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CASE OF STUDY ON VARIABILITIES IN A LINE OF PRODUCTION OF A PHARMACEUNTICAL INDUSTRY

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ABSTRACT

This article was developed in packing sector of a pharmaceutical industry and had as starting methodology macroergonomics of the company, and after that, the situated analysis. With the application of these methodologies, it was possible to obtain a larger view of studied issue, in a way, to contribute directly in 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 it's variability's.Ergonomic macro analysis allowed a more comprehensive evaluation of the company's management practices and policies, in this way it was possible to better understand the needs related to the workplace of the employees. The types of variability during the regulation processes in the product packaging line were identified, enabling the reformulation of workplaces and their activities.

KEYWORDS: Macroergonomics, Situated Ergonomics, Ergonomic Analysis, Variability, Pharmaceutical Industry

1. INTRODUCTION

The Pharmachemical Industry 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 a pioneer in the market for the launch of hyposensitizing vaccines. Currently, it occupies an industrial park that belonged to three pharmaceutical companies. In March 2004, Pharmachemical had 481 employees, including 207 employees in the production sector.

The main activity of the industry is the manufacturing of human and animal use medicines. As a result, in some production cells, especially in the Packaging Department, dysfunctions and incidents were observed in the production process and/or work process. This led the ergonomic study's focus to be directed towards the Packaging Department, confirming the Management Demand's referral.

In this way, starting with a macro assessment, it was possible to identify how the industry's management policies function and subsequently proceed to a situated evaluation, with the consequent observation of the workstations - situated ergonomics. The situated analysis was carried out at the workstation of a "semiautomatic packager." In this regard, the evaluation began with the collection of occupational characteristics of the industry within its production system, followed by an examination of the characteristics of the most produced products.

2. RODUCTS AND PROCESS

After conducting documentary surveys in the pharmachemical industry, it was possible to construct the table below, which illustrates, through the information provided, that the primary product in production is medicines sold in solid forms such as tablets and capsules:

Type of Product	Monthly Capacity	Production August 2005	Occupnc y Rate August	% of Cumulative Occupancy Until August 2005
Cosmetics (tubes)	346.500	55.982	16,16	27,20
Creams and Ointments (tubes)	395.010	98.320	24,89	21,64
Injectables (ampoules)	924.000	0	0	4,29
Liquids and Syrups (bottles)	582.120	208.586	35,83	50,58
Otic Liquids (bottles)	776.160	145.112	18,70	27,61
Solids (tablets and capsules)	**13.886.400**	**12.159.998**	**87,57**	**82,01**
Solids (powder in suspension)	400.000	0	0	0

Table 1: Products Manufactured at Pharmachemical

Note: In the first column, the numbers represent production capacity in kilograms. In the second column, the actual production. In the third column, we observe the occupancy rate for the month of August, and in the last column, the cumulative total for 2005 until August.

To carry out the ergonomic study proposed initially, a subset was selected for sampling, which included the following stages of the solid production line: mixing and granulation; compression; blistering; quarantine; cartoning; and final packaging of the manufactured products.

The described stages above are part of the production process in the pharmachemical industry and are carried out in independent production islands where raw materials are handled. In these different production islands, we aimed to highlight instances of non-conformity that were frequently identified and reported by the quality department of the pharmachemical company.

This situated analysis prompted an investigation in collaboration with the quality and occupational safety department of the pharmachemical company. The goal was to address the concerns and findings of the quality control and occupational safety departments in the five stages of this process, making it possible to identify incidental variabilities.

According to VIDAL (2000), the concept of variability is equally central in ergonomic work

analysis. It starts from the observation that, in a given production process, distinct performances at various measurement points are linked to the intrinsic nature of the technical process and the work process. ADISSI and VIDAL (1999) demonstrate 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 random changes in production. However, the reality of production processes is characterized by significant variability, shifting the focus from control to maintaining control, as noted by ROCHA and VIDAL (1996). Therefore, analyzing the activity means understanding how the operator or user manages variability in the work situation or in the context of product use and handling.

2.1 THE METHODOLOGY EMPLOYED

Simultaneously, the sociotechnical theory (WISNER, 2000) was employed to address the relationship between Humans - Technology - Organization. Subsequently, subjective techniques (VIDAL, 2001) were applied.

Within this context, in addition to analyzing the organization's policy and the commitment of its employees, we aimed to observe the employee within the context of their activities, namely, the actual work, with its needs, difficulties, and anxieties. Through the analysis of activity, facilitated by the AET methodology (VIDAL, 2001), observations take place in the interaction process between the organization and its employees at workstations, with the aim of accomplishing tasks.

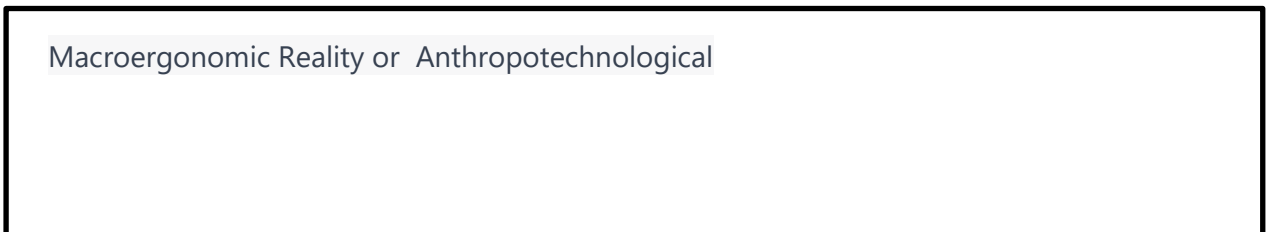
Field surveys were conducted with the purpose of enabling the identification of problems, their dysfunctions, and incidents, which, in turn, were often caused within the work process, passing through its sociotechnical reality. Additionally, these surveys contributed to aspects and criteria for organizational improvements within the pharmachemical industry.

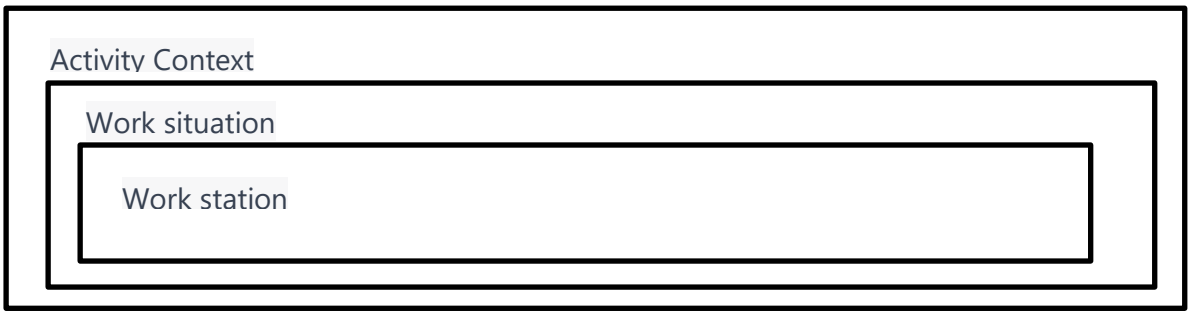
3. MACROERGONOMIC ANALYSIS AND SITUATED ERGONOMICS

The management system of companies is part of the context of Macroergonomics. Portraying Macroergonomics in the workplace involves addressing the policies and management of these companies.

This policy should be analyzed to identify how the company is organized, how it addresses employee satisfaction within the organization, and how it treats its employees. It's important to observe, within the macro environment of the company, the interaction of employees within the social and organizational context. The application of the macroergonomics tool will lead us from the broader levels of the company to the narrower and more detailed levels of the problem.In this article, it's not only about studying the interaction between humans and the organization but also adopting the sociotechnical approach proposed by WISNER (1999), considering the relationship between Humans-Technology-Organization, and emphasizing the "mentifacts," "artifacts," and "sociofacts" within the pharmachemical industry. Such a perspective was crucial for the macroergonomic analysis of work in this industry. The Ergonomic Analysis conducted in the pharmachemical industry had a particular interest in addressing Ergonomics in its modern concept, as presented by VIDAL (2000) through the model in the figure below.

Figure 1: Modern Context of Ergonomics





- The problems highlighted in this macroergonomic context in the pharmaceutical chemistry field were

Integration problems of new employees.

During the assessment conducted in the packaging department, with a semi-automatic packaging machine, it was identified that some operators would interrupt their tasks to assist newly integrated members of the group (on-the-job training). Through interviews with these employees, it was possible to highlight that this event occurred frequently, especially during periods of high production demand, when the pharmaceutical chemistry industry hired approximately 20 professionals to work on the production line in order to meet the product demand in the market - a demand-pull production demand.

- Training and Capacitation Issues (Knowledge Management)

Analyzing the training and skill development policy, during the evaluation of this workstation, it was observed that at a certain point, the industry was forced to halt production due to issues related to the lack of treated water used in the manufacturing and mixing of primary products (a requirement for water treatment by ANVISA). These events were evident due to the absence of an operator who worked individually, operating the reverse osmosis plant to produce the required water treatment for the production process. In these occurrences, it is clear that this problem exists due to the lack of training in the industry aimed at replacing an employee at their workstation, as only one among them was qualified to operate the system, resulting in a significant production problem due to the industry's training and skill development policy.

- Issues with Procedures for High-Risk Tasks

During the assessments conducted in the maintenance department, the absence of routine procedures for activities related to work on the electrical system, such as maintenance on the substation, electrical panels, etc., was evident. When asked the department manager about the existence of procedures for high-risk tasks, such as changing transformers with 13.8 KVA, he stated that there is no procedure for carrying out this type of task, thus contradicting the principles of NR-10.

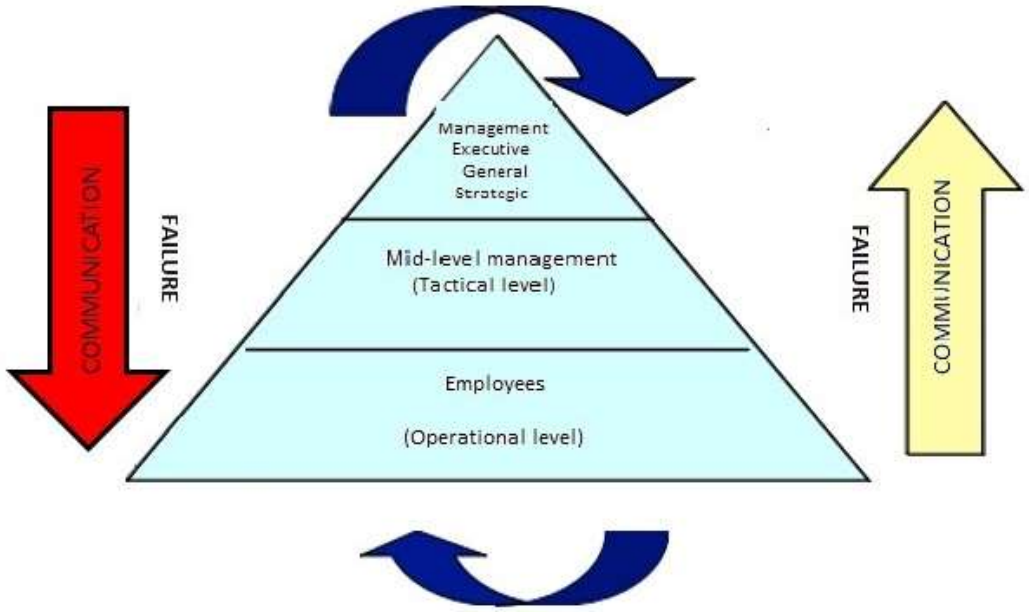
- Lack of Communication Issues Between Supervisors and Sector Workers

Statement from an employee: "I think we communicate poorly! I always find out what shift we'll be working on at the last minute! I never manage to know in advance what time I'll be working the next day."

In this regard, it was evident that communication in both directions, both top-down and bottom-up, is flawed because knowledge of the pharmaceutical company's policies and its ethical

principles is restricted to its managers. The knowledge provided by management to employees about the pharmaceutical company's policies is limited to the development of tasks prescribed by employees, as was evident in the packaging department.

Figure 2: Pharmaceutical Communication Context



- **Issues with Defined Environmental Policy with Responsible Technicians**

During one of the on-site assessments, which took place in the industry's waste park, conducted in collaboration with the support group, several issues were observed. These included improper storage of waste, inadequate labeling of the storage area, contrary to the Occupational Health and Safety Regulations, and improper handling of these waste materials, notably without the use of mandatory personal protective equipment (PPE). The justification provided by the pharmaceutical company's safety technician was that the organization did not have any officially responsible department for the environment, indicating a lack of environmental policy within the company's management.

4. VARIABILITIES

According to VIDAL (2000), variability can be classified into two distinct types: normal variability and incidental variability. Normal variability, as understood by this author, is that which can be expected even when all the guidelines, norms, and benchmarks for task execution are followed. Examples of normal variability include seasonal fluctuations in the production volume of medications for colds and allergies during the winter season, and increased demand for the production of sunscreen products during the summer, and so on. These variations, even though they can be anticipated, may vary in magnitude, depending on the context in which they occur, but they will still have a significant impact on the activities of the pharmaceutical industry. On the other hand, incidental variability has its origin in unexpected occurrences, meaning it arises as a surprise. Examples of incidental variability include a tool or equipment

breaking down in the middle of peak production, causing a halt in activity for several hours or days, or a workplace

Illustration 2: Occurrence of Incidental Variability in Process and Regulation Timing.

According to this author, variabilities can be of three types: Technical, organizational, and human. Technical variability refers to that which is connected to the production process itself, meaning 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 addressed. However, there are also organizational variabilities due to the fact that certain procedures are adjusted and new normative, provisional, or permanent instructions come into effect (often occurring at the level of reports and indicators). Another manifestation in this category occurs at the level of shift schedules and the replacement of team members due to absenteeism, absence, turnover, etc. There are also human variabilities, which can be subdivided into interindividual and intraindividual variabilities (accounting for differences between individuals, men/women; young/old, tall/short, personality, competence, etc.).

What was intended to be accomplished was a sampling, that is, a snapshot of the functioning of the pharmaceutical industry, specifically in the packaging sector, with the aim of understanding the activity itself and the ways in which the organization of work, involving humans and machines, takes place, encompassing the perspective of the activity as a whole and how it is carried out by the employee.

Illustration 3: Moment of human variability occurrence in the process and regulation.

Unfortunately, organizations, when determining their strategies and structuring their work processes, still embrace Taylorism as a means to achieve the best results, where the assembly line's equitability determines productivity. However, they forget that inherent within any activity is the variability in the behaviors of employees in the performance of their productive functions, i.e., the intraindividual variations, which are determined by operational reality, that is, the operational modes applied in task execution, and not solely by their prescription (WISNER, 1987).

According to GUERIN (2001, as cited in NUNES, 2002), diversity among individuals occurs at biological, physical, and cognitive levels, shaped by experiences or the cultural context of the individual.

The ergonomic analysis, when placed within the context of process variability, encourages a different perspective on the process. Many times, failures are attributed to the lack of competence of the employees, when in the vast majority of cases, they originate from the inadequacy of the process and the inherent production variabilities. According to ABRAHAO (2002, as cited in NUNES, 2002), considering variability seeks to strike a balance between the individual's characteristics and their work environment, aiming to achieve the production's expected results under the best possible conditions.

4. CONCLUSION

The methodology employed in this case study contributed to the evidence and validation obtained through the ergonomic assessment, bringing to light, in this context, the variabilities in the pharmaceutical production line within the packaging sector.

The field activities conducted by the group of researchers consistently received support and assistance from the pharmaceutical company's support team, demonstrating the organization's interest in understanding the work process and, thereby, creating criteria for its transformation. This support led to the development of a framework outlining the types of observable variables in the production process, aiming to identify the root causes of these events. This, in turn, revealed the various ways and forms in which these occurrences could take place, fostering the understanding that they could potentially result in a reduction in product reliability.

The analysis of the environment facilitated the construction of a scenario model for the application of ergonomics, directly providing information related to professionals, workplaces, the necessary infrastructure for their development, supports, communications, potentials, and possible expansions or reductions. In the end, it resulted in a fresh perspective on the process, workstations, sectors, areas, and their systems. This analysis extended to the detailed examination of locations and services, leading to the reconfiguration of these workplaces, their

activities, the existing physical layout, and culminating in the rationalization of tasks themselves.

The most important aspect to highlight in this ergonomic assessment is that it led to the understanding, both among the researchers and the team of employees and managers at the pharmaceutical company, that knowing the workplaces, engaging in conversations with employees and managers, and discussing with end customers is what enables such transformation.

Through these analyses, it was possible to identify the relationships between risks and their effects on health and production, optimizing the ways in which capabilities are utilized. In the end, it provided the pharmaceutical company with potential paths to effectively transform the situation presented at the beginning of the ergonomic assessment work. Problems and defects are not free; someone causes them and is paid for it.

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