that, depending on the number of iterations and whether these are short (in the same phase or between two phases) or long (when, in very advanced phases, returning to initial phases is required), one or another type is more convenient. In our case and in the designs of type: i) platform; ii) new concept: long and numerous iterations can be required when the product has new concepts and technologies; for the case of designs of type: iii) evolving development; and iv) customized products: normally, iterations will be shorter and in smaller amount.

PDP requires risk management, control of changes and documentation control in a permanent basis throughout the whole process. For the case of designs of type: i) platform; ii) new concept: all phases are required; the initial ones are decisive, for decisions that will define the company's technological path concerning the product are made in these steps. For the case of designs of type: iii) evolving development and iv) customized products: initial phases can be simpler. Since the company already has similar products it is easier to evaluate the users' needs. When the design is intended to improve the process for needs that the users already have, the existing one defines the new product's general concept. As the company knows the technology, the product does not present large risk of technical type because the solutions have been tested in practice. Regarding the market risk, it is easier to evaluate products with small changes than new concepts of product.

Therefore, a simplified model can be proposed for the case of low-risk designs without large uncertainties in SMEs not requiring complex procedural designs. Considering that the more common designs are type iii) evolving development, according to the explained previously, developing the products by families and in a modular way is a common practice

6. FINAL CONSIDERATIONS

Development of hospital furniture requires not only PDP elements from mechatronic product. It also must consider medical devices regulations and guidelines, as these are recent and are evolving. US and European regulations started in 1976 and 1993, respectively (SANTOS, GAZELLE, et al., 2012), whereas, generally, Latin America's regulations are less than 10 years old. Additionally, products like hospital furniture are included in TIC. Therefore, they can incorporate active functions in the disease treatment, diagnosis or mitigation, enhancing the risk classification of a specific product. Thus, regulation requirements regarding medical devices must be incorporated into the PDP.

A first approximation of a PDP management model for SMEs developing hospital furniture is proposed, taking PDP proposals of great mechanical and medical areas and medical devices regulations into account. The proposal considers the key elements found in the literature. However, a deeper study is required in order to determine the activities in a more detailed condition and establish other PDP elements, such as team organization, communication, responsibilities determination, among others. Field research is required for a deeper understanding. It is also important to determine the geographic region, since regulations and macroeconomic factors may influence the PDP.

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8. RESPONSIBILITY NOTICE

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