



## CASE STUDY ON VARIABILITIES IN THE PRODUCTION LINE OF A PHARMACEUTICAL INDUSTRY

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### Abstract

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This article was developed in the packing sector of the pharmaceutical industry and had as starting methodology macro ergonomics of the company, and after that, the situated ergonomics analysis. With the application of these methodologies, it was possible to obtain a larger view of the studied issue, in a way, to contribute directly to the ergonomic appreciation in a focused way in the subjects shown by the managing demand, identifying the characteristics, contingencies, and the situation of the company in the national industrial sector, as well the characteristics of the productive process and products and its variabilities.

**Keywords:** Macroergonomics, Ergonomic Analysis, Variability, Pharmaceutical industry.

### 1. INTRODUCTION

#### 1.1. Contextualization

Indústria Farmoquímica is located in a neighborhood in the North Zone of Rio de Janeiro. Its industrial plant has been in operation for 70 years and is the pioneer in the market in the launch of hyposensitizing vaccines. Currently, it occupies an industrial park that belonged to 03 (three) companies in the pharmaceutical sector. In March 2004, Farmoquímica had 481 employees, of which 207 were in the production sector.

The main activity of the industry is the manufacture of medicines for human and animal use. As a consequence, in some production cells, especially in the Packaging Sector, there were dysfunctions and incidents in the production process and/or in the work process. This made the focus of the ergonomic study refer to the Packaging Sector, confirming the referral of the Managerial Demand.

In this way, starting from a macro evaluation, it was possible to identify how the industry's management policies work and, subsequently, the referral to a situated evaluation, with the consequent observation of the workstations - situated ergonomics. The localized analysis was carried out at the workstation of a "semi-automatic packaging machine". In this

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sense, the evaluation began with surveys of the occupational characteristics of the industry, in its production system, and then observed the characteristics of the most produced products.

## 1.2. Products and Process

After conducting documentary surveys in the pharmachemical industry, it was possible to construct Table 1 below, in which it is possible to illustrate through the information that the main product in production are drugs sold in solid form such as tablets and capsules:

Table 1: Products produced at Farmoquímica

Product Type	Monthly Capacity	Production August 2005	% Occupancy August	% of accumulated occupation up to August 2005.
Cosmetics (tubes)	346,500	55,982	16.16	27.20
Creams and Ointments (tubes)	<b>395.010</b>	<b>98.320</b>	24.89	21.64
Injectables (ampoules)	924,000	<b>0</b>	<b>0</b>	4.29
Liquids and Syrups (bottles)	<b>582.120</b>	208,586	35.83	50.58
Otológic Liquids (bottles)	<b>776.160</b>	145,112	18.70	27.61
Solids (tablets and capsules)	13,886,400	12,159,998	87.57	82.01
Solids (suspended powder)	400,000	<b>0</b>	<b>0</b>	<b>0</b>

Note: In the first column the numbers in kg production capacity. In the second column what the actually produced. In the third column we observe the occupancy rate of the month of August and the last column the cumulative from 2005 to the month of August.

To carry out the ergonomic study initially proposed, a cut-out was made taking as a sample the following stages of the solids production line: mixing and granulation; compression; blistering; quarantine; cartoning and final packaging of the products produced.

The steps described in Table 1 are part of the production process in the pharmachemical industry and are carried out in independent production islands, where the raw materials are handled. An attempt was made to highlight these different production islands, investigating the cases of non-conformities that were frequently pointed out and detected by the quality sector of the pharmachemical industry.

This situated analysis provoked an investigation, together with the quality and safety sector of the pharmachemical industry, aiming to mitigate the considerations and evidence of the sectors responsible for quality control and occupational safety in the five stages of this process, and it is possible to highlight incidental variabilities.

According to Vidal (2002), the concept of variability is equally central in ergonomic analysis of work. It starts from the observation that, in a given production process, the different performances in its various moments of measurement are linked to the intrinsic nature of the



technical process and the work process. Vidal, (2002) shows that this characteristic of work prevents the adoption of global standards. Companies organize themselves so that their production processes are controlled and this leads them to legitimately seek to control the impact of changes of a random nature in production. However, the reality of production processes is marked by significant variability, shifting the concern with controlling to that of keeping under control (ROCHA, 1996). Therefore, analyzing the activity is to seek to understand how the operator or the user performs the management of variability in the work situation or in the context of use and handling of products.

## **2. THE METHODOLOGY USED**

First, the problems of the organization through Macroergonomics (Hendrick & Kleiner, 2001) were focused, namely: those related to the management system. Concomitantly, the sociotechnical theory (Wisner, 1976) was used to account for the relationship Man – Technology – Organization. Subsequently, subjective techniques were applied (Vidal, 2002).

Inserted in this context, in addition to an analysis of the Organization's policy and the commitment of its employees, we seek to observe the employee within his activities, that is, the real work, with his needs, difficulties and anguish. Through the analysis of the activity, provided by the AET methodology (Vidal, 2003), in which the observations occur in the process of interaction of the Organization with its employees at the workstations, aiming at the accomplishment of the tasks.

The field surveys were carried out with the purpose of enabling the identification of problems, their malfunctions and incidents, which in turn caused in the work process, going through its socio-technical reality, as well as contributing to the aspects and criteria of organizational improvements for the pharminochemical industry.

### **1.1. Macroergonomic Analysis and Situated Ergonomics**

The management system of companies is inserted in the context of Macroergonomics. Portraying Macroergonomics in the workplace is to address the policy and management of these companies. This policy must be analyzed and, through it, identify how the company is organized, how it works on the satisfaction of its employees with the organization, to which it is submitted and how it is treated. It is important to observe, within the company's macro environment, the employee's interaction in the social and organizational context. The application of the macroergonomics tool will take us to the most comprehensive levels of the company, reaching the most restricted and detailed levels of the problem. This article is



responsible for not only the study of the interaction between man and organization, but also the sociotechnical approach proposed by (Wisner, 1976), such as the relationship Man-Technology-Organization, highlighting the mindfacts, artifacts and socio-facts in pharmonochemistry. Such a view was fundamental for the macroergonomic analysis of work in this industry.

The Ergonomic Analysis promoted in pharmonochemistry had the particular interest of addressing Ergonomics in its modern concept. As presented to us (Vidal, 2002) through the modeling in Figure 2.

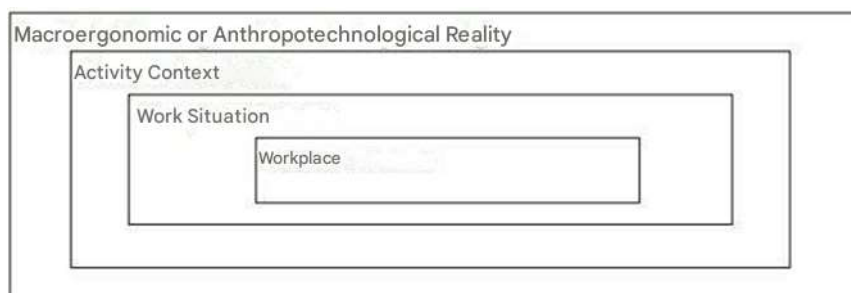


Figure 2. AET Model

### 3. RESULTS AND DISCUSSION

The problems evidenced in this macroergonomic context in pharmonochemistry are described below:

*Onboarding problems for new employees.*

During the evaluation carried out in the packaging sector, in a semi-automatic packaging machine, it was identified that some operators interrupted their tasks to help others newly integrated into the group (on-the-job training). With the interviews carried out with these employees, it was possible to show that this event was frequently repeated, especially in the period of high production demand, in which the pharmonochemical industry hired about 20 professionals to work in the production line in order to meet the demand for the product for the market – pull production demand.

*Training Problems (Knowledge Management)*

Analyzing the training and qualification policy, during the evaluation of this job, it was observed that in a certain period the industry was forced to stop production, for reasons related to the lack of treated water used in the manufacture and mixing of primary products (requirement of water treatment by ANVISA). These events were evidenced due to the absence



of an operator, who acted individually, putting the reverse osmosis plant to work, thus producing the treatment of the water necessary for the production process. In these occurrences, it is verified that this problem exists due to the absence of training in the industry, aiming at the replacement of an employee in his workstation, because only one among all was qualified to operate the system, causing a serious production problem, due to the industry's training and qualification policy.

*Problems in procedures for tasks with a high degree of risk*

During the evaluations located in the maintenance sector, it was evidenced the inexistence of procedural routines for activities related to the execution of the electrical system, such as maintenance in the substation, electrical panels, etc. When the sector manager was asked about the existence of procedures for tasks with a high degree of risk, such as: Replacement of transformers with 13.8 KVA, he informed that there is no procedure to carry out this type of task, thus contradicting the precepts of NR-10.

*Problems of lack of communication between supervisors and workers in the sector*

It was evidenced, as shown in Figure 3, that communication in both directions, both Top-Down and Bottom-up, are flawed, because the knowledge of pharmonochemical policies and its deontological principles are restricted to its managers. The knowledge provided by management to employees about pharmonochemical policies is restricted to the development of the tasks prescribed by employees, this is what was evidenced in the packaging sector.



Figure 3: Context of communication in pharmonochemistry

*Problems of environmental policy defined with the responsible technicians*

In one of the evaluations located, this one, in turn, in the industrial waste park, carried out together with the support group, some problems were observed such as inadequate storage of waste, deficient signage of the deposit, contrary to the NR's, inadequate handling of this waste, in particular, without the use of mandatory PPE. The justification presented by the pharmonochemical safety technician was that the Organization did not have any sector officially



responsible for the environment, characterizing a lack of environmental policy present in the company's management.

### *The Variabilities*

According to Vidal, (2002) variability admits two distinct genesis, namely: normal and incidental variability. By normal variability, this author understands it to be that which can be expected, even if all the precepts, norms and guidelines for the execution of the task are observed, as examples: seasonal variations in the volume of production of anti-flu and allergy drugs in the winter period, the growth in the demand for the production of sun protection products, in the summer period, etc. These variations, as much as they are expected, may be greater or smaller, depending on the context in which they occur, however, they will act considerably in the activities of the pharmaceutical industry. Incidental variability, on the other hand, as shown in Figure 4 – has its genesis of occurrence in an unexpected way, that is, it arises by surprise, as an example: a tool or equipment that breaks down in the middle of the production peak, paralyzing the activity for several hours or days, a work accident, etc.



Figure 4: Moment of occurrence of incidental variability in the process and regulation.

Also according to this author, variabilities can be of three types: Technical, organizational and Human. Technical variability is understood to be that which is linked to the production process itself, that is, that its origin is not linked to the human characteristics of production. Thus, normal and incidental variabilities are almost always technical and, as such, can be treated. There are, however, organizational variabilities, due to the fact that certain procedures are adjusted and new normative instructions, provisional or permanent, come into force (very often this occurs at the level of reports and indicators). Another manifestation in this category occurs at the level of shift schedule and replacement of employees in the team, due to absenteeism, absence, turnover, etc. There are also human variabilities, as shown in



Figure 5, which are subdivided into: interindividual and intraindividual variability (account for differences between people, men/women; young/old, tall/short, personality, competence, etc.).

What was intended to be carried out was a sampling, that is, an excerpt of the functioning of pharmonochemistry in the packaging sector, aiming to understand the activity itself, and the forms of organization of man-task-machine work, in which the view of the activity as a whole and how it is performed by the employee is inserted.



Figure 5: Moment of occurrence of human variability in the process and regulation.

Unfortunately, when organizations determine their strategies and structure their work processes, they still admit Taylorism as a way to obtain the best results, in which the equity of the production line determines productivity. They forget, however, that within any activity is the variability inherent to the behaviors of employees in the performance of their productive functions, that is, intra-individual variations, which is determined by the operational reality, that is, the operating modes, applied in the execution of the task and not by its prescription (Wisner, 1976).

According to (Guérin, 2001), diversity among people occurs at a biological, physical and cognitive level, structured from experiences or the cultural context of the individual.

The ergonomic analysis inserted in the context of the variabilities of the process, encourages the visualization of the process from another angle, because failures are often attributed to the lack of competence of the employees and, in the vast majority of times, have their origin in the lack of adequacy of the process and in the variabilities inherent to production. For (ABRAHÃO, 1986), when considering variability, a balance is sought between the characteristics of the subject and his work environment, aiming to obtain results expected by production, within the best possible conditions.



#### 4. CONCLUSION

The methodology used in this case study contributed to the evidence and validations obtained with the ergonomic appraisal elaborated, making emerge, in this context, in the work process the variabilities in the production line of pharмоchemistry, in the packaging sector.

The field activities, developed by the group of researchers, constantly had the support and assistance of the pharмоchemical support group, thus demonstrating the organization's interest in understanding the work process and, in this way, creating criteria to transform it, as it was possible to elaborate a table with the types of variables observable in the production process, in which it was sought to identify the basic causes of these events, thus bringing out the various ways and forms of their occurrences, creating the understanding that these could even generate a reduction in the reliability of the product.

The analysis of the environment provided the construction of a scenario model for the application of ergonomics, directly contributing with information regarding the professionals, the workplaces, the infrastructure necessary for its development, its supports, its communications, its potentialities and possible expansions and/or suppressions. In the end, a new view of the process, the workstations, the sectors, the areas and their systems resulted, leading this analysis to the detailing of the places and services until the reformulation of these workplaces, their activities, the existing physical disposition and ending with the rationalization of the tasks itself.

The most important thing to highlight in this ergonomic appreciation was the fact that it provoked the understanding, both of the researchers and of the staff and managers of the pharмоchemical company, that knowing the workplaces, talking to employees and managers and discussing with the end customers is what makes such a transformation possible.

From these analyses it was possible to identify the relationships between the risks and their effects on health and production, optimizing the modalities of use of capacities and indicating at the end to the pharмоchemistry the possible ways to effectively transform the situation presented at the beginning of the ergonomic assessment work, since problems and defects are not free, someone teases them and gets paid to do so.

#### 5. AUTHORSHIP

The present study is the result of a 191-page monograph for the acquisition of the title of Occupational Safety Engineering – Specialization offered by the Polytechnic School of Engineering of the Federal University of Rio de Janeiro (UFRJ).





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