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## THE IDENTIFICATION AND MITIGATION OF RISKS IN COSMETOLOGY PROJECTS FROM THE PERSPECTIVE OF THE NATIONAL SANITARY SURVEILLANCE AGENCY

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### ABSTRACT

The growing number of companies in the cosmetics industry and the demand for new products contribute to new product designs. Companies should include the definitions of the regulatory agency in their projects to avoid fines or delays, which can directly impact the success of the projects. The present study, which is qualitative in nature, used the exploratory bibliographic methodology. The objectives were to identify the risks of projects found in cosmetic companies from ANVISA's records, and to propose mitigations of the risks identified in the light of PMBoK. Eight risks were identified and 13 mitigations suggested. The contribution of the research is to help managers to include the risks and mitigations presented in their projects of the cosmetics sector.

**Keywords:** ANVISA, Risks in Projects, Cosmetics.

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## 1. INTRODUCTION

The area of *Higiene Pessoal, Perfumaria e Cosméticos* (HPPC - Toiletries, Perfumes and Cosmetics) demand more and more new products to meet an audience anxious for news. In this scenario, the need for projects to meet this need becomes imperative.

When defining a project, it is necessary to outline its objectives, relate its possible risks, estimate its costs and the people who will be involved (Chermont, 2001; PMI, 2013). In this sense, the topic of project management has become so relevant that there are companies that promote training to their employees in order to make them more effective (Patah et Carvalho, 2009).

Among the Project Management frameworks available on the market is PMBoK, which defines the project as a temporary effort undertaken to create a unique product, service or result (PMI, 2013). In a cosmetic company, projects must have, among other things, the required documentation and the use of good manufacturing practices defined by the regulatory agency (ANVISA, 2015b). Thus, if there is a lack of a requirement defined by ANVISA in the projects, the companies are fined.

Considering the above, this research intends to answer the following research question: "What risks can be identified within a cosmetics company and how can they be mitigated with the use of PMBoK?" The objectives are: (1) to identify the risks of projects found in cosmetic companies from the records of ANVISA, and (2) to propose mitigations of risks identified in the light of PMBoK.

The justifications for the development of this research are:

- Relevance of the theme: The number of cosmetic companies charged with irregularities is growing (ANVISA, 2015a) and project managers should be aware of the risks of new projects;
- Lack of risk-oriented studies in the sector: articles were identified regarding risks in IT projects (Coelho et al., 2015, Glória Júnior et Chaves, 2014), but not focused on risks in HPPC sector projects;
- Relevance of the data surveyed: ANVISA is the governmental body that defines the rules of regulation, registries and authorizations, supervision and monitoring for each sector, in this case the cosmetics sector;
- Academic Contribution: present the risks that can be found in the HPPC sector projects and their mitiga-

tion suggestions. The contribution to the practice is in the possibility for the project managers to apply the mitigations in their risk management.

The article is structured as follows: **Section 1** presents the research, objectives and contributions; **Section 2** establishes the theoretical reference regarding project management and the HPPC sector; **Section 3** defines the classification and planning of the research; **Section 4** presents the analysis, interpretation and discussion of results; **Section 5** presents the conclusions and guidelines for future work.

## 2. THEORETICAL FRAMEWORK

### 2.1. Cosmetics

The term cosmetic refers to some element used in the application of the face or other parts of the body in order to change the appearance and enhance the beauty of a person, such as hygiene and cleaning products (Mota *et al.*, 2014).

The industries must respect the criteria of good manufacturing practices so that they can carry out their activities. These criteria are a set of measures guaranteeing the sanitary quality of the companies' products and, consequently, the satisfaction of their customers (ANVISA, 2015a).

The companies, as well as their projects, must follow the Resolutions of the Board of Directors (RBD) that guide the actions, restrictions and characteristics of the products to be idealized and produced. DRC 48/2013 is one of the main companies, providing for the use of good manufacturing practices (ANVISA, 2013). The regulatory agency performs periodic audits (ANVISA, 2015b) and may authorize companies that do not have quality standards specified in the projects, to declared production capacity in the scope, lack of maintenance planning or lack of documentation of projects, products or services (ANVISA, 2015a). Thus, the need for project management is relevant to managers.

### 2.2. Project management

A project is an effort made during a delimited and specific period for the creation of a unique product, service or result. Project management consists of a set of actions for the execution of a project, grouped in ten sets of processes, called areas of knowledge (PMI, 2013):

- (1) **Project Integration Management.** It includes the processes and activities required to identify, define, combine, unify, and coordinate the various project management processes and activities;



- (2) **Scope Management.** It gathers the processes necessary to ensure the inclusion of all the necessary work, and only what is necessary for the project to be completed successfully (Kerzner, 2011; PMI, 2013);
- (3) **Time Management.** It consists of processes needed to finalize the project in the predicted or planned time (PMI, 2013) and can use auxiliary tools, such as the GANTT chart (Kerzner, 2011);
- (4) **Cost Management.** It includes the cost of a project with elaboration, forecasting and monitoring processes (PMI, 2013). It may also include processes for generating hypotheses (Kerzner, 2011);
- (5) **Quality Management.** It determines the characteristics of the product, service or unique result (PMI, 2013) in order to satisfy the necessary demands (Kerzner, 2011);
- (6) **Human Resource Management of the Project.** These are processes that identify the functions and competencies of the entire project team, as well as the identification and management of the organizational structure (Kerzner, 2011; PMI, 2013).
- (7) **Project Communications Management.** It constitutes the necessary procedures to ensure that project information is planned and that the technology to be employed, the frequency of the means, the formats and what information will be made available will be defined, (PMI, 2013);
- (8) **Project Acquisition Management.** It includes the processes required to purchase or acquire products, services or results external to the project team and third-party management (PMI, 2013).
- (9) **Concerned Parties Management.** It refers to the processes that will identify the parties involved and their interests in the project that can positively and negatively affect the project (Kerzner, 2011; PMI, 2013).
- (10) **Risk management.** It has the processes that will drive the activities of identification, mitigation, monitoring and control of project risks (PMI, 2013). Premature identification of risks is one of the factors of success in projects (Kerzner, 2011).

A risk that occurs is called problem (PMI, 2013). There are risks that can be found in projects more often than others (Glória Júnior e Chaves, 2014).

### 2.3 Risks in Cosmetology Project

Currently, the number of irregular companies is growing gradually. One of the possible causes is the lack of risk management in cosmetic projects, such as the lack of sanitary and operation authorization, both provided by ANVISA (ANVISA, 2015a).

Any establishment that carries out the procedure of extracting, producing, packaging, importing, manufacturing, transforming, repackaging, storing, exporting, distributing and dispatching products in the cosmetics sector must have an operating authorization, requiring renewal every year (ANVISA, 2015a).

According to RDC No. 128, dated May 9, 2002, manufacturers and importers of cosmetics, personal hygiene products, perfumes and related products are responsible for the qualification of suppliers of raw materials, inputs and components used in the manufacture of their products, according to established technical parameters (ANVISA, 2002), functioning as requirements in projects (PMI, 2013).

Products produced in companies that are not inspected by ANVISA carry a great risk to the users' health, since it does not contain any analysis that guarantees their effectiveness, safety and quality (ANVISA, 2015b).

### 3. METHODOLOGY

It is a qualitative study using the exploratory bibliographic methodology (Gil, 2008), whose object of analysis were the records of irregularities of companies existing on ANVISA's website that point out the reasons that led the companies to be charged. The units of analysis were the assessed companies (Martins et Theóphilo, 2009). The steps for the elaboration of the research were:

**Step 1. Identification of risks.** From the consultation to the website of the regulatory agency (<http://portal.anvisa.gov.br>), we collected the causes of irregularities, also called problems, and the number of companies that were assessed in the period from 2009 to 2015; and

**Step 2. Proposed mitigations.** Mitigating actions for identified risks based on PMBoK (PMI, 2013) were suggested. The suggestions were drawn from the causes of the problems, relating them to one or more project management processes that could be used to eliminate or mitigate their effects.



#### 4. ANALYSIS AND INTERPRETATION OF RESULTS

According to the information found, irregularities in the cosmetic products were identified in the period from November 2009 to November 2015 of companies that did not follow ANVISA regulations in relation to cosmetics production, as shown in Table 1 (ANVISA, 2015b).

It is possible to verify that, in 2009, a greater number of companies with irregularity were computed with ANVISA. In the years 2010, 2011 and 2012, there was a sharp fall, with a variation three times lower than the quantity identified in 2009. Compared to the years of 2013 and 2014, there was a slight increase in this number, compared to 2010, 2011 and 2012. The number of companies continues to decrease, but still represents 43 companies assessed.

**Table 1.** Irregular companies reported by ANVISA from 2009 to 2015

Year	2009	2010	2011	2012	2013	2014	2015
Number of irregular companies	138	41	37	39	53	59	43

Source: Based on ANVISA (2015b)

##### 4.1. Identification of risks

Considering the data provided by ANVISA, it was possible to identify that one of the items reported was the quality deviation of the cosmetic products (R01) resulting from their contamination. The absence of the operating registration (R02) required by ANVISA was also highlighted.

Regarding the characteristics of the product to be developed, the agency cites the divergence of information contained in the packaging (R03) that differs from the content and the established production procedure. The falsification (R04) resulting from adulteration in the documentation or product was also evidenced by ANVISA.

ANVISA charged companies that had no registered product (R05), which had their manufacturing process prohibited (R06), which had registered products overdue during the project (R07) and which had irregularities in the use of good practices in the requirements of the product manufacturing projects (R08).

##### 4.2. Mitigation

The mitigations were suggested in each of the risks identified, considering the areas of knowledge of PMBoK (PMI, 2013), as presented in table 3.

**Table 2.** Identification of risks in cosmetic companies, where the letter "R" corresponds to risk.

ID	Risks	Number of companies assessed
R01	Quality Deviation	18
R02	Company without registration	13
R03	Divergent packaging label	13
R04	Falsification	3
R05	Product without registration	1
R06	Prohibition of production	1
R07	Overdue Product Registration	1
R08	Irregularity in Good Manufacturing Practices	2

Source: Prepared from ANVISA (2015b)

##### 4.3. Discussion

ANVISA has some warnings to consumers as a way to reduce the undue sale, such as: request for an invoice, observation of promotions with prices well below the market and analysis of packaging conditions and labeling statements (the expiration date, date of manufacture, batch, record and other observations) (ANVISA, 2015a).

The mitigations suggested based on the PMBoK (PMI, 2013) were mainly actions related to quality, communication and scope management and to the project monitoring and control process.

From the results obtained, it was concluded that, from 2009 to 2015, there was a large reduction in the number of companies that do not comply with ANVISA standards in relation to the production of cosmetic products. Thus, there are indications that this number tends to decrease more and more, given the work carried out by ANVISA to supervise and suspend irregular companies in order to maintain good manufacturing practices in force. Only companies that are truly committed to legislation and, in this way, provide quality and safety products to the population will remain active.

Thus, the transfer of knowledge to project managers or equivalent employees on the concepts of risk management, communication, quality, scope and process of control and monitoring can promote the success of projects in the HPPC sector.

#### 5. CONCLUSION

The HPPC sector and the demand for new related products are growing, a scenario that contributes to the ge-



**Table 3.** Mitigation of the risks identified, where the “MT” corresponds to mitigation

ID	Risk	Mitigation
R01	Quality Deviation	(MT01) Quality Management: Verify that requirements have been met. (MT02) Monitoring and Control: during the manufacturing process.
R02	Company without registration	(MT03) Communication Management: Register the company at ANVISA
R03	Divergent packaging label	(MT04) Communication Management: ANVISA should be notified when there is an exchange of labeling (MT05) Scope Management: Review the scope parameters (requirements) and define the project objectives
R04	Falsification	(MT06) Quality Management: Verify that requirements have been met (MT07) Monitoring and Control: during the manufacturing process
R05	Product without registration	(MT08) Communication Management: Register or notify the product at ANVISA
R06	Prohibition of production	(MT09) Quality Management: Verify that requirements have been met. (MT10) Communication Management: Verify that the product or company is registered with ANVISA and is authorized to operate and manufacture.
R07	Overdue Product Registration	(MT11) Communication Management: Request a new record (MT12) Scope Management: Reassess Scope Parameters
R08	Irregularity in Good Manufacturing Practices	(MT13) Quality Management: Clearly define manufacturing processes and stages, manufacturing areas being equipped with infrastructure.

Source: Authors

neration of new product designs, which need to be in accordance with the regulatory agency’s definitions to avoid fines or delays, which may impact directly the success of the projects. In addition to other risks, the need to use a project management framework such as PMBoK can help managers.

Based on ANVISA’s assessments for the period from November 2009 to November 2015, the article identified eight risks to which companies in the sector are susceptible, including quality deviations, falsification and unregistered products. For the risks, 13 mitigations were defined, which are suggestions for controlling and monitoring the process, applying quality and scope processes.

The limitations of this work are the use of the companies assessed by ANVISA, not those that were notified, the lack of interviews with the managers of these companies and the empirical results of the suggested mitigations. The contribution to the theory is a list of risks to be studied and mitigations to be applied. In practice, project managers may include the risks and mitigations listed in their risk management. As future work, it is recommended to include interviews with the managers, the inclusion of the notified companies and the application of the mitigations presented.

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