

# INTERVENTION PROJECT FOR PRODUCT DEVELOPMENT PROCESS MANAGEMENT APPLIED TO SMALL AND MEDIUM ENTERPRISES WHICH PRODUCE DRUGS

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## ABSTRACT

In this paper an Intervention Project for Management of the Product Development Process (PDP) applied to Small and Medium Enterprises (SMEs) producing drugs is made. From the analysis of the information provided by the four companies interviewed, it can be concluded that, with respect to activities concerning the Product Development Process, they are at maturity level 1, in a basic level, and within it, in the sublevel 1.4. That is why it is necessary to make a transition between current practices and the situation to be achieved. The Intervention Project proposed aims to make that analyzed SMEs increase their level of maturity. Then, by applying successive Intervention Projects will achieve the appropriate systematization of PDP management.

**Keywords:** *Management, Drugs Development, SMEs, Intervention Project.*

## 1. INTRODUCTION

The new products development is an essential activity for survival and competitiveness of enterprises. Products must be managed in order to quickly enter the market, better meet customer needs, are easier to manufacture, are attractive in the market and ensure a profit for the company [1].

In this paper an Intervention Project for Management of the Product Development Process applied to SMEs which produces drugs is proposed [2]. An Intervention Project aims to introduce best practices in companies' product development process management (PDP), so as to increase the level and maturity. This incorporation achieved that companies engage in activities that did not perform before; apply specific methods or tools, to monitor their activities and, therefore, increase their effectiveness, among other benefits.

To this end, an exploratory research is conducted in four SMEs which produce drugs, in order to understand and analyze how they perform Product Development Process Management and identify strengths and weaknesses. Interviews, observation records and activities in situ are used. The questions in the questionnaire are divided into three groups: (i) general company information (size, structure, type of product manufacturing, supplying market), (ii) information about the procedures associated with the PDP Management, (iii) information about the difficulties in the management of PDP. Intervention Project for PDP Management is developed in order to improve the procedures performed for the Management of Product Development, given the corporate culture, so as to adjust, adapt and be accepted by the community productive, enabling lower failure rate in attempts to introduce new products on the market. The proposal is carried out in terms of the competitive environment, strategies and capabilities of companies, presenting concepts, tools and information flow applied in the diverse activities for understanding and translating customer requirements by improving product specifications, its production and process monitoring.

The PDP Management comprises a set of activities from the choice of a working methodology, starting with the identification of an unmet need in society, and continuing with a product that meets needs in the best way possible. Achieving develop a product successfully is not only a problem of marketing, design or manufacturing, is an issue that should be raised globally and therefore involves all these areas. Being an activity considered strategic for any company and since, in many of these, product development should be a continuous and cyclical activity, it is important that each company could establish its own methodology suited to its specific endogenous and exogenous framework in which it is inserted. It is essential that this activity is organized properly to optimize their performance so to develop a successful product [3].

Rozenfeld [4] divided the PDP Management in macro-phases called: pre-development, development and post-development. Each of these macro-phases is split into phases, activities and tasks. Although this model presents the stages sequentially, in the sublevels of activities and tasks it is normal to ensure synchronization. This depends on the type of activity to be performed and available resources. The model also includes, at the end of each stage, a specific activity for review and approval to proceed to the next. The structure of the PDP management is advantageous for all companies, as it improves the understanding of customer needs in the early stages of development, reduces duplication of work in the stages of development and helps control costs, quality and schedule during development. Figure 1 shows graphically the unified model of PDP proposed by Rozenfeld.

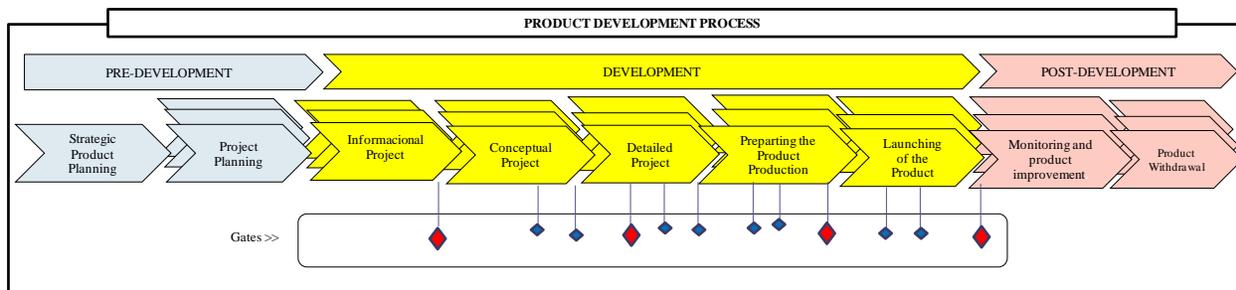


Figure 1. An Overview of the Rozenfeld Model

## 2. LEVEL OF MATURITY

Currently, it is necessary to generate methodologies and tools in order to make SMEs more competitive and creative, because it is of great interest that they be able to offer cutting-edge products at competitive prices and quality, both for domestic consumption and for export. To reach this point, it is necessary to go through the stage of design and development of new products, which should make the minimum possible errors, to be on time to market demands and rapidly changing. Innovation is a process that begins with the formulation of objectives and strategies for the products from the company's strategic planning, through product planning, production and marketing, and that does not end launching the product to market.

Most companies use the same basic elements of PDP proposed in the literature, but their survival depends on how they adapt to each specific environment. There is not a common solution for success in the PDP, but the companies that succeeded, increased flexibility and encouraged a culture of communication and integration. Therefore, the answer is not a procedural and operational, but cultural. As learning takes place inside companies, development processes evolve and mature. Thus, appropriate remedial actions for a particular process will depend on the level of maturity at the time of the process.

Rozenfeld proposes five levels of maturity: (i) Basic: only performed some PDP essential activities; (ii) Intermediate: activities are conducted under patterns and the results are predictable. They also use proven methods and tools for product development; (iii) Measurable: indicators exist and are used to measure the performance of the activities and the quality of the results; (iv) Controlled: the company works systematically to correct activities and (v) Continual improvement: support processes of "Change Management", "PDP Incremental Improvement" and "Transforming Process of PDP" are institutionalized and integrated.

From the analysis of the information provided by the four SMEs interviewed [5], it can be concluded that, with respect to activities concerning the PDP, they are at maturity level 1, that is, on a basic level, and within it, in the sublevel 1.4. At this level, companies systematically perform a set of essential practices for effective management of product development: integration with top management, definition of a detailed project scope, definition and implementation of requirements, among other. The sublevel 1.4 is characterized by companies working with product portfolios and analyze every project relative to others. Project planning is sophisticated and includes analysis of the economic viability and use of project management systems.

As it is not possible, nor would it be efficient, pretend that companies drastically raise the level of maturity of PDP management to level 3, which is best suited for companies producing drugs, is proposing an Intervention Project to guide the process of change and thus achieve a gradual rise in the level of maturity.

## 3. MODEL OF PRODUCT DEVELOPMENT PROCESS MANAGEMENT

The model which SMEs producing drugs should arrive [6, 7], like Rozenfeld's, taken as reference, contains macro-phases, phases and activities. There are three macro-phases and they are classified as: (i) Pre-Development, (ii) Development and (iii) Post-Development. The composition of each one is different from the one proposed by Rozenfeld. The Pre-Development macro-phase still has two phases: (i) Strategic Planning Product and (ii) Project Planning. The Development macro-phase consists of three phases: (i) development and product preparation, (ii) Planning and preparation of production and (iii) and launching the product to market. Finally, the post-development macro-phase has a single phase commissioned to accompany and enhance the product and withdrawn it from the market. Figure 2 shows the Model of PDP Management proposed. This model is intended to be for companies to adopt in the future, in order to systematize the process and achieve better results [8].

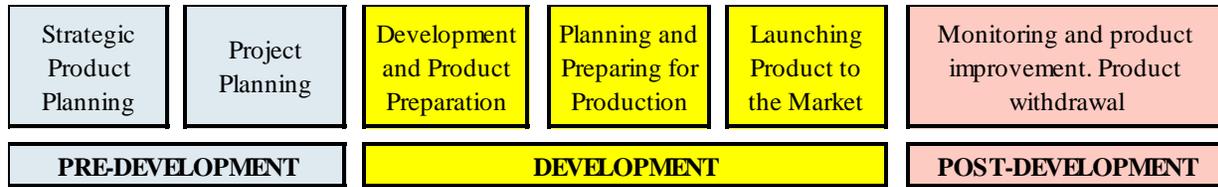


Figure 2. Management Model

Figure 3 shows the transition between the current situation of SMEs interviewed and the end result that you want to reach. Applying the Intervention Project allows a PDP improved. The subsequent implementation of successive Intervention Projects enable companies to systematize their PDP Management, managing to reach the final model.

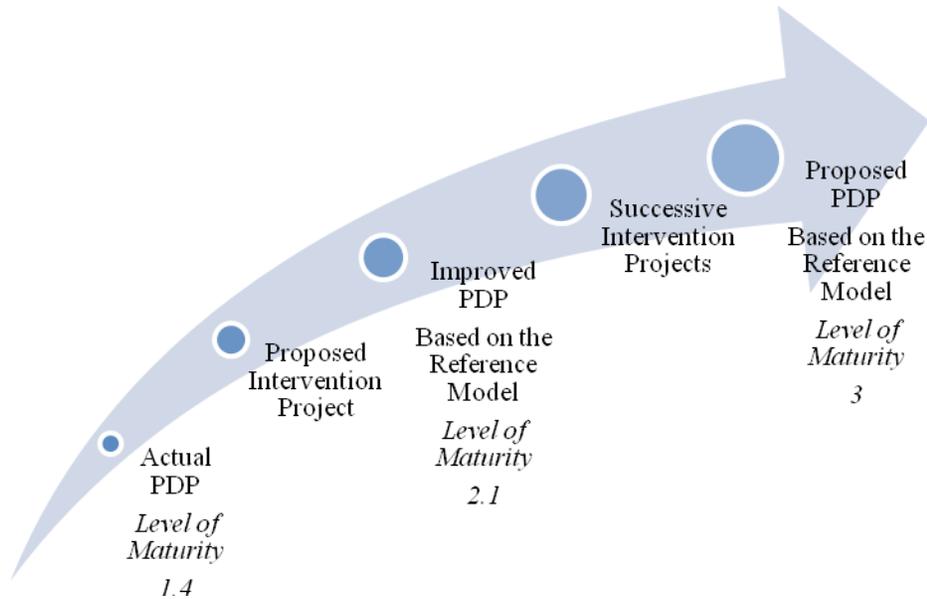


Figure 3. Representation of the transition between the current management of the PDP and the final model to achieve

**4. PROPOSAL OF AN INTERVENTION PROJECT**

The proposed Intervention Project seeks to introduce best practices in product development, increasing the level of maturity of the PDP management of companies under study, in order to solve chronic problems, improve PDP performance and adapt it to changes in the technological and market environment. Best practices can lead companies to engage in activities that did not perform before, to apply methods and tools that increase the effectiveness of such activities and control activities.

Regarding the proposal for this work highlights the applicability and ease to achieve the integration of the activities of the business reality. It should be mentioned that the Intervention Project can be implemented by the same members of the organization, without having to hire outsiders to it. Then, the purpose is structuring PDP Management, based on concepts of functional integration and involvement of top management in the critical moments of the PDP Management.

The Intervention Project proposal of this work focuses on the macro-phase Pre-Development, as it is the least organized in the companies studied, achieving strengthen or consolidate in the PDP of the SMEs under study and thus get to raise the level of maturity in managing this process. After reaching that objective, and by applying successive intervention projects, companies will be able to arrive at the proposed management model for SMEs under study.

Analyzed SMEs argue not make appropriate strategic planning for different reasons. First, because they usually are devoted to the solution of everyday problems and have no time to plan. Also, as planning no produce any marketable marketable, is often seeing as a waste of time. However, the time used in planning is an investment. It should be noted that in any project planning is a determinant key of success or failure.

Figure 4 shows the proposed Intervention Project for the Pre-Development macro-phase. It is structured around the following dimensions: (i) process, (ii) strategic, (iii) organization and leadership, (iv) tools and resources and (v) performance evaluation.

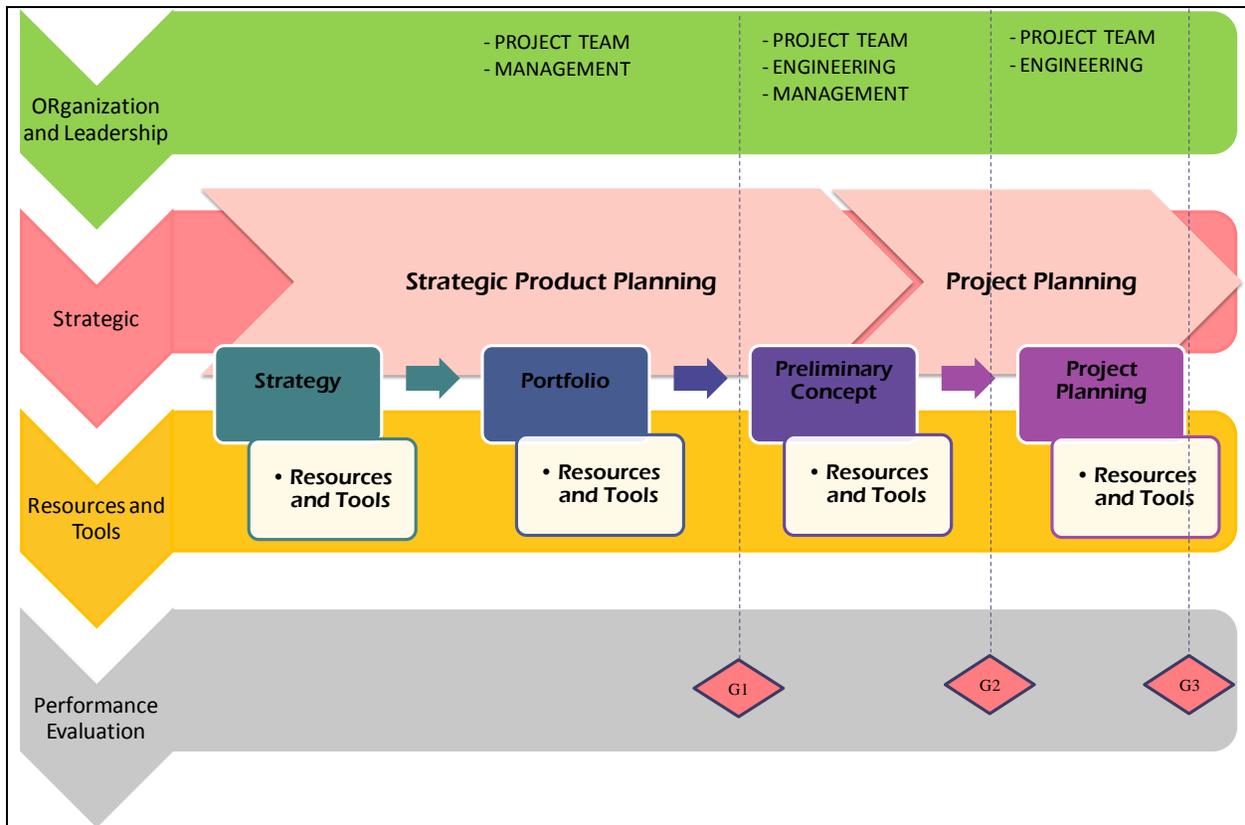


Figure 4. Intervention Project for Pre-Development Macro-phase

Dimension "Process" is shown in the center of the model, in the form of a set of phases: (i) Strategic Product Planning and (ii) Project Planning. "Strategic" Dimension is linked to planning and provides guidelines for other components of the model. "Organization and Leadership" Dimension, located at the top, corresponds to the organizational aspects accompanying the full PDP. It should be noted that the implementation phase is related to the "Tools and Resources"; this dimension determines the set of appropriate tools for each stage of the PDP. Finally, "Performance Evaluation" dimension, presented at the bottom of the figure, consists of the control system and possible improvements to the model.

#### 4.1 Organization and Leadership

This dimension includes the allocation of responsibilities in the PDP and is made according to a specific organizational structure. Regarding the organization of teams of PDP is proposed that the activities are carried out by the following sectors or departments: Management, Research and Development, Quality and Production and Finance.

During the interviews it became evident that SMEs under study have a functional organizational structure type. For this reason, the application model will not bring too many problems. To this end, the formation of two teams is proposed. The first one is the Project Management Team (Strategic Team) and it will be formed by the top leaders of each of the SMEs. This team is responsible for the strategic management of the PDP, to analyze new product opportunities and project portfolio management, and evaluating and monitoring projects are underway. The second team is responsible for the execution of new product designs and is made up of professionals from the departments involved in the phases of the PDP.

The choice of the project leader must be thorough, since it plays an important role in the model. It should be noted that those projects conducted and/or managed by professionals with technical expertise, management vision and good communication skills arrive at better results. For this reason, it is extremely important to consider the skills and abilities needed to fulfill this role.

#### 4.2 Strategic

The purpose of this dimension is to make that SMEs direct PDP activities strategically, through the development and implementation of: (i) marketing strategies, (ii) product development strategies and (iii) planning and portfolio management.

The Strategic Business Plan, which takes place before the PDP, serves as input to market strategies and own strategy for new product development. The technological and market strategies also serve as input for the formulation of product strategies.

With respect to market strategies, companies should worry about set in which market segments are going to act and how they will compete in them. Market strategies must be established for each of the segments to which companies want to target.

#### 4.3 Process

One of the main elements of the reference model is the process view. The project is structured on the basis of a hierarchical subdivision of the PDP in three aggregation levels presented in Table 1. First, the macro-phase is divided into phases, these in sub-phases and finally in activities. In its determination, considering the need to simplify the PDP to meet the characteristics of SMEs studied and incorporates the key factors of success.

*Table 1. Phases and Activities of Pre-Development*

Macro-phases	Phases	Sub-phases	Activities
PRE-DEVELOPMENT	1. Strategic Product Planning	Strategy	1.1 Check the Strategic Plan <ul style="list-style-type: none"> <li>• Review the organizational guidelines</li> <li>• Review SWOT analysis</li> <li>• Review Functional Plans</li> </ul> 1.2 Review Market Strategies and Technological Strategies <ul style="list-style-type: none"> <li>• Review technological strategy</li> <li>• Review market strategy</li> <li>• Update technology and market data</li> </ul> 1.3 Define strategy for Product Development

*Table 1. Phases and Activities of Pre-Development (cont.)*

Macro-phases	Phases	Sub-phases	Activities
PRE-DEVELOPMENT	2. Project Planning	Portafolio	2.1 Defining Product Portfolio <ul style="list-style-type: none"> <li>• Evaluate products and company's current projects</li> <li>• Assess the technology used</li> <li>• Evaluate new ideas for new products</li> <li>• Define new configuration of the portfolio</li> <li>• Assess the availability of resources</li> <li>• Approve the new product portfolio.</li> </ul> 2.2 Accompany the implementation of product portfolio <ul style="list-style-type: none"> <li>• Monitor the product portfolio and identify dates of new projects</li> <li>• Formalize the start of a project</li> </ul>
		Preliminary Concept	3.1 Constitute the development team 3.2 Revise Project Memorandum <ul style="list-style-type: none"> <li>• Analyze available technologies and necessary ones</li> <li>• Investigate competing products</li> </ul> 3.3 Identify customer needs <ul style="list-style-type: none"> <li>• Find out about customer needs</li> <li>• Assess needs identified</li> </ul> 3.4 Translate needs in product requirements <ul style="list-style-type: none"> <li>• Identify product requirements</li> <li>• Match customer needs with product requirements</li> <li>• Develop a set of product specifications-meta</li> <li>• Formalize the product concept.</li> </ul> 3.5 Evaluate the economical and financial feasibility of the product

		Project Planning	4.1 Define project scope 4.2 Define the activities and sequences <ul style="list-style-type: none"> <li>• Develop the WBS (work breakdown structure)</li> <li>• Identify work packages and activities</li> <li>• Define relationships between activities</li> </ul> 4.3 Prepare the project schedule <ul style="list-style-type: none"> <li>• Estimate efforts and allocate resources for activities</li> <li>• Estimate the likely risks and contingencies</li> <li>• Formalize the schedule</li> </ul> 4.4 Prepare project budget <ul style="list-style-type: none"> <li>• Define the costs associated with the activities and resources</li> </ul> 4.5 Prepare the Project Plan <ul style="list-style-type: none"> <li>• Discussion and drafting the project plan</li> </ul>
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The purpose of the Strategy subphase is to formulate strategies for the development of products that include: (i) the objectives and targets for new products, (ii) the strategic areas of action in terms of markets, technologies and product families and their priorities, (iii) the criteria for the allocation of resources among strategic areas and projects of new products and (iv) the definition of a set of actions associated with the launch of new products. This phase is closely related to the phase of Portfolio, in which the company analyzes the number of current projects and products and proposes changes in its configuration.

The Preliminary Concept subphase begins once a project is formally authorized by the Project Management Team and the Top Management. It has two main objectives: the first is to ratify the business opportunity identified in the subphase Portfolio and the second is to generate the new product concept. During interviews demonstrated that projects are initiated without a clear conception of the new products. The project team had little technical and economic information, which caused many changes in projects and, as a result, additional costs.

In the Project Planning subphase identify project activities, will provide the necessary resources, establishing the timetable and the best way to integrate all of these items for the project to generate the least amount of errors. The final document is the project plan and contains relevant information to the implementation. Upon execution of this subphase begins the Development macro-phase.

#### 4.4 Performance Evaluation

This dimension of the intervention project provides a set of checkpoints or gates at the end of some of the PDP subphases. In these, the Project Management Team decides on the continuation or not of the project to the next subphase. These points form the structure of project decisions.

For Pre-Development macro-phase three gates are proposed, which represent the different types of decisions along the PDP. The gate 1 (G1) is linked to the first two sub-phases of the pre-development (Strategy and Portfolio) and has two purposes. The first is the adoption of the product portfolio of the company, therefore, their decisions not only dealing with a specific project, but on the whole portfolio. In this regard, the Project Management Team will evaluate it to include new projects in the current portfolio, selecting projects to be developed and the products remain on the market. The second purpose of the G1 is to decide on the formal launch of new product designs, which were already in the portfolio.

At the end of the preliminary concept subphase is the second gate (G2), in which are considered commercial and technical risks. At this point, the approval is based on the following analysis of feasibility: economic viability of the product, market viability (size and attractive market to be exploited), technical feasibility (availability of resources within the company to implement the project); technological feasibility (capacity to apply technology to the product) and the main features and benefits expected from the product.

In the project planning subphase, the decision to continue or not with the project is related to the viability of the estimated time for completion of it, and especially with the estimated costs for their development. Therefore, the gate 3 (G3) corresponds to the planning approval of the project in relation to the viability of the timing and estimated costs.

#### 4.5 Resources and Tools

Studied SMEs use few management tools in regard to the PDP. Therefore, we propose methods, tools and support resources that enable improved effectiveness and efficiency of the activities of the PDP. Table 2 shows suggested tools for each of the subphases of the Intervention Project proposed for PDP Management.

Table 2. Tools, Methods and Resources Proposed

Macro-phase	Phase	Sub-phase	Tools and Methods
PRE-DEVELOPMENT	Strategic Product Planning	Strategy	<ul style="list-style-type: none"> <li>• SWOT Analysis</li> <li>• Project/Product Matrix Analysis</li> <li>• Technical and economic feasibility analysis: NPV, IRR, recovery period of investment.</li> <li>• Benchmarking.</li> </ul>
		Portafolio	<ul style="list-style-type: none"> <li>• SWOT Analysis</li> <li>• Project/Product Matrix Analysis</li> <li>• Technical and economic feasibility analysis: NPV, IRR, recovery period of investment.</li> <li>• Benchmarking.</li> </ul>
		Preliminary Concept	<ul style="list-style-type: none"> <li>• Original QFD Matrix</li> <li>• Brainstorming</li> <li>• Analysis of competitors</li> <li>• Analysis of consumers</li> <li>• Market Study</li> <li>• Economic feasibility analysis</li> </ul>
	Project Planning	Project Planning	<ul style="list-style-type: none"> <li>• Gantt Chart</li> <li>• Project Evaluation and Review Techniques (PERT)</li> <li>• Risk Assessment</li> <li>• Project Specifications</li> <li>• Project Management Tools</li> </ul>

## 6. PROPOSAL IMPLEMENTATION

As explained above, the companies studied have as a common characteristic the absence of a clear vision of strategic planning, as well as the lack of systematization in the Product Development Process. This places them in a relatively low level of maturity.

Generally, SMEs know where they are and where they want to, but the way of transition between the current situation and the future is not well defined. Moreover, the most technically perfect strategic plan will do little if not implemented. Many organizations tend to spend an untold amount of time, money and effort in developing the strategic plan, but consider the means and the circumstances in which they are implemented as afterthoughts. Change comes with the implementation and evaluation, not with the plan itself.

A project has unique and temporal characteristics, which carries certain implications when making planning. Should be considered an adequate period of time between the idea and the product launch to market. The role of the project manager in the pre-development is crucial to perform project planning. It must carry out the following activities: estimate the effort required, determine the availability of resources and analyze time and establish a timeline. For this it has a project team and must take advantage of the best possible way in order to get the desired results.

Given that the interviewed companies are SMEs and that, as such, have a small structure and communication should be smooth, the adoption of the intervention project proposed should take place without any problems. Change must occur globally, relating to the structure, strategies, reward systems and control systems. The change, however, is slow, must be planned properly and executed in stages, gradually, with the full support of top management and become a continuous process with feedback at all levels.

The dynamics of change that will be generated with the Intervention Project implementation can be synthesized by three steps: (i) melting of the initial situation, (ii) move to the desired location and (iii) freezing of the new situation. The first stage aims to break the status quo, ie the initial steady state that prevails in each organization studied, before the change due to the implementation of the proposed Project. The defrost draws of the driving forces of change and is opposed by the restraining forces that do not want change because of fears associated with its impact on individuals or groups within the organization. The movement of the desired initial state is facilitated by an incentive policy that weakens the resistance to change, either by reducing or increasing the restraining forces driving forces.

Once implemented the change, the new situation should be frozen for the change is lasting. This is achieved by balancing the driving forces and restrictive, and initially requires monitoring by management, until the working group itself is able to maintain the new equilibrium. Note that resistance to change is likely to exist and that it can be both individual and organizational. The individual resistance is due to fear of the unknown, as this involves

uncertainty and risk. Organizational resistance to change caused by a project, however, is linked to factors such as structural inertia, which occurs because SMEs prefer to do things as they always do.

What is recommended to take to avoid any delay or problem, is the education and training of employees to develop their activities more efficiently. It is worth remembering that the Pre-Development macro-phase is perhaps the most important one, because if the activities that make up is done properly, can prevent further problems. If not taken into account, this problems could determine the project's failure.

The first step is to create awareness about the need for change and the benefits it will generate for companies under review the implementation of the Project Management Intervention for PDP. Subsequently, it should organize a team of people who will be responsible for guiding the process of change. The third step is to define the vision and strategies for change. Then it is necessary to communicate them to all members of the organization, for the group to commit to them.

It seeks to achieve the best practices of PDP management, such as integration between departments, systematization, multidisciplinary, planning and control activities, information exchange and customer orientation, among others. The implementation of any of these principles must have the active participation of those affected by the change.

Multidisciplinary and integration between departments are the most important premises of the newest models of the PDP management [9]. Therefore, it is emphasized that all departments must participate in an organized way to manage this process. Then proceed to remove the obstacles to change and select some aspects or key areas of the organization where the proposed change will begin. The change process is a comprehensive and systematic process that must involve the whole organization. During the process of change is advisable for the leader to achieve set milestones, to show quickly some results of the change.

The next step is adding new people to the change process, until it extends to the entire enterprise. The final stage is the institutionalization of change, ie the incorporation of new intervention project to manage the product development process and its alignment with the routines and the objectives of each of the companies under study.

With regard to the training of workers, it is recommended that it is done in office, ie in the workplace. The first step is to prepare employees. At this stage you must get employees to feel comfortable, assigning them to appropriate positions, determining what they know and what not and also creating interest in learning them. Then it proceeds to present the operations, describing the tasks, highlighting the key points and instructing them clearly and precisely. Then test the performance. This is done by employees to perform the task and correcting any mistakes. Finally tracked. This should be checked frequently executed tasks. It should be noted that it is extremely important documentary record, for each project, all activities and development, so as a guide for future action and to capture conflict mitigation methodologies, techniques systematized, repetitive procedures, etc.

Summarizing, the correct Intervention Project formulation does not warrant that its implementation will also be successful. Proper implementation of the project requires the support, discipline and hard work of managers and employees motivated.

## 6. OVERALL CONCLUSIONS

Many companies have not yet systematized Product Development Process (PDP) Management and some reasons for this are: (i) lack of vision of the PDP as a process, (ii) lack of knowledge about engineering product practices, (iii) organizational difficulties of each company that operates in unstable environments, with social and cultural difficulties and (iv) other external features that harm the internal performance of the companies.

That is why this paper is to develop an Intervention Project for Product Development Process Management applicable to SMEs producing drugs, proposing and implementing improvements, in order to increase the level of maturity of the process in studied SMEs.

To gather the necessary information interviews systems, activities records and observation in situ are used. After the analysis of the interviews conducted, it is concluded that SMEs under study have numerous shortcomings with regard to the management of its PDP and that: (i) do not have a defined PDP Management model, (ii) do not have the habit to register and formalize this process and (iii) the knowledge and PDP tools and Project Management tools are not sufficiently disclosed. They have a basic level of maturity with respect to the Product Development Process Management, ranking in sublevel 1.4. That is why it is necessary to transition between current practices and the situation to be achieved.

The proposed Intervention Project aims to make SMEs analyzed to increase the level of maturity. Then, by applying successive Intervention Projects will achieve the proper systematization of PDP Management.

The proposed actions tend to improve strategic planning of SMEs and to better align it with the Product Development Process. It is for this reason that the proposed Intervention Project focuses on Pre-Development macro-phase.

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