



23 a 27 de novembro de 2020

## THE CONTRIBUTION OF ERGONOMICS TO ENABLE THE TRACEABILITY OF HOMEOPATHIC PRODUCTION IN THE CONTEXT OF THE UNIVERSITY PHARMACY.

**Ana Luísa da Silva Alves**

Graduanda em Engenharia de Produção – TGP/UFF  
analuisaalves@id.uff.br

**Amanda de Souza Nardin**

Graduanda em Engenharia de Produção – TGP/UFF  
anardin@id.uff.br

**Júlio César Bispo Neves**

Departamento de Engenharia de Produção TEP/UFF  
juliobispo@id.uff.br

### Abstract

The university pharmacy represents a healthcare establishment that provides teaching, research, and drug manipulation activities. In this regard, its contribution to society is of utmost importance as it makes medications more accessible at reduced costs. The aim of this work is to identify possible issues within the entire process of providing homeopathic and herbal medicines for the application of ergonomic solutions based on the principles of Work Ergonomic Analysis. The methodology employed includes the selection and focal analysis of characteristic situations that identified initial impressions arising from interviews with experts on-site, followed by pre-diagnosis and focused analysis. The results showed the need to investigate solutions for the traceability of medications, complying with current Ministry of Health legislation and contributing to more efficient pharmaceutical assistance and a healthier work environment.

**Keywords:** Ergonomics. Homeopathic medicines. University Pharmacy. Medication traceability.

### 1. INTRODUCTION

The university pharmacy (FAU) aims, in addition to providing medication to the community while ensuring therapeutic efficacy, to be a suitable place for the development of future professionals in this field. In this perspective, pharmacy students consolidate all theoretical learning by gaining practical experience under the supervision of a pharmacist. It is a healthcare establishment where students have the opportunity to assist in the provision of pharmaceutical services, whether in the manipulation or dispensing of medications, promoting the exchange between theory, social issues, and learning (De Sousa Vieira et al., 2018).

The study presented was conducted at the FAU linked to the Federal Fluminense University - UFF. Inaugurated in March 1996 and located in the municipality of Niterói - RJ,

it significantly contributes by offering manipulation and dispensing services for allopathic and homeopathic medications, providing the local population access to these drugs at reduced prices. Furthermore, in the academic field, it develops teaching, research, and extension activities. The University Pharmacy seeks to provide students with the daily life of a professional by adding practical knowledge, expanding learning beyond the university classrooms.

The production of drugs and its related activities have been the subject of Ergonomics, as shown in some academic works that range from the analysis of cases of work-related musculoskeletal disorders (Bordin, 2004), through the analysis of design, visual comfort, and identification of errors in interpreting safety information on leaflets (Da Silva, 2008 and Blum, 2015) to the use of fuzzy set theory to establish a methodology for evaluating resilience in organizations dealing with hazardous technologies (Grecco, 2012).

In this work, the methodological approach of Ergonomics, supported by current legislation, allowed for the improvement of the traceability of the production process of homeopathic and herbal medications (tinctures). As a result, practical and applicable solutions were proposed for the context of registering crucial production information for the proper traceability of these drugs, complying with RDC 67 of ANVISA<sup>1</sup> (Brazil, 2007), with an impact on improving the process and reducing stressors to the well-being of FAU workers.

## **2. METHODOLOGY**

The methodology adopted in this study was built based on the fundamentals of Ergonomic Work Analysis, as characterized by Vidal (2001) in five typical phases:

- a. Selection of Characteristic Situations;
- b. Focused Analyses in Characteristic Situations;
- c. Pre-diagnosis;
- d. Focused Analyses;
- e. Ergonomic Brief.

The information presented below was obtained through situated observations and conversational action with the pharmacist at the Homeopathy Laboratory of FAU/UFF during field visits.

### **2.1. About FAU/UFF**

The University Pharmacy (FAU) is affiliated with the Faculty of Pharmacy at the Federal Fluminense University - UFF. It was inaugurated in March 1996, with public service starting in July of the same year. In this perspective, in addition to contributing to the training of pharmacists within the academic setting, it plays a significant role in providing access to medications for the population of the municipality of Niterói - RJ and surrounding areas by offering compounded (allopathic and homeopathic) and industrialized medications at a reduced price.

---

<sup>1</sup> National Health Surveillance Agency.

The FAU/UFF staff consists of public servants - administrative technicians and pharmacists - and, as an institution, serves as a reference for practical classes by professors and scholarship students from the Pharmacy course at UFF in subjects such as pharmaceutical technology and homeopathy. The public service hours are from 9:00 am to 5:00 pm (Monday to Friday, except holidays). According to data from 2019, the FAU served a total of 6,038 individuals and sold 10,161 medications (both allopathic and homeopathic).

## **2.2. Focused Analysis**

After the initial visits, it was possible to list a set of situations with the potential for further analysis, as described below:

I. Considering the context of the process of homeopathic manipulation in the workplace referred to as the pharmacist's room, where information from the prescription is recorded and production sheets are printed, the main adversity found was the absence of entry of batch number and expiration date of the pharmaceutical ingredients.

II. Cleaning and sterilization of materials after use in manipulation procedures, both in the homeopathy and allopathy laboratories, are carried out in the same washing area, increasing the risk of material contamination. This working condition requires increased attention to care during material manipulation beyond what would be necessary if there were a dedicated washing area for both types of medications.

III. The gels used in manipulation in the semisolid laboratory were not differentiated on the production sheet. According to the report from the specialized pharmacist, the lack of differentiation not only complicates the prediction of the quantity needed for the most demanded types but also requires pharmacists and trainee students to perform manual work that requires more effort than necessary in their routine, leading to work overload.

IV. In the dispensing sector, inadequate staff allocations were observed. The limited number of employees due to restrictions on public job openings at UFF resulted in administrative technicians providing customer service. Thus, it was found that pharmaceutical assistance was provided by an unqualified individual.

## **2.3. Pre-diagnosis**

Initially, among the characteristic situations collected, we chose to delve into the analysis of the occurrence of non-compliance with an adequate protocol for separating materials from homeopathy and allopathy to avoid contamination with substances - a protocol provided for in legislation. However, after a more comprehensive investigation and validation with the responsible specialist, we focused our efforts on addressing the demand of the homeopathy laboratory.

In addressing the demand of the homeopathy laboratory, three significant problems were identified through observations made during the demand instruction process. They are: (i) the production sheet of the medication lacking the batch number of the raw materials (tinctures and gels), (ii) the filling record of the tinctures, and when it comes to homeopathic medicine, (iii) manual completion of the batch and expiry date on the production sheet.

With these observations, we found that the reported problems can be viewed in the light of organizational and cognitive ergonomics, given their immediate consequences for people and the process, in the following aspects:

I. The pharmacist spends a considerable amount of their working day manually filling out and verifying data that are not contained in the production sheet, making it possible to make mistakes in controlling these inputs in production and impacting productivity in strictly manual tasks.

II. The role requires a high level of concentration, which can lead to fatigue and prolonged stress.

III. A negative effect may be found in reverse logistics when the patient returns to the pharmacy with the product, and the pharmacist must promptly identify all the information identifying each input contained in the drug.

IV. Compliance with ANVISA RDC No. 67, which addresses good practices for the manipulation of magistral and officinal preparations for human use in pharmacies. This resolution indicates, in sub-item 5.19, that "the entire manipulation process must be documented, with written procedures defining the specificity of the operations and allowing product traceability," and in sub-item 3, it states that "the pharmacy must have a Prescription Book, whether computerized or not, and record the information regarding the prescription of each compounded medication."

## 2.4 Focused Analysis

Regarding the focused analysis, we are dealing with a set of micro-processes that characterize a set of operational actions. Thus, the situation's scope includes the customer, the purchaser of the medication, the product (pharmaceuticals), and the pharmacist in the production chain. Fig. 1 presents a flowchart developed from systematic observations and conversations with different employees, from the service sector, administration, to the medication manipulation sectors.

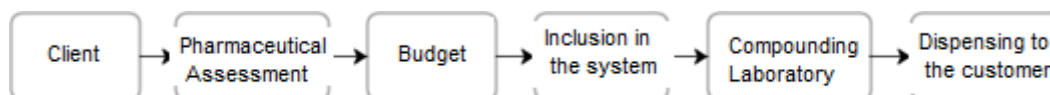


Figure 1. General Process Flowchart.

As shown in Figure 1, the customer provides the necessary data to the administrative staff to check the availability of the inputs and thus determine the budget. At this point, the product code, patient name, price, and delivery date are recorded on paper and attached to the prescription for the customer to present at the cashier for payment. Subsequently, the production sheet is included in the system, and its identification is linked to the insertion of the generated code in the operating system. After the medication is manipulated, the pharmacist notes the batch and expiration date on the production sheet and then proceeds with labeling, sending it to dispensing, where the medication is stored for the patient's pickup.

The process described is similar for herbal medicines; the administrative technician must similarly fill in the tincture code on paper attached to the prescription. However, in this context, all tinctures belong to a single identification number. In practice, to determine the quantity sold of this input, it is necessary to manually count and verify the quantity recorded by hand on each paper. Internal control, in this perspective, is carried out doubly, both on the production sheet and on the filling record of the tinctures.

The absence of the batch number on the production sheet and the presence of a single code for all homeopathic medicine tinctures became the object of study. This is justified by considering the minimum requirements set forth in RDC No. 67, which deals with compounding activities of magistral propositions. Together with on-site observations and conversational analysis with the specialist, it is understood that medication traceability is

essential to ensure not only compliance with legislation but also adequate patient care.

Furthermore, the persistence of these problems impacts, to some extent, the forecast of demand for these inputs and the identification of crucial information for the manipulated medication in a more productive and efficient manner. Additionally, this situation creates a stressful work environment and an excess of work for the pharmacist, compromising not only their health but also the pharmacy's productivity.

In order to identify the root causes of the unpredictability of homeopathic medication traceability, the Ishikawa Diagram (also known as the Fishbone Diagram) was used, the result of which is shown below:

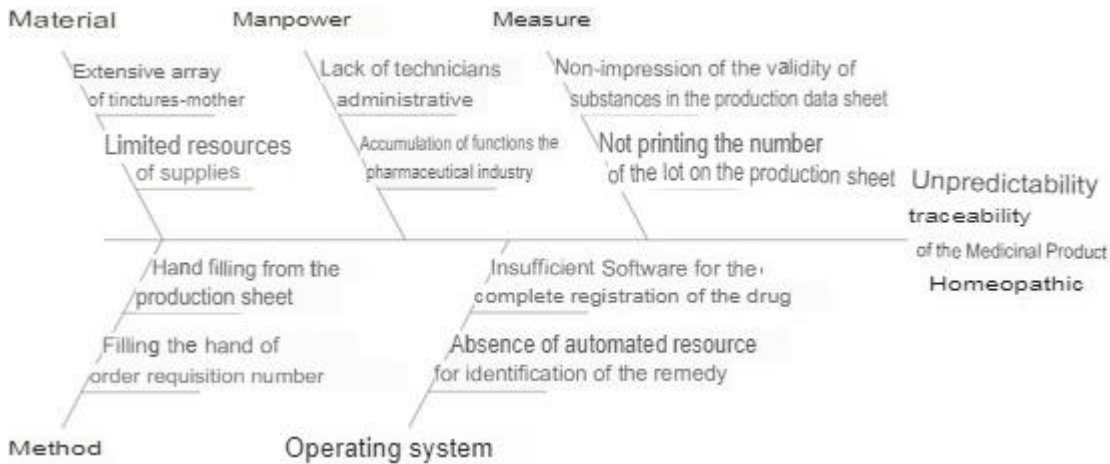


Figure 2. Root Cause Analysis of the Homeopathic Medication Traceability Problem.

This diagram enabled the identification of the causes related to non-compliance with RDC No. 67, which fall under the categories of measurement and method as shown in Figure 2. Therefore, to correct the traceability problem, a proposed solution should focus on modifying the production sheet preparation procedure.

#### 4. ERGONOMIC REQUIREMENTS NOTEBOOK

As a result of the analyses, it is suggested, as a proposal for practical application, the creation of a matrix of unique codes for each tincture and gel, associating them with their scientific and common names to be identified using a barcode label. In practice, the data would be consolidated in an Excel spreadsheet. Additionally, a label template for printing with the purpose of identifying the bottles of these inputs is indicated (see figure below).

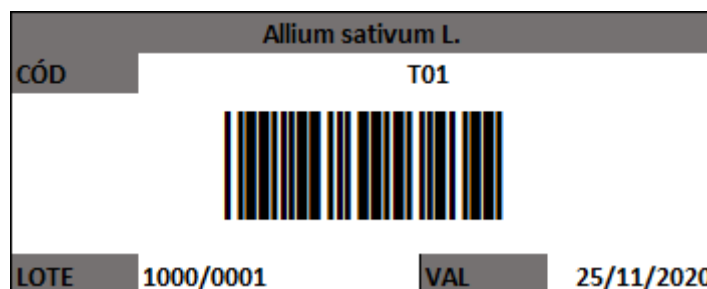


Figure 3. Proposed Label Template.

The spreadsheet is structured into two tabs, each with its objective as follows:

- Gathering all the labels (in the model from Fig. 3) for organization for subsequent printing;

**A contribuição da Ergonomia na viabilização da rastreabilidade da produção de homeopáticos em contexto da farmácia universitária**

Alves, Ana Luísa da Silva.; Nardin, Amanda de Souza.; Neves, Júlio César Bispo

b. Tables for controlling all the information (name, code, batch, and expiration date) of each label, allowing changes such as deletion and addition of references.

This model includes the registration of missing data, as pointed out by the Measurement category in Fig. 2. It also conditions this registration for automated tracking, replacing the manual control that is more prone to human error, eliminating the causes presented by the Method category in Fig. 2. Therefore, besides the gain in quality, it contributes to productivity by reducing the time for the pharmacist to prepare and review production sheet data. Additionally, for the human factor, it provides better working conditions, reducing stress in the pharmacist's daily routine.

The change in the process with the application of the proposed solution is shown in the flowchart below (Fig. 4), where it is possible, graphically, to identify that data consolidation reduces the presence of manual activities.

The inclusion of the prescription in the operational system already present in the pharmacy will be interconnected with the proposed tool for use (graphically highlighted in yellow), as the tincture matrices will be registered and constantly updated as needed for production, and the control data (name, expiration date, and batch number) will be linked to the compounded medication. The Excel spreadsheet containing all the aforementioned information will also serve for internal control registration.

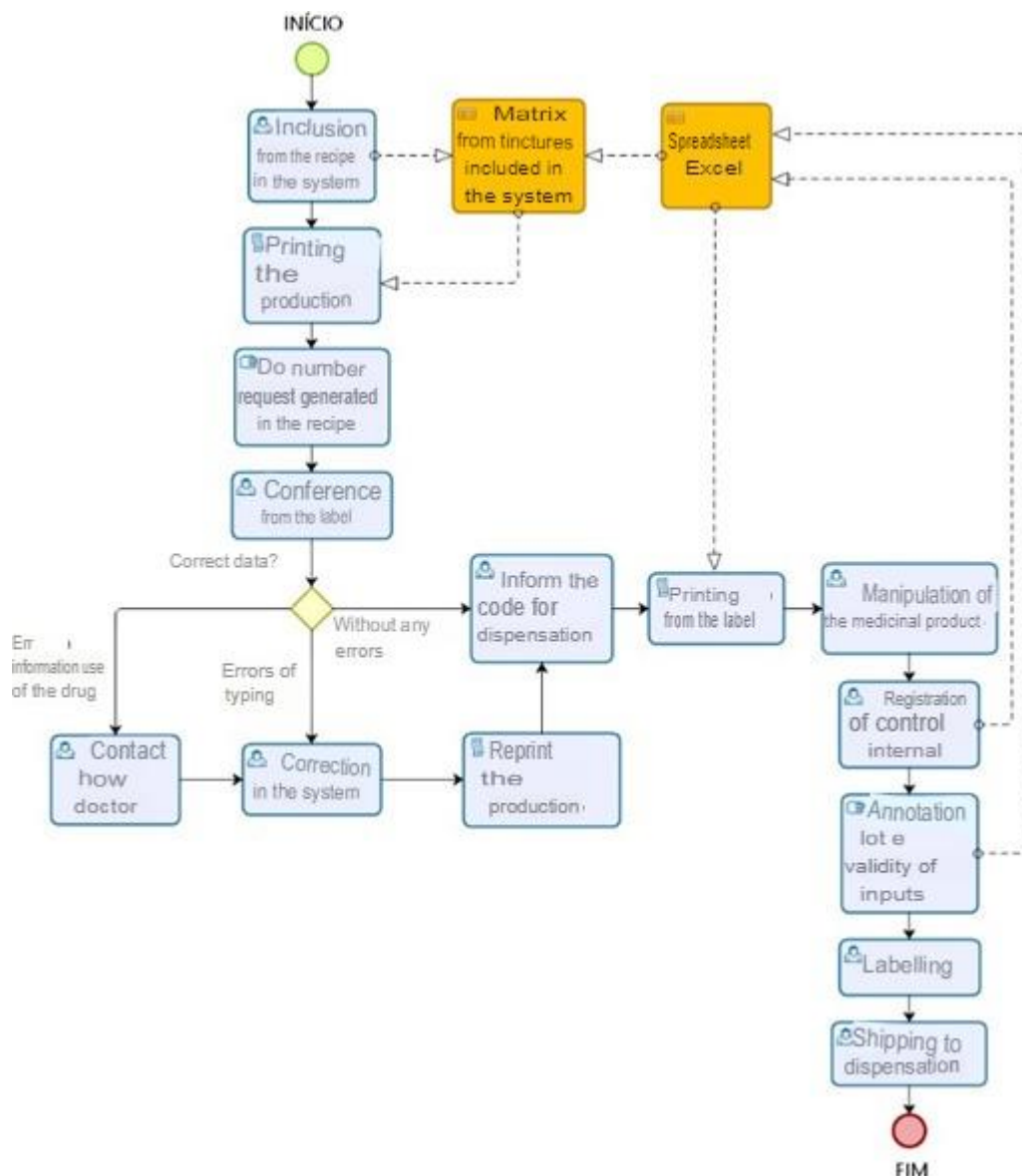


Figure 4. Homeopathic Medication Flowchart

## 5. DISCUSSION

The implementation of barcode labels contributes to reducing the time spent by the pharmacist in controlling the inputs used for each compounded preparation. In this perspective, the proposed solution presented to the specialist mitigates problems related to the methods used to fill in medication production data.

Automated filling allows the user to be less exposed to the inherent variability in the production process, as it allows for pre-formatting restrictions for filling fields with the possibility of invalidating the data. Additionally, in the context of workload allocation for the pharmacist, this tool allows for optimization, resulting in less time spent on information data control activities.

Finally, for patients, providing medication traceability meets the need for post-dispensation assistance in cases of returns due to dosage complaints or side effects.

The study presented has future prospects for improvement in implementation. In this sense, it is aimed that the information consolidated on the labels be incorporated into a QR Code system. Given the extensive amount of data, related to medications and necessary for a more comprehensive tracking, it is proposed that the labels have this printed feature, to be read by a mobile application by the pharmacist at the dispensing site and eventually during production.

It is important to highlight that within the scope of the project, however, there are some relevant premises such as: maintaining authorization for entry into the pharmacy by the institution's management; the pharmacist must be committed to applying the measures to make the solution applicable; training schedules must be agreed upon in advance so as not to disrupt the work routine, and the necessary material for printing labels must be available for use.

As for the possible identified risks: the tool may not be executable due to hardware problems; non-adherence in the practical routine of the users, and the threat to the continuity of the use of the proposed tool in the homeopathy laboratory in case of a change in management.

## 6. REFERENCES

- Blum, A. e Merino, E.A.D., 2015. "Ergonomia em Rótulos de Medicamentos: Uma Análise a Partir de Princípios do Conforto Visual". *Blucher Design Proceedings*, 2(1), p. 1002-1013.
- Bordin, L.H.V., 2004. "Avaliação Ergonômica e Melhoria das Condições de Trabalho e do Processo Produtivo de Nutrição Parenteral Total em Farmácias de Manipulação: Um estudo de caso". Dissertação de Mestrado, UFRGS, Brasil.
- Brasil. ANVISA. Agência Nacional de Vigilância Sanitária, 2007. *Resolução da Diretoria Colegiada – RDC nº 67, de 8 de Outubro de 2007*. Brasília, DF.
- Da Silva, C.R.L., 2008. "Contribuições da ergonomia cultural para a representação gráfica em advertências de medicamentos". Dissertação de Mestrado, UFPE, Brasil.
- De Souza Vieira, B., Neto, E. M. R., de Oliveira Vasconcelos, L. M., de Almeida Melo, M. M., de Lima, J. P., dos Santos, S. L. F., & Barros, K. B. N. T., 2018. "A importância da Farmácia Universitária frente aos serviços clínicos prestados à comunidade". *Revista Sustinere*, 6(2), p. 321-336.
- Grecco, C.H.S., 2012. "Avaliação da resiliência em organizações que lidam com tecnologias perigosas: o caso da expedição de radiofármacos". Tese de Doutorado, UFRJ, Brasil.
- Vidal, M.C.R., 2001. *"Ergonomia na Empresa: útil, prática e aplicada"*. Editora Virtual Científica, 1ª edição.
- Vidal, M.C.R., 2003. *"Guia para Análise Ergonômica do Trabalho (AET) na Empresa: Uma Metodologia Realista, Ordenada e Sistematizada"*. Editora Virtual Científica, 1ª edição.

## **7. TERMO DE RESPONSABILIDADE**

Os autores são os únicos responsáveis pelas informações incluídas neste trabalho e autorizam a publicação deste trabalho nos canais de divulgação científica do ABERGO 2020.