In order to guarantee the proper quality of medical products and medicines, the mandatory application of Good Manufacturing Practices (GMP) norms in almost all countries is provided by law. Given the importance of nutritional provision of human portrebs in emergencies, the use of GMP is also relevant in the production of food products for special medical purposes. The object of research is the methodological base, approaches, and norms of GMP application in the manufacture of this product category. It is determined that the implementation of these practices is ensured mainly through measures for raw materials, equipment, personnel, premises, compliance with hygienic requirements, journaling, internal control, response to complaints, monitoring, traceability, product recall. It is established that the basic principle of GMP application is the production of products that will meet the purpose and provisions of the registration dossier.

At the same time, ensuring product quality is a comprehensive concept of ensuring compliance with properties, combining organizational measures at all stages. This activity should be carried out taking into account risk-oriented thinking based on the control of raw materials, packaging, testing in the production and release of goods to the declared characteristics, ensuring high competence of personnel, process and analytical validation. Recommendations on a set of measures aimed at introducing good manufacturing practices at enterprises producing food products for special medical purposes have been compiled and presented. The essence of these recommendations is to identify technological processes, monitor their implementation, provide the necessary resources and measures, establish the process of documenting actions, validation at all stages, including self-inspection

Keywords: good manufacturing practices, good quality, food products for special medical purposes

UDC 664:615.012.014
DOI: 10.15587/1729-4061.2023.279371

APPLICATION OF GOOD MANUFACTURING PRACTICES IN THE PRODUCTION OF FOOD PRODUCTS FOR SPECIAL MEDICAL PURPOSES

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Received date 06.03.2023
Accepted date 10.05.2023
Published date 30.06.2023

How to Cite: *Prytulska, N., Antiushko, D., Osyka, V., Sienohonova, L., Volodavchyk, V., Sienohonova, H. (2023). Application of good manufacturing practices in the production of food products for special medical purposes. Eastern-European Journal of Enterprise Technologies, 3 (13 (123)), 52–58. doi: https://doi.org/10.15587/1729-4061.2023.279371*

1. Introduction

Universally recognized both at the global and national levels are the rights of consumers to safety and proper quality of food products [1–3]. They acquire especially relevant importance for people in emergencies when the body is characterized by certain features of metabolic processes. With increased psycho-emotional, physical stress, diseases and injuries, including somatic, during the rehabilitation period, the human body needs a special, functionally oriented, nutritional provision, in particular high protein content [4–6]. In view of this, the consumption of food products for special medical purposes, specially designed and produced for feeding as prescribed by a doctor, has become widespread in modern nutritional practice [4, 5]. One of the types of food products for special medical purposes are products for enteral nutrition. These products, intended for oral consumption and/or introduction into the gastrointestinal system through a probe, with the help of a specially simulated composition of ingredients in the treatment and rehabilitation can provide correction of impaired metabolism [4, 5].

It is generally recognized that in the production and maintenance of market circulation of food products, it is mandatory to apply procedures based on the principles of the system of analysis of hazards and control at critical points. The need to use Good Manufacturing Practice (GMP) in the manufacture of medicines intended for human consumption (use) and veterinary use is defined by law both in the EU countries [7–9] and Ukraine [10, 11]. It is also important to note that the current regulatory framework does not provide for mandatory appli-

cation of the principles of good manufacturing practice in the production of food products for special medical purposes.

To ensure the proper level of safety, quality, and effectiveness of the functional action of this group of special food products, the application of GMP standards is promising. At the same time, it is appropriate to note that the implementation of the rules of good manufacturing practice in the production of the studied products, especially at the national level of Eastern European countries, is not widespread, defining the problems of this study. The results of the work will be useful in the practical field since their use by manufacturers of special products will help ensure an adequate level of safety, quality, and risk management and, as a result, increase competitiveness and business reputation. As regards target consumers of these food products, the results of relevant studies, in turn, will improve awareness of the factors ensuring the effectiveness of physiological action for making informed choices in the market.

2. Literature review and problem statement

In [12], approaches to ensuring the production of medicines of the proper level of quality in accordance with GMP standards at the international and national levels are analyzed. This paper also examines recommendations for ensuring the pharmaceutical quality system, the role of qualified personnel, raw materials, equipment, analysis of suppliers' work, ensuring traceability of products, application of risk management. However, the presented results of the study relate mainly to the stipulated legislative and regulatory requirements for the formation and achievement of the required quality of pharmaceutical products, their common and distinctive features are compared.

The authors of work [13] analyzed the role and effectiveness of GMP implementation in the production of physiologically active components of medicinal therapeutic agents. This study pays considerable attention to the importance of proper control in the manufacture of medicines but does not analyze the basic norms of GMP use, principles, and measures aimed at their effective implementation. Also, the importance of using good manufacturing practices in obtaining pharmaceutical products has been investigated in [14], which establishes the need to ensure special conditions, processes of additional verification due to the spread of the pandemic caused by the Covid-19 virus. At the same time, the main attention is focused on measures aimed at preventing the spread of acute coronavirus infection, material on the methodology for implementing processes for ensuring and guaranteeing the proper quality of products is not disclosed.

Study [15] analyzed the importance of introducing good manufacturing practices in the manufacture of vaccines and antibodies, in particular, determined the importance of quality control, compliance with production conditions, personnel, raw materials. However, the organizational aspects of GMP application, their relationship with other management systems are not considered, recommendations for optimizing the implementation of certain norms are not presented.

In [16], the importance of comprehensive compliance with the rules of good manufacturing practices for obtaining highly effective medicines is analyzed. The requirements provided for the production process in accordance with GMP rules, features of application, verification process by the relevant regulatory authorities, prospects for sales of pharmaceutical products manufactured in accordance with these standards are also investigated. At the same time, the presented data are focused on the requirements for the production of phage therapy drugs, the use of necessary raw materials, the manufacturing process, packaging, control of their functional action of active components.

Study [17] analyzed the role and importance of applying good manufacturing practices in the process of obtaining drugs for cell therapy, conducting laboratory studies of their clinical effectiveness, increasing productivity. However, the focus of the work is on creating optimal conditions for clinical trials while the methodological aspects of GMP application in production have not been analyzed.

In [18], approaches to the implementation of GMP in the field of pharmaceutical research are investigated, in particular the concept of quality assurance at all stages of the product life cycle (QbD), starting from the moment of its design. The authors have established that it is based on risk-oriented thinking, in particular when planning experiments and studying the technology of foreseen processes, identifying the main dangers that may arise, actions to eliminate them. However, the application of this approach should be comprehensive, taking into account other principles of implementation of good manufacturing practices, which necessitates further detailed analysis of the essence and other fundamental methodological principles of using the GMP concept.

Successful production activities in the market, in particular the presentation of special-purpose goods, which will be characterized by an appropriate level of safety, quality and trust of consumers (patients, medical personnel), necessitates the use of best world practices. One of them is the concept of good manufacturing practices, which will ensure an appropriate level of competitiveness of products, primarily necessary for the formation and preservation of human health. Thus, the application of GMP norms is a universally recognized and necessary trend in the manufacture of medical devices. Taking into account the specifics of use and physiological effects, it is advisable to include food products for special medical purposes to products in the production of which good manufacturing practices should be applied, which will contribute to improving their level of quality. This, in turn, will guarantee the predicted level of envisaged properties, expand the contingent of target consumers of these goods, increase the level of competitiveness and trust in organizations that produce them.

3. The aim and objectives of the study

The aim of this study is to ensure the application of good manufacturing practices in the production of food products for special medical purposes. This will help guarantee the compliance of this category of food products with modern requirements for safety, proper quality and effectiveness of physiological effects on the body of consumers, increasing their level of confidence in these products.

To accomplish the aim, the following tasks have been set:

– to investigate the state, legislative and regulatory support, essence, determine the main aspects and principles of application of good manufacturing practices (GMP);

– to identify the main differences in GMP norms, benefits from application;

– to develop recommendations for the implementation of GMP at enterprises producing food products for special medical purposes.

4. The study materials and methods

The object of the study was Good Manufacturing Practices (GMP).

The hypothesis of the study assumed that the application of Good Manufacturing Practices (GMP) in the production of food products for special medical purposes could ensure and guarantee their properly high level of quality.

As a methodological basis for scientific research, data on the use of GMP norms by international and Ukrainian manufacturing enterprises, current legislative and regulatory support in this area, guidelines for optimizing the implementation of the studied activities were used. Open information and reference data, results of professional research, information on the experience gained and advantages achieved, positions of leading specialists and practitioners on the studied issue were also applied.

For the implementation of scientific research, methods of scientific analysis, holistic approach, comparison, induction, deduction, research isolation, systematization, modeling, optimization were used.

5. Results of research into the methodological basis for the application of good manufacturing practices in the production of food products for special medical purposes

5. 1. Results of research on the status, legislative, and regulatory framework and fundamental principles of GMP use

Based on the results of the analysis of sources [13, 14, 17, 19, 20], it is determined that the application of good manufacturing practices is widespread at manufacturing enterprises, especially enterprises producing pharmaceutical products, cosmetics, some food industry enterprises. According to international legislation [6, 7], it is determined that in order to guarantee the proper quality of medical devices and medicines, enterprises that produce them must provide a quality system based on good manufacturing practice. The norms of Ukrainian regulatory documents [9, 10] also provide for the need for application at enterprises manufacturing pharmaceutical products. It is appropriate to note that according to the Order of the Ministry of Health of Ukraine No. 391 as of 30.10.2002 [10], it is mandatory to confirm the compliance of the conditions of manufacturing of medicinal products with the requirements of good manufacturing practice. In accordance with the norms defined in Ukraine [10], this activity is carried out by the State Service of Ukraine on Medicines.

It has been established that it is common to introduce good manufacturing practice not only by enterprises producing medicines and cosmetics but also by those that produce dietary supplements, baby food, special food products.

The essence of good manufacturing practices involves the constant and strict use of the requirements stipulated by the regulatory framework [11, 19, 21] that must be met by the manufacturer. According to its content and stipulated norms, GMP represents not only recommendations for the production of certain types of products but also fairly clear and comprehensive requirements to ensure consumer confidence. In particular, the stipulated rules relate to raw materials, production equipment, personnel, their competence, premises, compliance with hygienic requirements, process documentation, quality management, internal control, response to complaints, monitoring and recall of finished products. It is determined that the implementation of GMP recommendations should be constantly updated through a constant review of requirements in connection with the development of new information and data. This, in turn, in some cases necessitates the application of additional actions, equivalent to the name "current good manufacturing practice (cGMP)" [22]. It should be noted that changes and clarifications that should be made to optimize activities and ensure stable results of work are designed to ensure a consistently high level of quality, to guarantee consumers the necessary level of satisfaction of needs.

Analysis of GMP application rules [11, 19, 21] shows that the basic principle of this activity is the production of products that will meet the purpose, provisions of the registration dossier, exclude the risk associated with insufficient safety, quality, effectiveness. The provisions provided for in [11, 19, 21] also stipulate that production activities and the GMP control measures used must ensure a guaranteed level of quality, compliance with the purpose, requirements of the trade license, product specification.

It has been determined that the main means of realizing the primary goal of GMP application, defined as ensuring consistently proper quality, is the involvement of all personnel of the manufacturing organization, certain employees of suppliers, distributors.

The analysis of information [11, 18-21] shows that for this purpose the organization should develop and ensure the functioning of a comprehensive, appropriately documented quality system based on production activities and risk management. According to GMP norms [11, 19, 21], the necessary conditions for the full functioning of the quality system are the provision of professional personnel, territory and premises, necessary equipment, technological resources. Thus, one of the most effective means of achieving quality assurance monitoring defined by GMP rules, proper control of its effectiveness is conducting internal audits (audits of the first party). It is important to note that according to certain practice [11, 12, 19, 21], the functions of a person authorized to issue a permit for the sale of manufactured goods are envisaged. It is also determined that the legal responsibility for ensuring the quality of products manufactured in accordance with GMP norms in the organization is borne by the owner of the license for the manufacture of the provided products and the authorized person.

It is investigated that according to the principles of GMP [11, 12, 15, 19, 21], ensuring product quality is a comprehensive concept of guaranteeing appropriate quality, combining organizational measures at all stages, from development to distribution. The established provisions [11, 19, 21] stipulate that in order to confirm the quality, the characteristics declared in the registration dossier should be monitored for the conformity of raw materials, packaging, tests in the production and release of goods. Advanced in this aspect is the methodology of Space Design, the essence of which is to ensure the quality of the final product by controlling at the intermediate stages of the production process, its parameters, starting from the design stage [18, 22]. It should be noted that to apply this approach, it is necessary to carry out process-analytical validation, which requires highly qualified employees. Also a significant advantage of use is the absence of the need to check manufactured products before referral for implementation.

The requirements for the implementation of GMP [11–15, 19, 21, 23] provide for the standardization of production

processes, their regular review and improvement to take into account best practices, to guarantee the proper level of product quality. At the same time, the need for continuous analysis of procedures for ensuring product quality to track the occurrence of deviations and apply measures to eliminate them has been determined. It is envisaged that the introduction of GMP requires due attention from top management, in particular regarding the use of necessary premises and equipment, raw materials, packaging resources, attracting highly skilled workers, increasing their competence, documenting processes [11, 19, 21]. It should be noted that decision-making based on actually confirmed data and risk management is especially important to ensure compliance with the level of quality in accordance with GMP standards [11, 15, 19, 21]. Thus, it should be systematic, based on a risk-oriented approach, compliance with actions, their formalism and documentation of factors that may pose a certain threat to the quality of manufactured products, ensure the possibility of their recall.

Based on the results of the data analysis [10–14, 19, 21, 22], it was found that the basic principles of implementation and application of GMP are:

– ensuring the availability of standard operating procedures and instructions for establishing controlled and sustainable performance;

– documented compliance with procedures and instructions;

– fast and accurate documentation of processes to ensure compliance and traceability;

– validation of the systems and means used to confirm their functionality and effectiveness;

– proper identification and design of the systems and process equipment used;

– proper maintenance and observance of premises, equipment and devices, their calibration;

– determination, development, and confirmation of professional competence of personnel;

– protection of products from contamination;

– design and quality control of products;

– regular internal and external audits to ensure compliance.

5. 2. Research results of the main differences between GMP norms and advantages of their application

Based on the analysis of the experience of GMP application, it was found that the use of these standards provides an increased level of safety and quality of products compared to the most widely used standards (Table 1) [24, 25]. First of all, it concerns the content of regulatory documents ISO 22000, 9001.

It is found that the basic difference between GMP is explained by more thorough quality control of products at all stages of production, circulation, in particular by checking intermediate products, parameters of the production process, while ISO standards provide for selective control.

In the course of analyzing the content of the provisions of GMP [11, 12, 15, 19, 21], it is determined that due to the need to ensure stable conditions of activity, sustainable quality of products, the idea of continuous improvement of the production process of products, expansion of its range is not provided. This statement concerns both ensuring the same properties of products both within a certain batch produced and, ideally, all products of this type produced by the organization as a whole. At the same time, it has been established that, despite this, GMP standards determine the possibility of making the necessary changes that will contribute to progress, the introduction of new methods and methods of production [9, 10].

Table 1

Characteristics of the main differences between GMP norms in comparison with the provisions of ISO 22000, 9001 standards

Distinctive feature	GMP	ISO 22000, 9001 standards
Level of control	Continuous at all stages of production and circulation	Selective, carried out with a certain frequency
The possibility of sustainable improvement of the production process	Not provided	Identified to ensure systemic development
Spheres of application	Pharmaceutical and other vital products	All products and services
Nature of use	Mandatory	Voluntary
Development and improvement period	Since 1967	Since the 1980s

It is determined that another distinctive feature of the envisaged GMP norms is the scope for which they are provided in the first place. Thus, initially these requirements were developed and focused specifically on pharmaceutical products, for consumers (patients and medical personnel) whose level of compliance with its characteristics is vital.

It is investigated that an important difference between the GMP requirements is mainly the mandatory nature of their application, while standards, in particular ISO, are voluntary for application, recommended.

It is analyzed that due to a longer period of creation, improvement of GMP (adopted and updated since 1967, while ISO standards for management systems – since the 1980s) [26] are characterized by a higher level of content, detail.

As a result of the analysis, it is also investigated that the main advantages of GMP application are ensuring a consistently proper level of product quality, reducing material costs for monitoring compliance with the provided properties. As a result, the costs of recalling, processing, and disposal of defective products, and resolving consumer disputes will be minimized. This, as a result, will increase the competitiveness of the products manufactured by the organization, the formation of its bona fide and socially responsible reputation and business image.

5. 3. Recommendations for GMP implementation at target enterprises

Based on the results of the study of methodological bases of application of good manufacturing practices in the production of food products for special medical purposes, systemic recommendations for the implementation of GMP standards by relevant organizations have been developed and presented. They can be represented in the following form:

– describe all technological processes used within the organization for the production of products, provide for control measures over them;

– validate certain processes;

– within the framework of certain processes to provide the necessary premises (including to provide for their zoning), equipment;

– to provide staff training, employee awareness of the GMP system, carry out measures to monitor compliance with the prescribed measures and regular staff development;

– to control the level of quality, sanitary and hygienic condition of raw materials, packaging, auxiliary materials (primarily at the stage of acceptance), finished products, proper handling, storage (especially with regard to glass and plastic) and transportation;

– to establish and work out a clear system of personal hygiene of personnel, their provision with overalls and other necessary means, the proper condition of the premises and equipment used;

– to provide industrial premises with the necessary amount of clean air and water;

– to maintain control of flows of raw materials, semi-finished products, finished products, workers to prevent cross-contamination;

– to record and document work at all stages;

– to ensure constant monitoring at all stages and self-inspection of work results.

6. Discussion of results of investigating the status, principles, differences, advantages of GMP application

Based on the results of the analysis of the current state of implementation of GMP norms, it is investigated that this experience is quite common. Good manufacturing practices are used primarily in organizations specializing in the production of medical, medical, cosmetics [13–18], due to legislative requirements, the need to ensure confidence, trust of target consumers (patients, medical personnel, society). The practice of applying these rules by some food industry enterprises has been established, which, in turn, is explained by the possibility of increasing the norms used to manage the safety and quality of food products, the level of ensuring competitiveness, social responsibility. It is determined that, first of all, this result is ensured by continuous control of manufactured products in the process of all stages of its production.

The peculiarity of the study is to analyze and provide an understanding of GMP norms, taking into account the specifics of the activities of organizations producing food products for special medical purposes. Disclosure of the specifics of the application of these practices in the manufacture of these products, the development of specially adapted recommendations for implementation will significantly contribute to ensuring a guaranteed high level of product quality, competitiveness and profitability of these enterprises.

It is established that in accordance with the legislation of most states, the mandatory use of GMP in the manufacture of pharmaceutical products is provided. This practice is used to provide the population with proper medical care, the formation and preservation of health, which are the primary responsibilities of the state.

Based on the study of the fundamental principles of GMP use, it has been determined that the essence of their use is in the continuous application by the manufacturer of measures to achieve confidence of interested parties in the proper quality of products, satisfaction of its needs. It is established that for this purpose the production of goods must be ensured that will meet the intended purpose, the provisions of the registration dossier, will be characterized by appropriate indicators of safety, quality, physiological effectiveness of the special food product. To confirm this, the production activities of the organization must be accompanied by GMP control measures, which will confirm the guaranteed level of product quality provided for by the requirements of the trade license and internal organizational norms. It is determined that these results should be ensured by establishing and complying with the stipulated GMP requirements for raw materials, production equipment, personnel, premises, hygienic and sanitary standards, documentation, control, traceability of products. It is important to note that the implementation of this involves decision-making taking into account the need to make decisions based on actually confirmed data and the risk of oriented thinking.

Based on the analysis of the basic principles of GMP application, it is determined that they are aimed at stable production of products of the proper level of safety and quality through constant monitoring of the properties of products, resources for their manufacture. It is also worth noting the importance of the envisaged verification of systems and tools to confirm their functionality and effectiveness, which allows maintaining a high level of productivity of the application of good manufacturing practices. This makes it possible to ensure the production of food products for special medical purposes, which will be characterized by zero level of defectiveness and high functional orientation in consumption (use). To ensure this, constant monitoring should be carried out at all stages of production, including the acceptance of appropriate raw materials, the implementation of technological operations, the high competence of personnel should be maintained, which initially requires the use of additional financial resources.

The study of differences in GMP norms in comparison with the requirements of the most used standards (Table 1) shows that the basic level is the highest level of quality control provided for when checking intermediate products and production process parameters. Thanks to this, the use of the requirements of good manufacturing practices makes it possible to ensure a high level of efficiency of use since they are provided, first of all, for products that significantly affect human health. It is also determined that other significant differences are the foreseen importance of ensuring the stability of production activities, focus on products that are fundamentally important for maintaining health, the envisaged nature of use. When analyzing the differences in the rules defined in GMP documents, it is appropriate to note the longer-term nature of their evolution and improvement. The result of this, in turn, is their better content with the stipulated norms and, as a result, wider benefits from the application.

Based on the analysis of the advantages that open up to manufacturing organizations that use GMP norms in their activities, a sufficiently high prospects for their implementation have been determined. The main advantages are ensuring stable product quality, reducing the cost of monitoring conformity, its recall, processing and disposal in case of certain defects. Another important aspect is to prevent complaints from consumers (patients, medical staff and society as a whole), disputes with them and, as a result, an increase in customer confidence. In business terms, this will help strengthen and increase the competitiveness of products, the formation of a fair business reputation of production organizations, the realization of their socially responsible position in the market.

It is assumed that the developed and proposed recommendations for the implementation of the GMP system at enterprises producing food products for special medical purposes will contribute to the establishment of a stable production of these products of a guaranteed level of quality. It

is expected that their application will not be burdensome for target organizations in terms of the use of material, labor and time resources. It is also advisable to note that the implementation of the proposed provisions will contribute to optimization efforts in the implementation of good manufacturing practices, optimal distribution of attention in certain areas.

When implementing the results of work on the implementation of GMP, relevant organizations should take into account restrictions on the need to involve in this process all organizations supplying certain ingredients or providing certain production or other support.

It should also be noted that in the practical implementation of the results of scientific research, interested organizations in the field of food production for special medical purposes need to take into account the individual characteristics of their production cycle. In this regard, the prospects for further research are the development of systems and programs of measures aimed at implementing GMP, individual to each organization in this area, studying the results obtained.

7. Conclusions

1. It has been determined that the main essence of introduction of GMP is the constant use by the manufacturer of the stipulated norms that will provide consumer confidence in the appropriate level of product quality. It is determined that these requirements relate mainly to raw materials, production support, personnel, premises, compliance with hygienic requirements, documentation of processes, quality management, internal control, response to complaints, traceability and recall of finished products. It is determined that ensuring product quality in accordance with the principles of GMP is a comprehensive concept of guaranteeing appropriate quality, combining organizational measures at all stages. Confirmation of the appropriate product quality should be carried out on the basis of control of raw materials, packaging, testing in the production and release of goods to the declared characteristics, ensuring high competence of personnel, process-analytical validation.

2. The analysis of GMP norms allows us to state that the main difference in comparison with similar ones set forth in other standards is a more thorough quality control by checking intermediate products and production process parameters. Also, distinctive features are the need to ensure stable operating conditions, homogeneity of product quality, target scope, mandatory nature of application provided in most cases, a longer period of development and improvement of GMP requirements. It is determined that the advantages of these standards are ensuring consistently proper product quality, reducing material costs for compliance control, minimizing the costs of recall, processing, disposal of defective products and resolving consumer disputes. As a result of the implementation of the studied practices, organizations will be able to increase the competitiveness of their products, improve business reputation and social image. about responsible reputation and business image.

3. Based on the results of the analytical study, recommendations on a set of measures aimed at introducing good manufacturing practices in enterprises producing food products for special medical purposes have been developed and presented. The main essence of these recommendations is to identify technological processes, monitor their implementation, provide the necessary resources and measures, establish the process of documenting actions, validation at all stages, including self-inspection.

Conflicts of interest

The authors declare that they have no conflicts of interest in relation to the current study, including financial, personal, authorship, or any other, that could affect the study and the results reported in this paper.

Funding

The study was conducted without financial support.

Data availability

All data are available in the main text of the manuscript.

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