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Presentation of a model of the standard operating procedures according to ANVISA's resolution RDC NO. 275 used in a pasta industry

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ABSTRACT
With the advanced growth and use of technology in the food industry, it has become essential to create a competitive edge in companies by improving product quality, so that this determines which products will remain on the market. According to Slack et al. (2002), the awareness that high quality goods and services allow an organization to have a considerable competitive advantage is growing. Therefore, providing safe quality products and/or services is essential for the survival of organizations. Food handling must be managed and controlled. If this control does not occur, contamination can be triggered, which affects food safety.

Keywords: Operating procedures, ANVISA, Pasta.

INTRODUCTION

With the advanced growth and use of technologies in the food industry, it is essential to create a competitive advantage in companies by improving the quality of products, so that this determines which ones will remain in the market. According to Slack et al. (2002), there is a growing awareness that high-quality goods and services enable an organization to present a considerable competitive advantage. Therefore, providing products and/or services of safe quality is essential for the survival of organizations. Food handling must be managed and controlled. If this control does not occur, contamination can be triggered, which affects food safety.

The purchase of healthy food is a consumer right and a duty of the food industries. Health authorities have the duty to draft and enforce laws to ensure the health of the population. Providing food that is not harmful to health is actually very difficult, and failure to comply with it can cause serious infections, affecting the consumer, causing everything from simple intestinal discomfort to neurological disorders and death. Bacteria, fungi, protozoa and viruses are the main groups of microorganisms that cause eating disorders and due to their diversity and pathogenicity, bacteria are by far the most important group (Miranda and Barreto, 2012). To prevent this from occurring, Good Manufacturing Practices (GMP) must be adopted from the receipt of raw materials, during the production process, until their arrival at the consumer. In this way, the implementation of Good Manufacturing Practices is a fundamental

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instrument for companies linked to the food sector to achieve excellence. Also, it is very important that all controls carried out, both process, hygiene, inspections, are documented and archived, for possible later references.

In order to protect consumers against the ingestion of foods that are harmful to health, countries have been seeking better organizational methods and the instrumentalization of public health actions throughout history. Sanitary surveillance has become more comprehensive, effective and flexible, facilitating its implementation through technical standards that follow the scientific and technological evolution in the food production and manufacturing sector (MIGUEL et al., 2000).

This project was developed in a food production unit, located in Maracanaú - Ceará. The main objective was to present the model of Standard Operating Procedures (SOPs) to comply with Resolution RDC No. 275, of October 21, 2002 of ANVISA (National Health Surveillance Agency), which provides for the Technical Regulation of Standard Operating Procedures applied to food producing/processing establishments.

To meet the requirements of RDC No. 275, the proposed methodology is classified into 8 SOPs: Cleaning of facilities, equipment, furniture and utensils; Control of water potability; Hygiene and health of handlers; Waste management; Preventive maintenance and calibration of equipment; Integrated control of vectors and urban pests; Selection of raw materials, ingredients and packaging; Food collection program.

It was chosen to study this specific feeding unit due to the ease of data collection and the fact that the author is already part of the company, following all the documentation and implementation of the SOPs since the beginning of this activity in the company. The work adopts the case study as a methodological approach. In order to fulfill its objectives, the work establishes the theoretical framework, methodological procedures adopted, empirical results and, finally, its conclusions.

OBJECTIVE

This work will aim to describe the development of SOPs in a pasta company, according to current legislation, adapting it according to its working conditions and structure, aiming at continuous improvement in the quality of the products produced, adapting to the current legislation and using them as a tool to reduce errors. It will present the methodology used to put it into practice and its importance for the development of the company, ensuring its continuous improvement. The results will be expressed through the presentation of the model of the SOPs applied in the company, will also express the status of the company before and after the implementation of the SOPs, and will show the use of the SOP as a tool to reduce errors and improve quality.

METHODOLOGY

The studied company produces pasta, such as: baked breads, frozen breads and pastry dough. It is located in the municipality of Maracanaú, state of Ceará. The company has a manufacturing unit of 990 m², 40 employees and is present in the state market and some states in the Northeast.

Before starting the preparation of the SOPs, the work began with an inspection of the company, making a more detailed diagnosis of the situation it was in. The following were verified: operation of production, handling of products, structure, stock of raw materials and stock of finished product, equipment used, physical state of employees. The routine of receiving raw materials, production and shipping was monitored. Issues were also investigated on: hygiene of facilities, control of vectors and urban pests, water supply, waste management, practices of food handlers, preparation, transportation and distribution of food, documentation and records.

After all the data collection, the second stage of the work began, where the GMP checklist was applied to the company, according to the legislation RDC No. 275, ANVISA, in order to document the activities of each process and develop the standard operating procedures and the opportunities for improvement were verified.

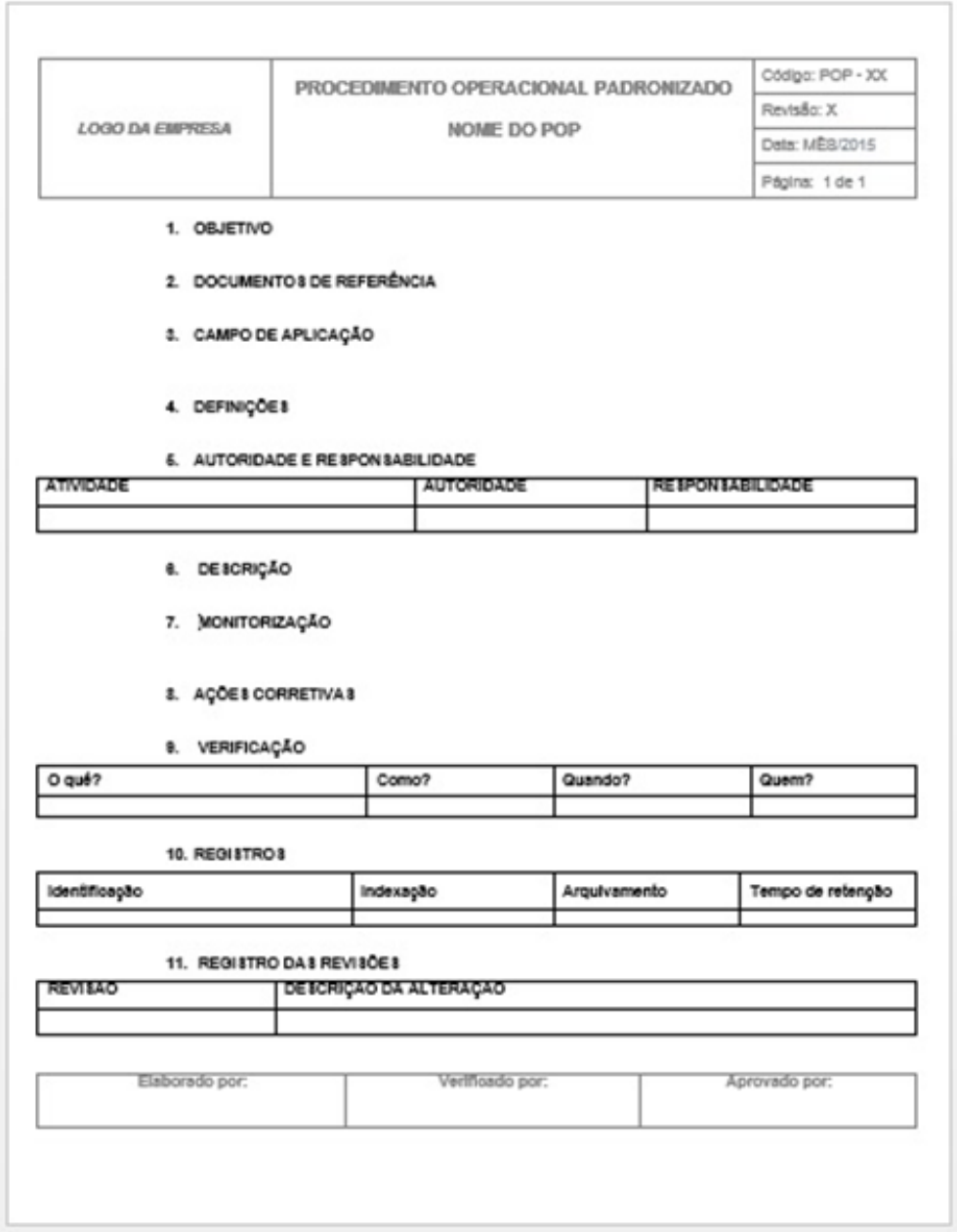
This study was characterized by the intervention carried out in the company's production sectors. The SOPs were created in accordance with RDC No. 275/2002, RDC No. 216/2004, RDC No. 52/2009, RDC No. 18/2000, Ordinance No. 326/1997, Ordinance No. 1428/1993 and DECREE-LAW No. 986/1969.

The use of standardization in processes makes the proper fulfillment of the activities performed in an organization, in such a way that each person is able to take responsibility for the results of their own work. The most appropriate way to obtain effective performance of operational functions is through the construction of standard operating procedures (SOP), an important component in any organization that seeks efficiency in its processes and collaborates to satisfy customer requirements and reduce costs of losses and rejects of processes (VARGAS et al., 2008).

For the company studied, 8 SOPs were elaborated, choosing the name for each one according to the current legislation and easily accessible to employees.

Each SOP has its own configuration, as shown in figure 1, and consists of eleven items, which are explained below.

Figure 1 - SOP model.



LOGO DA EMPRESA	PROCEDIMENTO OPERACIONAL PADRONIZADO NOME DO POP	Código: POP - XX Revisão: X Data: MÊS/2015 Página: 1 de 1

1. OBJETIVO
2. DOCUMENTO S DE REFERÊNCIA
3. CAMPO DE APLICAÇÃO
4. DEFINIÇÕE S
5. AUTORIDADE E RESPONSABILIDADE

ATIVIDADE	AUTORIDADE	RESPONSABILIDADE

6. DESCRIÇÃO
7. MONITORIZAÇÃO
8. AÇÕES CORRETIVAS
9. VERIFICAÇÃO

O quê?	Como?	Quando?	Quem?

10. REGISTROS

Identificação	Indexação	Arquivamento	Tempo de retenção

11. REGISTRO DAS REVISÕES

REVISÃO	DESCRIÇÃO DA ALTERAÇÃO

Elaborado por:	Verificado por:	Aprovado por:

Source: Personal archive, 2015.

Field 1 of the SOP describes the objective of the SOP, showing what is intended to be achieved when the SOP is carried out;

Field 2 comprises the reference documents, which cite the legislation that was used to prepare that document;

In field 3, the field of application is defined, i.e., it defines where that SOP will be used, for which environment or sector it is destined;

In field 4, the definitions are presented, in which the meaning of specific words used in the SOP is presented, thus facilitating the understanding of those who will apply it;

Field 5 defines authority and responsibility, and a table was prepared with three items: activity, authority and responsibility, which define who the perpetrators are and the competencies to charge and supervise the performance of that procedure;

Field 6 shows the description of the SOP, which explains step by step how the procedure should be performed;

Field 7 contemplates monitoring, which will tell how the monitoring of the performance of that procedure will be carried out, how often it will be recorded and after verification defines where it will be noted in the registration document;

Field 8 shows the corrective actions, if the procedure does not come out in the pattern, in this item it is described in detail how to do it until the standard is reached;

Field 9 is the check. A spreadsheet was prepared where we have: what?; how?; when?; And who?. It describes what has to be checked, how it is done, mentions how often it should be checked and who should do the checking;

Field 10 shows the records, and a spreadsheet was also made with: identification; indexing; archiving and retention time. Identifies what the record is, what its classification is, where it is filed and how long it will be retained in the company;

Field 11 shows the record of revisions, if there is a change in the procedure, it must be recorded in this item which change was made.

Finally, on each page of the procedures there is a footer where it is specified who prepared the SOP, who verified the preparation and who approved it.

The work endows the case study as a methodological approach, which, according to Cauchick Miguel (2010) is an empirical work that investigates a given phenomenon within a real contemporary context through in-depth analysis of one or more objects of analysis (cases), enabling broad and detailed knowledge about the phenomenon, even allowing the generation of theory. The data, predominantly qualitative, were interpreted, seeking divergence and convergence, confronting the current theory with the practical information collected in the company, through which the case was constructed, as reported below.

DEVELOPMENT

Next, a theoretical foundation is presented regarding the Standard Operating Procedure and Good Manufacturing Practices (GMP), in order to establish the view of the literature so that, later, the analyses can be carried out in comparison with the fieldwork observed in the object of analysis.

STANDARD OPERATING PROCEDURE (SOP) CONCEPT

The SOP is a relevant management tool for the assurance of the quality of the services provided and according to Lousana (2005, p. 6), an SOP can be described as: "A procedure that seeks to ensure that a process, regardless of the area, can always be carried out in the same way, allowing the verification of each of its stages. It must be written in detail to obtain uniformity of an operational routine, whether in production or in the provision of services."

Standard Operating Procedure (SOP) is a standardized scheme, that is, it is a detailed roadmap of all the operations required for the execution of an activity. Its first objective is to make people who perform the same task do it in the same way, that is, by standardizing the process or activity (LIMA, 2005).

The Standard Operating Procedure (SOP) is the objectively written procedure that establishes sequential instructions for carrying out routine and specific operations in the production, storage and transportation of food. This Procedure may present other nomenclatures as long as it complies with the content established in RDC No. 275. The SOPs can be presented as an annex to the establishment's Good Manufacturing Practices Manual (BRASIL, 2002). Colenghi (2007) stated that the purpose of the Standard Operating Procedures is to ensure, through standardization, the outputs expected by each process performed. Standardization is a method that allows you to reduce the variability of a process.

Gonçalves (2000, p. 1) said, "the definition of basic processes is essential for some strategies to improve the functioning of companies, since groups of resources will be allocated to them, both for execution and management". Using the concept of process, there is a formidable level of analysis and enables a more integrated and comprehensive view of managerial behavior.

According to Chen et al. (2003), among the key processes of the quality system are: management responsibility, resource management, process management, and measurement, analysis, and improvement. According to Gonçalves (2000), it is essential to recognize the process as the common way of performing work to determine the basic form of organization of people and other company resources. Process is a fundamental definition in the design of the means by which a company intends to produce and deliver its products and services to your customers. Gonçalves (2000) stated that several of the processes in organizations are repetitive and involve, in their entirety, most of the company's people.

According to Campos (1994), "mastery of the work process is only possible through standardization, which is the same thing as saying: master the patterns of the factors and you will obtain the expected result". In this author's conception, the standardization of the work process, especially with the sufficiently known routine, is of paramount importance. Thus, process standardization is a technique that aims to reduce the variability of processes, without affecting their flexibility, that is, products and services must constantly meet customer expectations and at the lowest possible cost.

GOOD MANUFACTURING PRACTICES (GMP) CONCEPT

According to the National Health Surveillance Agency (ANVISA), Good Manufacturing Practices (GMP) refer to a set of procedures that must be followed by food industries in order to ensure sanitary quality and compliance of food products with technical regulations. These measures cover from the arrival of the raw material, during the process, until its arrival at the final consumer. The federal sanitary legislation regulates these measures in general, applicable to all types of food industry and specific, aimed at industries that process certain categories of food (BRASIL, 2002).

LEGISLATION

The following are reports on some of the laws in force in Brazil, which are established through Ordinances and Resolutions of the National Health Surveillance Agency (ANVISA). They establish the general requirements on hygienic-sanitary conditions and Good Manufacturing Practices for food producing/processing establishments.

RDC No. 216, of September 15, 2004

Provides for the technical regulation of Good Handling Practices for food services.

RDC No. 275, of October 21, 2002

Technical Regulation of Standard Operating Procedures applied to food producing/processing establishments. It is a complementary normative act to Ordinance No. 326, introduces the continuous control of GMP and the Standard Operating Procedures. It has a GMP checklist in food producing/processing establishments. This checklist can be grouped according to your application.

RDC No. 52, of October 22, 2009

Provides for general rules for the operation of companies specialized in the provision of vector and urban pest control services and makes other provisions.

RDC No. 18, of February 29, 2000

This standard aims to establish guidelines, definitions and general conditions for the operation of Specialized Companies controlling urban pests, aiming at compliance with Good Operational Practices, in order to ensure the quality and safety of the service provided and minimize the impact on the environment, the health of the consumer and the applicator.

Ordinance No. 326, of July 30, 1997

Establishes the general requirements on hygienic-sanitary conditions and Good Manufacturing Practices for food producing/processing establishments.

Ordinance No. 1428 of November 26, 1993

It presents guidelines for the establishment of Good Practices for production and service provision in the food area.

DECREE-LAW No. 986, of October 21, 1969

It establishes basic rules on food.

PRESENTATION AND DISCUSSION OF RESULTS

The investment for the implementation of the SOPs in the establishment was considerably high in relation to the size of the company. However, the management was concerned with meeting the requirements of the resolution, being aware that only with investments in the area of quality, it will be possible to survive and grow in the market, since it is highly competitive (FIOCCHI and MIGUEL, 2003).

The results obtained with the elaboration of the SOPs ensured the standardization of the procedures according to the legislation RDC No. 275, ANVISA.

The following are the non-conformities before the company adopts the use of SOPs and the importance of implementing them. Improvements and error reductions from the use of SOPs are also presented.

SOP 01 - CLEANING OF FACILITIES, EQUIPMENT, FURNITURE AND UTENSILS

In the first SOP on hygiene and facilities, equipment, furniture and utensils, the company presented many non-conformities before having the SOP, which were: it did not have a deposit for cleaning material (DML); there was no record of preventive/corrective maintenance of the equipment; There was only one men's bathroom, which was inside the production; there were no identified and pedal-operated trash cans; there was no weighing room, no utensil; freezers and refrigerators were not identified; there was no signage in the company; damaged aluminum screens were used and difficult to sanitize; the pallets and pallets were made of wood; walls, floors, and ceilings were deteriorated and paint was in disagreement; drains and windows were unprotected; There was no cafeteria for the employees and only one hand-washing sink was identified, not equipped with disposable paper, neutral soap and an identified trash can.

With the elaboration of SOP 01 and its implementation, all non-conformities were met according to the current legislation, for this it was also necessary to change the layout of the company.

SOP 02 - WATER POTABILITY CONTROL

Prior to the execution of POP 02, the company did not prove potability of the water, because it did not have semiannual laboratory reports to prove the good quality of the water and there were no records of cleaning of the water tank and cleaning of the filters of the drinking fountains.

With the implementation of POP 02, the water tank now has a lid and there are no leakage problems. The water tank is washed and disinfected by a third-party company, according to Work Instruction (IT): "Cleaning of water tanks". The company is responsible for the maintenance of the water tank. The company has three filters for the water used in production. After the water tank is cleaned, the water is collected for laboratory analysis by a specialized and suitable laboratory, and the documentation described below is requested at the time of contracting and whenever necessary:

- Copy of the updated Health Registry;
- Copy of the Business License;
- Copy of the Technical Responsibility Communication – CRQ.

The potability of the water is attested by microbiological and physicochemical analysis every six months.

SOP 03 - HYGIENE AND HEALTH OF HANDLERS

Regarding the handlers, it was verified that there were no posters in the company to guide them. It was observed that the handlers spoke unnecessarily and hummed during the performance of the activities. Persons employed in food handling activities shall avoid behaviors that can contaminate food, for example, smoking, spitting, chewing, sneezing or coughing (ABERC, 2003). There was no control and record of the periodic examinations of the employees and they did not use personal protective equipment (PPE).

After the elaboration of SOP 03, educational posters related to "how to wash hands" were placed and maintained in all toilets and washbasins; Posters relating to personal hygiene conduct are placed and maintained in the processing areas; The handling room has a hand basin stocked with liquid soap, hand sanitizer, paper towel and trash can. Sanitary facilities (toilets, sinks, showers) are working. The waste collectors have a lid, pedal operation and are sanitized and filled daily with plastic bags.

Handlers wear clean work clothes (pants, blouse, apron, boots and cap) and are instructed to sanitize them; handlers are instructed on how to remove adornments (watches, bracelets, cords, earrings, etc.); handlers do not use perfumes that may impart odor to food; Employees are instructed to wash their hands. Handlers are instructed to proceed with hand and forearm hygiene, according to IT – "Hand hygiene".

All handlers underwent medical examinations upon admission and annually. Handlers who present any alterations will be referred to a doctor for appropriate action. If the handler has any health problems, he or she is immediately removed from his or her duties.

All employees are trained to carry out their activities with the necessary hygienic care, through training carried out in the establishment itself.

SOP 04 - WASTE MANAGEMENT

The company did not prove the existence of an adequate place to remove the garbage, there was no selection of waste, it did not have waste collectors activated without manual contact and there was an accumulation of garbage in the vicinity.

After the implementation of SOP 04, the solid waste is placed in appropriate bags; the containers are equipped with pedal actuation and identified; Food and packaging waste is removed daily from the sectors and stored in an appropriate place for garbage collection. Waste collectors are sanitized in accordance with the Work Instruction: •"Sanitization of waste containers". The employee responsible for this activity is trained.

SOP 05 - PREVENTIVE MAINTENANCE AND CALIBRATION OF EQUIPMENT

There was no record of the maintenance performed on the equipment in the company. The scales did not undergo periodic calibrations.

With the application of SOP 05, the calibration of the scale is performed by a third-party company and checked by IPEM/Inmetro. This is carried out annually and in the occurrence of changes perceived by employees.

The equipment is inspected by the technician of a technical assistance company, outsourced every six months and in the occurrence of changes perceived by the employees. After the equipment is maintained, it is cleaned, and everything is noted in the registration documents.

SOP 06 - INTEGRATED PEST CONTROL

The company did not have springs and barriers that prevented vectors from entering the doors and windows. There were no records of periodic disinfestation. There were unprotected drains.

With the implementation of SOP 06, the company's management assigns one of the team members to evaluate the conditions of the drains, pipes and dumpsters. Food and packaging waste is removed daily from the sectors and stored in an appropriate place for garbage collection. The waste collectors and the storage area are sanitized daily according to the SOP of sanitization of equipment, furniture and utensils. Environmental conditions that may facilitate the development and proliferation of pests are evaluated.

A company was hired to carry out the disinfestation service every three months or when necessary. The contractor provides a document that confirms that all compounds used comply with the current law for use in food establishments and a copy of the updated sanitary registration of the executing company. The company has a certificate provided by the company hired to carry out integrated pest control, guaranteeing the validity of the service for 3 (three) months. The contracted company presents a Service Order in all visits made to the establishment with the details of all activities carried out.

The packaging of the products is observed, avoiding receiving food infested with pests (weevils, cockroaches, ants, etc.).

The chemical treatment is applied safely, taking into account the handling of food. All utensils and deposits are removed from the cabinets/shelves and placed in another area protected/covered.

It is not allowed to leave materials positioned in front of places that must be treated; screens, storage rooms and utensils are protected; Countertops are left unoccupied. The outsourced company's professional is informed about the existence of hollow spaces, walls, ceilings, floors, table bases. These spots can serve as a shelter for pests. Access to all areas is permitted.

SOP 07 - SELECTION OF RAW MATERIAL, INGREDIENT AND PACKAGING

When the raw material arrived at the company, there was no selection and there were no records of receipt control.

After the implementation of SOP 07, the quality control (environment and handlers) of the supplier is recognized; the temperature of the transport is checked according to the product received; During the reception of the products, the following sensory changes (appearance, colour, odour, taste and texture) are observed; expiration date and manufacture; intact and clean product packaging; hygienic conditions of the delivery person; labeling containing date of manufacture and expiration, registration number of the tax agency, CGC, storage conditions and quantity.

Hygiene conditions, storage of the transport; it is checked that they are well protected, without risk of suffering contamination of any kind; The integrity of the packaging (holes and dirt) is observed.

SOP 08 - FOOD COLLECTION

When there was a complaint about a product of the company, only the product was refunded, without any record or investigation of the problem. The company's production has always been recorded in batches, through electronic spreadsheets.

With the implementation of SOP 08, after a complaint, internal traceability is made: the batch is determined by the date of manufacture and the name of the product according to the daily production. The identification of this is carried out through the production report and electronic system. The possible

consequences and the need to recall the products from the market are verified. With the identification of the batch, it is checked where the distribution of the products was made through route loading.

After this, external traceability is made where it is identified through the electronic system, where the sales control counts. The manager informs the sellers about possible failures in production and that the collection must be made at the market. The products are identified and evaluated according to the failure that occurred in the process, and after the failures are evaluated, the products are placed in a separate and identified location, while their destination is determined.

FINAL THOUGHTS

With the work performed, it is possible to verify the importance of implementing Good Manufacturing Practices in a food producing company. The implementation of GMP is the basis of quality control in a food company, it is a continuous process, which must always have adaptations and innovations that seek the continuous improvement of the products and the establishment.

The implementation of traceability occurs in full currently, as the company records the date of receipt, manufacture, expiration and unit batch of the raw materials received, and it is possible to verify in the receipt record the possible raw materials used on a given production day.

The company is able to have a food collection program, which is an item required by ANVISA and of paramount importance in the food industry.

Employees received GMP training during the work, however, it is of fundamental importance that these trainings are repeated, as a way of remembering the importance that GMP represents and the basic standards that must be followed. It is also essential that if a new employee is hired, he does not start his practices in the company, without being able to exercise them. This also applies to SOPs, when they are included in their daily activities.

The method used for the implementation of the SOPs was practical and functional, allowing non-conformities to be quickly identified and regularized in an organized and objective manner. The result was satisfactory, as the rate of non-compliance dropped significantly. A new vision of the meaning of quality in a food industry was built, and employees and management were encouraged to continue working for continuous improvement.

It was found that SOPs bring benefits such as standardization of activities and reduction of errors, compliance with current legislation, production of safe and quality food, a more pleasant, clean and safe work environment, improvement of the company's image and commercial advantages. It is concluded that the implementation of the SOPs in this company was successfully executed, achieving the proposed objectives, observing how complex the full implementation of the GMP is and that there is a need for constant improvements, using quality tools.

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