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IMPROVEMENT IN THE MANAGEMENT OF PROCESSES FOR THE ACQUISITION AND STANDARDIZATION OF PHARMACEUTICAL INGREDIENTS IN A SCHOOL LABORATORY

Elaine Forgoza, Jorge Magalhães
Professional Postgraduate Program in Management, Research and Development in Pharmaceutical Industry at Institute of Drugs Technology/Farmanguinhos, Oswaldo Cruz Foundation/Fiocruz, Brazil
E-mail: elainerforgoza@gmail.com, jorge.magalhaesr@fiocruz.br

Abstract

The pharmaceutical industry is a dynamic sector in terms of innovation and management. The sector generates around US$ 1.5 trillion a year. In this sense, continuous improvement actions in the management of its processes are constantly present. However, the training of its professionals permeates strict knowledge in the field of quality, pharmaceutical legislation, and public health since education generates knowledge and provides innovation. Therefore, studying quality management, processes and innovation for the education sector and industry are fundamental for companies and organizations in the health area in the 21st century to improve the management of the acquisition of inputs. The results point to gains for the implementation of the Guideline for Standardization and Acquisition of pharmaceutical ingredients in their respective processes.

Keywords: *knowledge management, process control, quality management, pharmaceutical laboratory*

Introduction

Until the 20th century, the pharmaceutical industry produced its medicines by hand. Doctors and pharmacists were the main producers (Halas & Sampaio, 2020). An extremely important factor for its unfolding was research and its innovation process, since the constitution of the competition pattern of this industry took place through the launch of new or improved products (Bastos, 2005; Halas & Sampaio, 2020).

At the end of the 19th century, the world pharmaceutical sector began to organize itself based on the chemical revolution. According to Achilladelis and Antonakis (2001), in the years 1820-1880, the first generation of pharmaceutical innovations appeared on the European continent, introduced by the researcher Lavoisier and the French School of Chemistry (Basil Achilladelis, 2001; Kornis et al., 2014). After 1945, with the end of World War II, there was a pharmacological explosion and the emergence of the North American pharmaceutical industry, which inherited the spoils of the German pharmaceutical sector, focusing on chemical synthesis. Pharmaceutical industries began to restructure their strategy. Queiroz and Velásquez (2001), companies began to invest in R&D of new drugs (1st stage), industrial production of these inputs (2nd stage), as well as in the production of pharmaceutical specialties (3rd stage) and marketing and commercialization (4th stage).

With the entry of the third generation of innovation, there was an intensification of research, with the adoption of intensive marketing methods aimed at doctors, hospitals, and pharmacies. In this way, the fourth generation innovations emerged, resulting from the change

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in the scientific basis of the chemical and pharmacology industry with the life sciences (Kornis et al., 2014).

Thus, with the increase in innovations, the pharmaceutical market became concentrated, moving from broader competition to oligopoly. With this advance, the US emerges as the leader of the world pharmaceutical industry, even after the reconstruction of Europe. This fact was provided by the favorable institutional environment, which enabled technological innovations (Antunes, AMS & Magalhaes, JL, 2008). In this perspective, the world scenario, after the Second World War, served as the cradle for the modern pharmaceutical company, with an increase in the competitiveness of companies through strategies of internationalization of their activities. Industries have gained a leadership position in the development of corporate structures and marketing and sales practices. This fact guaranteed the return on investments in research and development and the profitability of the pharmaceutical industry worldwide (Magalhaes, JL et al., 2008).

According to Vargas et al. (2012), the world's pharmaceutical industries have adopted management strategies, such as: centralized decision-making process, with the global decentralization of the productive sector and Research and Development (R&D); achieving global economies of scale and scope through acquisitions and mergers; and diversification of productive activity through the production of generic and unethical drugs. In addition, the pharmaceutical sector used market dominance to acquire technology externally, through licensing agreements, R&D contracts, joint ventures, alliances and acquisitions of biotechnology companies (Kornis et al., 2014).

For the effectiveness of pharmaceutical products, an entire regulatory framework is issued by health surveillance agencies, as well as all training of skills and professionals in the area are governed by multidisciplinary areas such as chemistry, biology, pharmacy, and others, as the pharmacy is the main area (Souza & Gomes Filho, 2020).

Good Manufacturing Practices (GMP) are a set of procedures aimed at reducing the risks inherent in production practices, being a constituent part of Quality Assurance intended to be an instrument by which it is ensured that products are consistently produced and controlled with high quality standard (Calarge et al., 2007). This concept of GMP emerged in 1941, when there was a failure in the recall of an antibiotic that had cross contamination in its formulation, leading to the death of 300 people in the USA. As a result, the Food and Drug Administration (FDA) was asked to initiate a review of manufacturing requirements, where the production process should have greater control over its production. However, it was only in 1973 that the GMP began to have legal support in the United States and companies began to verify their compliance to avoid sanctions by the supervisory bodies (*FDA Guidance for Industry: Process Validation: General Principles and Practices - ECA Academy*, 2011). Nevertheless, quality standards are important and strict requirements to be managed by professionals in the sector. Good Manufacturing Products (GMP) are the main requirements that guide pharmaceutical production.

Good Laboratory Practices (GLP) are applied to test facilities that carry out studies required by regulatory bodies for the registration of pesticides, pharmaceuticals, food and feed additives, cosmetics, veterinary products, industrial chemicals, genetically modified organisms - GMOs, aiming to assess their environmental risk and human health (*FDA Guidance for Industry: Process Validation: General Principles and Practices - ECA Academy*, 2011). As this study is based on a technical course, whose practical classes take place in a laboratory, professors, students and employees must pay attention to (GLP), to guarantee the quality of the process of using and handling medication and to minimize human errors resulting from the lack of standardization (National Service for Commercial Learning Laboratory School, 2021).

Given that, considering that the 21st century has in vogue the issue of the knowledge era, companies increasingly need effective and innovative processes to remain in a global

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competitive environment and ensure the quality of the services provided (Magalhaes, JL & Quoniam, 2015). Likewise, the search for excellence in processes must permeate institutions through quality management, as well as the training of skills that will work in this segment. Therefore, this work aimed to contribute to the identification and proposition of a better management in the processes of acquisition of Pharmaceutical ingredients for the Laboratory School of a Brazilian institution.

Research Methodology

Research is characterized by an applied, qualitative, and exploratory nature. It seeks to identify the application of theoretical concepts about flow in the productive process of the National Service for Commercial Learning Laboratory School (SENAC - Brazilian term). The state of the art took place in indexed databases, such as SciELO and Scopus. The keywords involved "Education", "Technical Education", "Pharmaceutical Industry in Brazil", "World Pharmaceutical Industry", "School laboratory", "Good Manufacturing Practices", "Quality Tools", "Pharmaceutical Inputs" and "Good Manufacturing".

The temporal scope of the research was between October 2021 and November 2022. For the analysis of the retrieved documents, specific manuscripts for education, quality, pharmaceutical production, and Good Laboratory Practices were segregated. Data were processed in Microsoft 365 - excel, version 2211 and subsequently read and analyzed.

Research Results

The pharmaceutical industry is a sector that grows annually. Regardless of economic or health crises, the sector innovates and increases its participation in public health (J. Magalhães et al., 2020). The sector generates around US$ 1.5 trillion a year (Quintiles IMS Institute Forecast, 2022). Given the relevance for humanity, in 1975, the World Health Organization, in the 28th Assembly, determined that it was mandatory to adopt Good Manufacturing Practices (GMP) and Quality Control of Medicines, likewise, implement a Quality Certification System for Pharmaceutical Products in the international trade of health supplies. Thus, all member states were obliged to apply the requirements set out in these documents (WHO, 2008).

In Brazil, GMP regulation is coordinated and supervised by the National Health Surveillance Agency (ANVISA). All drug manufacturers must comply with the guidelines of the Technical Regulation of Good Practices for the Manufacture of Medicines (Brasil, 2001). Regarding the regulatory norms applied to the SENAC School Laboratory, the following were identified: theoretical foundations of quality, quality management system, quality tools and good manufacturing practices. The compiled and summarized data are shown in Table 1:

Table 1
Sanitary Guides to the Pharmaceutical Industry

Brazilian General Guidelines for Good Manufacturing Practices for Medicines	Year
ANVISA – RDC 658	2022
INMETRO NIT- DICLA 035	2019

Source: (ANVISA, 2022)

Concerning the SENAC pedagogical model, applied to professionals to be trained for the pharmaceutical sector, the documents listed in table 2 were identified.

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Table 2
SENAC Pedagogical Model for Professional Pharmaceutical Class

SENAC Pedagogical Model	Year
Technical Course Plan in Pharmacy Professional Technical Qualification at Medium Level	2015

Source: (SENAC, 2021).

Regarding the professional to be trained to work in the pharmaceutical market, he must be a professional specialized in the area, but with a holistic and multidisciplinary view. The areas of science are correlational and the presence of transdisciplinary skills increasingly strengthens the specific sector, contributing to the management and innovation of its processes and services (Araujo et al., 2022; J. L. Magalhães et al., 2014; Pesqueira et al., 2020).

Education in some world societies is considered as a simple service that a party (State or private companies) offer to clients or consumers (D. Silva et al., 2018). In the United States of America (USA) this change assumes an air of normality and naturalness and of supposedly new and original activities (Ravitch, 2011; D. Silva et al., 2018).

The main characteristics of professional education in some countries that are among the seven largest economies in the world are: United States, Germany Japan, France, and United Kingdom - with a focus on England (table 3).

Table 3
Main Characteristics of Professional Education in the Main World Economies

Countries	Historical highlights	Current configuration
United States	Tradition of promoting professional education since the 19th century.	- There are three “schools”, the academic one, preparatory to higher education; the vocational one, which also gives access to higher education, however, due to the emphasis on professionalization, it provides students with lower academic conditions than the first one, and the general one, which tends to bring together low-achieving students around fewer demanding curricula; - The country facilitates the completion of secondary education, "continuing" "continuing" seeking to ensure universal schooling for all up to the twelfth year, being an essential "continuing" condition for employability.
Germany	Dual system, inspired by medieval guilds, guilds of craftsmen and artists.	- Germany's dual system is based on the early separation of those who go on to higher education (between 11 and 12 years old) and professionalization; - Despite this, there is a certain prestige for professional education, while there is the occurrence of return transfers, whereby higher-level students enroll in technical courses to better build bridges between theories and practices and between education and training. the work; -Possibilities have been established for graduates from professional education to continue their studies in higher education, which is diversified and flexible, comprising universities, polytechnic schools, technological universities, and professional colleges. However, graduates of academic or general education courses have a higher education.
Japan	Tradition of school preparation, strong state influence and modest demand for professional education.	Education and training are largely “continued” “continued” separate, the former in the Ministry of Education and the latter in the Ministry of Labor.

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France	It developed one of the historical matrices of professional education, which had wide repercussions in the world, including in Brazil. This model is centralized, state-owned and embedded in the educational system, with roots in Napoleonic and other reforms.	-The single school goes up to 14 years old and, from 15 to 18 years old, extends to upper secondary education, with several options of general and professional education, culminating in a final exam; -Approximately 37% of students in lower secondary education enroll in a career choice, because of an orientation process in which the choice of the student and family tends to be less important than the student's performance in school and the decision of the advisors; -In this sense, as in other countries, educational guidance is accused of being a smooth process of scholastic and social selection, which reflects the strong influence of the students' social origins. Students and parents are free to choose, but admission is determined by the school, based on performance and other characteristics.
United Kingdom with focus England	Faced with the challenges of a globalized economy and competitiveness, the United Kingdom and England, have taken great steps towards improving vocational education since the 1980s.	-Flexible, quasi-market system, with less State participation; -Demanding evaluation processes, providing data and information to increase public awareness of options.

Source: (SENAC, 2021; D. Silva et al., 2018).

As for the mapping carried out of the process of purchasing inputs, it was shown that it follows ANVISA guidelines, according to RDC 658/2022. Therefore, these documents demonstrate that for each delivery of raw material, the containers are checked for integrity of the packaging, including the tamper evidence seal where applicable, the correspondence between the delivery note, the purchase order, supplier labels and information approved by the drug manufacturer. About points of improvement, in the light of current legislation, the absence of analysis certificates, inappropriate storage conditions of pharmaceutical supplies, packaging that is not consistent with the guidelines of RDC 658/2022, as well as the lack of information on the identification of inputs in the fractionation act, must be observed and followed (ANVISA, 2022).

Discussion

The manufacture of the pharmaceutical sector is characterized far beyond the simple production of medicines. It is an intense sector that involves education, research, development and innovation of its processes and products. However, the management of production, quality, operations and knowledge are essential characteristics for success and avant-garde in the 21st century (Magalhaes, JL et al., 2008; Pezzola & Sweet, 2016; Souza & Gomes Filho, 2020).

Before the industrial revolution, manufacturing had quality controlled by the craftsman himself, he defined his criteria and these directly influenced productivity, because the more quality, accuracy in the product's shape, the less production, making the value of the product higher for use more expensive inputs and take longer to manufacture. The artisanal processes faced industrial production, in which the machines were able to meet a greater demand for products, but the quality dropped, since the process was segmented and each part had a person in charge, with no control over the realization of the whole (Olivares, 2019).

Administrative sciences evolved with the various attempts at productive growth among workers, with mechanisms of incentive and stimulus based on financial improvements, methods that encouraged faster and quality work through awards and promotions within the company. Scientific management was a model that strengthened product quality based on controlled

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processes, analysis and skills training (Figueiredo & Silveira, 2020). According to Bravo (2010), scientific management is the global combination of science, harmony, cooperation and greater performance in substitution of empiricism, discord, individualism and reduced production respectively, all revolving around human development with a focus on efficiency and personal growth and satisfaction.

The history of quality began in Japan and the main people responsible for the great transformation were Deming, Juran, and Ishikawa who, after the Second World War, with the application of their quality concepts, began a process of industrial revitalization. In this scenario, quality underwent a major revolution in the 20th century, starting from an inspection that was carried out by craftsmen on finished products to strategic business management (Olivares, 2015).

With the increase in production, products began to be analyzed by sampling, using statistical quality control techniques, such as the statistical process control chart that made it possible to identify occurrences of defects throughout production. The quality function began to reach the level of defect prevention and care was extended to the process and not just the product (Fonseca, 2015).

It is observed that rapid changes - both economic and social - that occurred, mainly after the phenomenon of globalization, generated greater competitiveness in the conquest of markets by companies. Several technological innovations and new organizational management practices introduced by companies were often not enough to achieve the desired objectives, which generated greater commercial competition in several markets, taking as an example the market of retail banks with strong competition in the segment (Vale et al., 2018).

Quality then becomes a highlight in the search for competitive advantages (Drucker, 2006). In this context, quality management is a management model that generates awareness of quality in all stages of a process within an organization, in which all people involved must be focused on contributing to the execution of quality control, from employees to their suppliers (Camargo, 2011). According to (2000), quality management works as an ally for every company that is working in the search for a better positioning throughout its operation, which involves all hierarchical levels and sectors.

In Brazil, the ANVISA Resolution – RDC n° 658/2022, maintains Brazil adequate to the world standards of manufacture of pharmaceutical products, in accordance with the regulatory requirements of the GMP. Therefore, it obliges manufacturers in this segment to comply with the guidelines of this resolution. Regarding professional education, the countries present the following aspects: educational duality (professional education and propaedeutic education - initial education for later specialization), flexible quasi-market system and professional education as access to employability (D. Silva et al., 2018).

Empirically, the first practices of professional teaching began with the arrival of the Portuguese to the settlements of their colonies, where the Jesuits trained indigenous and black people, free or enslaved, for methodical work. In the first two centuries of colonization, the Jesuits created religious colleges in the main urban centers, called workshop schools, which trained artisans and people to work in other trades. These schools are considered the first professional training centers in the country (Soldão & Filho, 2021).

Professional education in Brazil has its origins within a welfare perspective with the objective of "supporting orphans and other disadvantaged people", that is, to assist those who did not have satisfactory social conditions, so that they would not continue to practice actions that were contrary to good customs (Ramos, 2020; V. M. P. da Silva, 2018; Thiesen, 2008).

The modality of commercial teaching expands in Brazil according to economic, social, and political demands. The development of education is intrinsically linked to the country's economy, which sees in it a possibility of advancement. The relationships that may exist between the educational system and the economic system are thus deeper: they are measured not only in

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terms of lag, but also in terms of the real requirements of the economic mode. Both determine the degree of advancement or delay of the school (Romanelli, 2011; Soldão & Filho, 2021).

In this scenario, the National Service for Commercial Learning (SENAC – Brazilian term), is an institution governed by private law, subordinate to the National Confederation of Commerce (CNC – Brazilian term), which has been responding to requests from commerce since 1946, governed by Decree No. decree n° 61,843, in 1967. In 2021, SENAC made available to the population a network of 548 school units, 403 professional education centers, 30 pedagogical companies, 10 specialized professional education centers, 81 mobile school units, 24 units higher education, 40 administrative units. It has a total staff of 33,234 employees, of which 20,887 are professors and instructors. It offers more than two thousand courses grouped into seven technological axes: environment, health and safety; educational support; management and business; hospitality and leisure; information and communication; infrastructure; and, finally, cultural production and design (SENAC, 2021). Among them, the technical course in Pharmacy, which has a total workload of 1,200 hours, whose objective is to train professionals with skills to act and intervene in their field of work, focusing on results. The technical course in pharmacy addresses a pedagogical plan model with 14 curricular units, involving activities in the processes of: inventory control, quality assurance, quality control, manipulation, production, and supply of medicines in drugstores, pharmacies and in the SUS.

Trends point to the need for greater professionalization of activities in the pharmaceutical sector and the urgent need to adopt new management tools to guarantee the survival of companies in this highly competitive context. This same scenario also indicates that the technical professional qualification Retail Pharmacist Clerk will imply a technical advance in the activities carried out by pharmaceutical retail professionals, qualifying them and providing better customer service in this sector (SENAC, 2021).

The laboratory is normally considered an adverse place, and due to the risk factors in this work environment, the safety of laboratory practices represents fundamental element of teaching, so that students perform their technical activities, with quality and productivity (Furtado, 2011; C. M. da Silva & Fiori, 2022). The analysis of this reality demonstrates that it is necessary to disseminate the principles of GLP at all levels of education, to make laboratory procedures safer for everyone. Therefore, risks must be monitored, and codes of conduct must be drawn up and respected to reduce risks (Furtado, 2011).

The learning of GLP principles by students who need to use the laboratories is fundamental for professional development, as it makes learning more practical and contextualized with the objectives of professional training. Therefore, the elaboration and implementation of GLP teaching for students is relevant, as well as awareness and awareness of the risks of exposure to chemical agents, in educational environments ((C. M. da Silva & Fiori, 2022).

The GMP are procedures that guarantee hygiene and safety in the work environment, aiming to guarantee the quality of the manufacturing process and handling of medicines, minimizing human errors resulting from the lack of standardization. In general, this content is offered through discussions of legislation by the National Health Surveillance Agency (ANVISA) and quality standards published by the Brazilian Association of Technical Standards - ABNT (ANVISA, 2022).

In this context, SENAC's contribution to teaching professionals for the pharmaceutical sector is urgent and fundamental. Braga et al. (2012), for example, defend the importance of experimental activities and the didactic laboratory for the formation of more complex views about the nature of science, through a framework of great discussions on epistemological issues related to the role of experimentation in the construction of scientific knowledge. This role of using experimental classes for didactic purposes not only points to a formative character of citizenship, in a better understanding of the importance of science in the modern world, but also to a technical character, because better understanding some of the tools with which one

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works in the laboratory it is of great importance for those who will do science or work with technology professionally. Knowing science from a historical-philosophical point of view, it is possible to understand scientific concepts and, mainly, to use this knowledge to understand the contemporary world. Modern science is the result of the historical process, and it is from it that mathematics and experimentation are incorporated into science. Students must understand the entire context in which the pharmaceutical product is produced, and the pharmaceutical sector is no different (Cavalcanti; Queiroz, 2018).

Conclusions

The pharmaceutical sector is intense in research, development, and innovation. It is a primordial industry for the public health of the people. Professional education in the pharmaceutical area must be multidisciplinary and comprehensive, in tune with the best teaching practices and sanitary regulatory guidelines, to contribute to holistic and competent training in the area in question.

It is noted, gaps to be improved, for better compliance with regulatory guidelines to improve the process of receiving inputs for the School Laboratory. Thus, a Guideline, guiding the stages of the flow from the purchase order to receipt, must be detailed, to avoid loss of analysis certificates, storage conditions and, also, quality tests. These actions will further contribute to the safety and effectiveness of the production process at the Escola Laboratory. Although the "in-school process" is not audited by the GMP guidelines required in the industry, it is beneficial for students to understand what they will demonstrate within the pharmaceutical sector. The adoption of GMP practices at the School Laboratory makes professional training even more complete.

It is noteworthy that routine management ensures that activities produce the expected results, eliminating task rework, making it possible to adapt processes to current regulations and scale the number of people needed to meet the objectives of the areas, reducing work overload and operating costs.

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Declaration of Interest

The authors declare no competing interest.

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Elaine Ribeiro Forgoza *(Corresponding author)*	Master Candidate in the Professional Postgraduate Program in Management, Research and Development in Pharmaceutical Industry at Institute of Drugs Technology – Farmanguinhos, Oswaldo Cruz Foundation – Fiocruz. Rua Sizenando Nabuco, 100 – Manguinhos, CEP 21.041-250, Brazil. E-mail: elainerforgoza@gmail.com ORCID: https://orcid.org/0000-0002-2623-0379
Jorge Magalhães	PhD, Researcher in Public Health, Oswaldo Cruz Foundation/FIOCRUZ, Farmanguinhos, Rua Sizenando Nabuco, 100 – Manguinhos, CEP 21.041-250, Brazil. Global Health and Tropical Medicine, GHTM, Institute of Hygiene and Tropical Medicine, IHMT, NOVA University Lisbon – UNL, Portugal. E-mail: jorge.magalhaes@fiocruz.br ORCID ID: https://orcid.org/0000-0003-2219-5446