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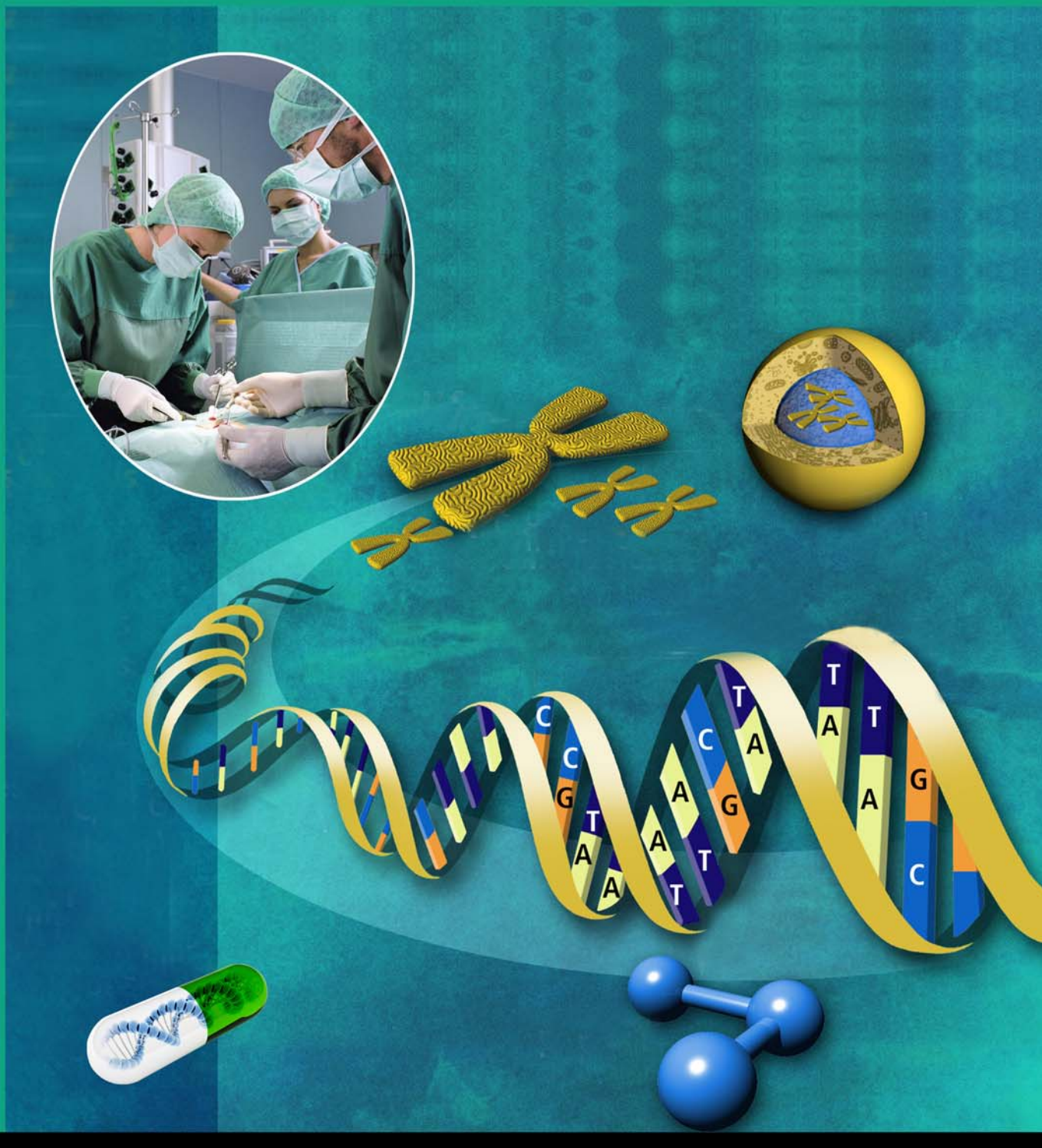

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Research Paper

COMPLIANCE TO BIOSAFETY STANDARDS OF THE PRINCIPAL LABORATORIES GENERATING CHEMICAL WASTE OF THE PHARMACEUTICAL DEPARTMENT OF UFPE

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Waste management has been an increasingly common practice in industries and laboratories for teaching and research across the country. Although some of these units have demonstrated interest in meeting the standards of biosafety, much still needs to be done to address the environmental issues and develope renewable technologies. The Pharmaceutical Department of UFPE has several laboratories, including research and extension groups whose activities, while of a heterogeneous nature, are directly linked to the use of chemical substances, production of medicines and other pharmaceuticals. The present work aimed to implement measures comprising a Chemical Waste Management Plan in the major chemical waste producing laboratories of that department, suggesting adjustments in physical structure, internal procedures, management of substances and educational activities. There are indications that these units will soon submit plans to conform to a Chemical Waste Management Program, still non-existent in the institution.

Keywords: Biosafety, Medicines, Management, Production

INTRODUCTION

Chemical waste is defined as anysubstance of a chemical nature that has physical and chemical characteristics, such as corrosivity, toxicity, melting and boiling points, density, reactivity, among others (Tomazini *et al*., 2011). For the management of waste, a set of actions is necessary that involve biosafety, rational reduction of production and actions that minimize environmental impacts. In recent decades, waste management programs have been gaining strength within pharmaceutical-chemical industries, whether of a small or large scale (Azevedo, 2008). Brazil, in its position as an industrialized country in a state of accelerated economic development, has raised significantly its production of wastes, exponentially increasing the risk to the health of workers and the

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environment. This growth makes it necessary that the country implement ecologically conscientious measures and align to the principles of sustainability which are defended worldwide (Alberguini *et al.*, 2007). Although there have been several discussions regarding appropriate procedures for handling of chemical wastes, much must still be done to meet legal requirements.

Successful experiences such as those carried out by some educational and research institutions merit attention. The Federal University of São Carlos (UFSCar), University of São Paulo (USP), University of Campinas (UNICAMP), Federal University of Paraná (UFPR) have served as references in adoption of Chemical Waste Management Programs (CWMP), adopting distinct procedures, even when they have the same goals, due to the heterogeneity of waste production (Conto, 2010).

The of Pharmaceutical Department (PD)-Center for Health Sciences (CHS), is part of the Federal University of Pernambuco, one of the largest teaching and research centers of the North and Northeast regions of Brazil. Research developed in this department include synthesis, planning of new drugs, toxicological and phytochemical assays, validation of methodologies and research with natural products, using chemical reagents that are directly involved in the production of wastes. As it is included within the university context, the PD does not have its own Waste Management Plan, which has hindered the logistics of the activities developed in this department. Concerned about the safety of the academic community (students, technicians, teachers) and of the environment, isolated actions have been gaining strength in UFPE. Groups like the Núcleo de Biossegurança e Meio-ambiente (NuBIOMA) have sought the transformation of knowledge into actions, aiming at the compliance of the various facilities, diagnosis of the situation of the campus and the itemization of environmental issues and risks. This study had as its main objective to diagnose the principal chemical waste generating laboratories of the PD and provide theoretical and practical support for compliance to basic biosafety standards.

MATERIALS AND METHODS

During the realization of this study, five laboratories of the PD located on the Recife campus of the Federal University of Pernambuco were accompanied. The laboratories were selected due to the nature of the pharmaceutical and chemical activities and include most of the waste generating units inside this department serving the academic community, other institutions (such as ANVISA, the institution responsible for Brazilian pharmaceuticals) and other federal universities.

Diagnostic Record of the Situation of Laboratories Investigated

The data obtained were results of observation of the activities developed in each laboratory and filling an individual record regarding the points raised. The records used included topics relevant to biosafety: adoption of Standard Operating Procedures; presence of an agent responsible for the disposal of waste generated during local activities; existence of inventory; identification of commonly produced wastes, management implemented for waste disposal, among others.

Preparation and Distribution of a Mini-booklet Containing Information for the Implementation of a Chemical Waste Management Plan in the Pharmaceutical Department/CHS of UFPE

Before the initial observations, a mini-booklet was developed and distributed, which contained basic information and immediate procedures for deployment of a Chemical Waste Management Plan. The mini-booklet was distributed in printed form and contains important definitions about biosafety and waste management, as well as useful attachments such as templates for Standard Operating Procedures (SOP) for disposal of wastes, labelling, inventory and Material Safety Data Sheets; Test Table with Liabilities; packaging and incompatibility between wastes.

Subsequent Surveys to Check Adjustments

In order to clarify questions of users, periodic visits were carried out after the distribution of the booklet. Additionally, a form was distributed to each waste generating unit for it to record, quantify and qualify the nature of the waste produced on a weekly basis, allowing for individual accompaniment of each unit.

RESULTS AND DISCUSSION

The visited laboratories represent the largest producers of chemical wastes in the activities of teaching, research, and extension of the PD. The information obtained reveals the heterogeneous nature of the activities carried out in this department. Each visit was observational and informative, and guidelines were passed on to the responsible agent for biosafety and waste management (when applicable) and/or to the members designated by the heads and researchers of each unit.

After the visits, it was noted that only 40% of the laboratories had a technician and/or students with a minimum level of undergraduate education responsible for the biosafety and/or waste management. After the first visits, all laboratories appointed a responsible agent, who contributed during the course of this study.

The laboratories that develop activities with external partners (40%), already had previous initiatives for waste management and biosafety of staff and students. In the performance of research with external institutions, the UFPE apparently promotes greater rigor in the procedures carried out in the laboratories in question, due to periodic surveillance by the other institutions.

Adaptation of the Physical Space of Each Laboratory and use of Collective and Individual Protection Equipment

Although none of the laboratories visited are connected to a network of sewage treatment, 40% showed physical conditions satisfactory for performing procedures involving chemicals (fume hoods, physical space divisions based on the physical and chemical nature of the compounds handled: solids, semi-solids, liquids, among others), while 60% had difficulty in adapting to the organizational demand of the physical space available.

The difficulties of organization found, in large part, are due to the physical structure of the building, which was built more than 50 years ago and does not conform to the current standards required for a laboratory unit. The results show a need for restructuring of the physical space to allow for the environment to meet the needs of the nature of the research carried out there.

A low compliance was observed of most groups to collective protection equipment. There are no emergency showers or eye-wash stations in accessible locations, nor fire extinguishers in accordance with the specific inherent risks. The use of individual protection equipment, however, is more widespread. The use of gloves, gowns, masks and glasses is routine, despite the amount available in the laboratory being insufficient and thus often resulting in the re-use of disposable material.

Without a proper physical structure, it was observed that the packaging of chemical assets and liabilities occurred in inappropriate locations such as the floor and near sources of heat and electricity. Another point that drew attention was the use of sinks for different purposes: from the disposal of chemicals to handwashing, which sets up a possible risk of injury to users and damage to the environment. Unfortunately, this reality is not exclusive to the PD, being also observed in most departments and centers of Brazilian universities. Emergency measures such as the establishment of a research network for sustainable management of wastes and effluents has been held by the current management of UFPE, in partnership with the management headquarters of Cidade Universitária.

Presence of Inventory of Reagents and Adoption of MSDS

Among the laboratories studied 60% stated that they do not have an inventory of the chemicals used. In these laboratories, there are also no Chemical Compatibility Tables (CCT) and Material Safety Data Sheet (MSDS). These sheets should contain important information regarding the risks of each substance and of possible incompatibilities: data that are critical to the choice of the best way of packaging, storage and treatment of wastes generated.

Prior Existence of a Chemical Waste Management Plan

Only 20% of the laboratories had practices and procedures that integrate a Management Plan, such as reduced production at source, segregation, immediate treatment of assets, packaging, transportation and adequate final destination. The other laboratories exhibited non-standard procedures or did not entirely comply with the minimum requirements for a plan.

Prior Practice of Waste Quantification and Labelling Criteria

Surprisingly, 100% of the laboratories declared never having performed any kind of quantification and registration of waste produced in daily activities (assets), hindering, therefore, effective identification of existing liabilities.

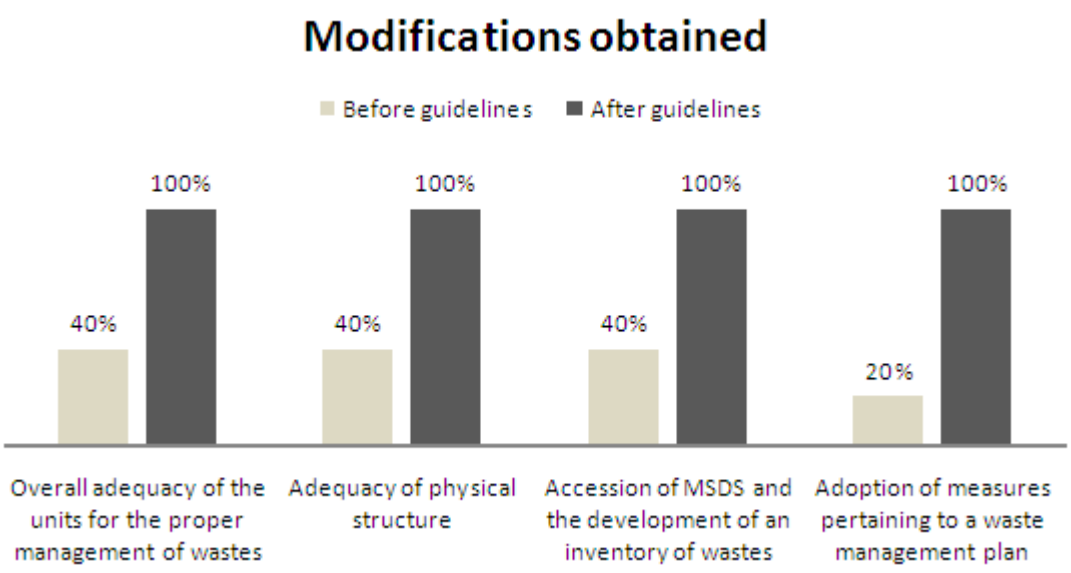
Only 40% of the units visited feature an adequate labelling program that follows international standards for labelling, which must present all the information concerning stored chemical waste. The remainder (60%) showed little or no special care towards meeting the recommended criteria for labelling.

Modifications Obtained

The guidelines recommended by the mini-booklet are being adopted gradually, and the trend in adoption of the set of practices that contemplate a CWMP can be seen in Figure 1.

The approach adopted for this study contributed to the awareness of the professionals and students working in the laboratories investigated. After the distribution of the material and the informational visits all units visited designated a responsible agent for biosafety in

Figure 1: Overview of Principal Modifications Obtained by the End of the Development of the Pilot Project



their unit. These professionals correspond to the people to which the guidelines were directed as well as those who received the material, in the form of a mini-booklet. The importance of this professional is justified by their role as a sentry, since throughout the process, they become a reference in training for various activities, assisting in the organization and in the maintenance of the measures proposed in the long term.

Adequacy of the Physical Space of each Laboratory and use of Suitable Collective and Individual Protection Equipment

Despite the limitations and structural problems of the building, we observed a great effort on the part of those responsible for the laboratories to obtain proper organization. All units performed small or medium-sized modifications for better storing of chemical reagents and their wastes, observing a 60% increase in the number of laboratories that performed these improvements.

There was greater attention to the purchase or reinforcement of Personal Protective Equipment. In relation to Collective Protection Equipment, there was no time for the acquisition of such materials by the laboratories visited. These are more costly and often require structural changes in the physical space.

In Figure 1, can observe the increase of inventories accompanied by MSDS on the part of the responsible agents of the visited units. According to Jardim (1998), the presence of the inventory of assets and liabilities is also of great importance to know the nature and quantity of wastes generated by allowing for greater planning and handling security.

Existence of Measures Pertaining to a Chemical Waste Management Plan

The adoption of measures that make up a Management Plan increased in relation to the initial period of the project. A total of 80% of the laboratories adopted the various practices

suggested during the visits, as well as in the material distributed in the mini-booklets.

Prior Quantification Practice

Figure 1 demonstrates the importance of the work done. Previously, no laboratory knew how to estimate the monthly volume of waste generated. In the end, 100% practiced quantification and qualification of their wastes. Despite the low volume generated (on average 5 L/week), there is a great diversity in chemical nature, demonstrating the typical profile of pharmaceutical teaching and research laboratories without industrial-scale production.

Despite the significant results, there was a little (only 20%) adoption of labelling criteria, so that the situation of liabilities remained unchanged in relation to identification.

The total volume of pre-existing liabilities remained stored in the same way, waiting for a later pickup by a specialized company. Incorrect disposal, directly in the sink and without prior treatment also continues to occur, probably due to the lack of control mechanisms and effective supervision.

Related to this, there is a likely ignorance on the part of the generators of the environmental impact of these substances in nature. According to Resolutions 306/2004 of ANVISA – Agência Nacional de Vigilância Sanitária and 358 2005 of CONAMA-Conselho Nacional do Meio Ambiente, responsibility from generation to appropriate management belongs to the unit that produces them, comprising a series of responsibilities that range from the storage conditions that precede generation and packaging to the final destination. Although these resolutions are directed to the wastes from health services, these residues feature guidelines whose applications extend to several other wastes generated. According to GIL (2007), for the storage of wastes proper segregation is necessary, which should be made judiciously to ensure a safe work environment.

CONCLUSION

On the verge of the development and establishment of a Chemical Waste Management Program (CWMP) on the campus of UFPE, it is necessary for each unit to adapt, by means of synchronized procedures, in order to ensure the maintenance of the program. This means that the adoption of a CWMP should be an attitude common for all laboratories involved. The model implemented by the Pharmaceutical Department is an important step for the consolidation of institutional-level pilot projects.

Quantification and qualification of impacts produced, during and after the actions taken will make it possible to outline new goals, correct possible errors and consolidate new initiatives, as well as to implement the recommendations presented in the mini-booklet that are fundamental and necessary steps for implementation of a CWMP.

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REFERENCES

1. ANVISA (Agência Nacional de Vigilância Sanitária) (2010), *Resolução RDC n. 306, de 7 de dezembro de 2004*. Dispõe sobre o regulamento técnico para o gerenciamento de resíduos de serviços de saúde. Available at: <www.anvisa.gov.br>Accessed in: April.

2. Alberguini L B A *et al.* (2007), Tratamento de Resíduos Químicos-Guia Prático para a Solução dos Resíduos Químicos em Instituições de Ensino Superior, Edição/ reimpressão: 2007, São Carlos, Editoria RIMA, Vol. 1, p. 104 .
3. Azevedo S L Z (2008), "Manual de Biossegurança - Secretaria da Saúde. Superintendência de Vigilância", available at: <http://www.ccs.saude.gov.br/visa/publicacoes/arquivos/p1_introducao.pdf> Accessed on: 22/March/2013
4. CONAMA (Conselho Nacional do Meio Ambiente) (2013), Resolução RDC nº 358, de 29 de abril de 2005. Dispõe sobre resíduos químicos e implicações a favor do gerenciamento do mesmo. Available at: <http://www.mma.gov.br/port/conama/res/res05/res35805.pdf> Accessed on: 26/March/2013
5. Conto M S (2010), "Gestão de resíduos em universidades", *Rio Grande do Sul: Educs*, pp. 185-204.
6. Gil E S, Negron A C V, Souza A R, Conceicao E C, Santiago M F and Garrote C D (2007), Aspectos tecnicos e legais do gerenciamento de resíduos químico-farmacêuticos, RBCF, Revista Brasileira de Ciências Farmacêuticas, Vol. 43, pp. 19-29.
7. Jardim W F (1998), Gerenciamento de resíduos químicos em laboratórios de ensino e pesquisa. Quím. Nova,São Paulo, Vol.. 21, No. 5, Outubro de 1998.
8. Tomazini F M *et al*. (2012), Cartilha de Orientação de descarte de resíduo no sistema FMUSP- HC <http://medicina.fm.usp.br/gdc/docs/grss_2_cartilha.pdf >accessed on: 8 April 2012.

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