Basic aspects of the organization of the pharmaceutical industry

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Abstract: The implementation of the state policy of the pharmaceutical industry requires institutional, infrastructural development and investment measures, as well as system-wide state measures of the pharmaceutical industry of the Republic of Kazakhstan. At the present stage the implementation of GMP methodology of developed countries became unavailable for the pharmaceutical company of Kazakhstan due to a high commercial value of the services of international experts. In connection with the above there occurred the problem on working out methodological approaches of rules for the organization of pharmaceutical production in accordance with international requirements. To assess the reliability of all elements of the production cycle, as well as the detailed preparation and planning of the different phases and stages it's necessary to adhere to the organization of the pharmaceutical production algorithm. Organization of pharmaceutical production is a complex and demanding task that requires knowledge and skills not only in business, informational technologies, training personnel and a variety of other areas, but in the organizational design (engineering). We determined the basic principles of organizational design and an algorithm of organizational designing for the pharmaceutical industry.
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1. Introduction

For today the pharmaceutical market of CIS is characterized by rather fast development, but functions against late formation of the effective legislation. In the majority of the countries the regulatory systems are notable for compilation and combine as the elements which have remained in heritage from Soviet period, so the blocks harmonized with foreign standards [1].

It is obvious today that in conditions of high level of the competition, domestic pharmaceutical producers cannot develop steadily without carrying out global modernization of the capacities and transition to standards of manufacturing GMP practice that, in turn, demands an active participation of the state.

Realization of the state development policy of pharmaceutical branch assumes institutional, infrastructure and investment measures of development, and also all-system state measures of pharmaceutical branch development of the Republic of Kazakhstan (Fig. 1). The basic measures of the state support of competitiveness of domestic pharmaceutical producers on internal and foreign markets is intended to introduce GMP standards, improvement of system of the state registration and certification of medicines, ensuring availability of medicines with appropriate quality, an exchange and introduction of innovative technological solutions in production of domestic medicines, participation and support of the state in building new pharmaceutical productions and modernization of existing ones, increase of personnel capacity of pharmaceutical branch on the basis of an education reforming system and close cooperation with foreign companies and experts.

One of the priorities of Kazakhstan economy as the President Republic of Kazakhstan outlined is the pharmaceutical industry in which Kazakhstan is able to secure the industrial breakthrough. Thus, creating a competitive domestic pharmaceutical industry - not just a matter of economy, but also national security. So the state should pay much attention for supporting of domestic manufacturers in this industry.

In August 2010 the government of the Republic of Kazakhstan approved the Program intended for pharmaceutical industry development for 2010-2014. The basic task of the program is modernization of functional pharmaceutical productions and formation of new pharmaceutical enterprises. According to the decision of Public Health Ministry of the Republic of Kazakhstan the producers have to pass on to the standard by the end of 2014. There is no doubt that GMP implementation is an important step to essential quality improvement of the products, that would be competitive in the international pharmaceutical market.

The GMP rules are the general management that establishes the procedure of an organization production process and monitoring. Such conditions contain the minimum practical instructions on modern correct conducting production. The documents and standards are created for the purpose of GMP rules development. They permit to regulate and concretize conditions of the organization and conduct manufacturing process of separate types of pharmaceutical production [2].

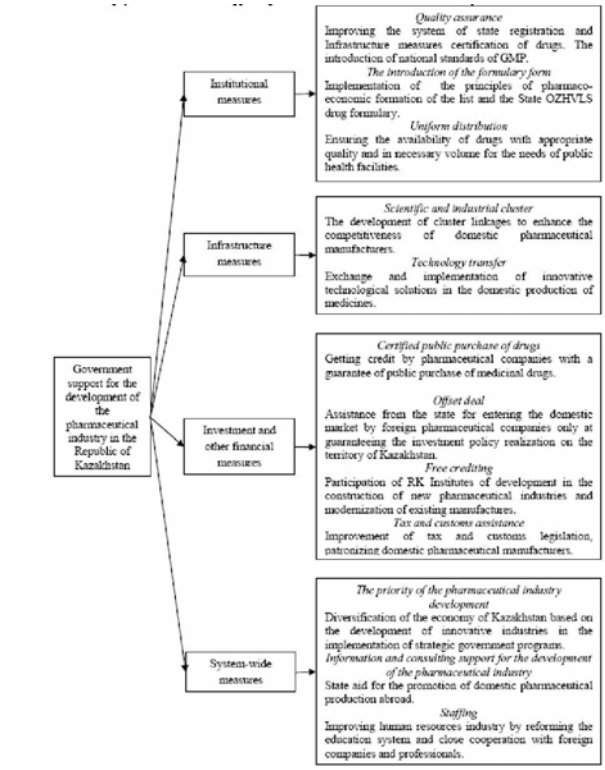

Figure 1. The basic measures of state support of the domestic pharmaceutical industry

Kazakhstan has begun the transition on international standards of GMP manufacturing practice since 2008. The same principle is in a basis of all existing GMP models which provides safety, quality and efficiency of drugs production. This is the code of rules and recommendations, urged to provide medicinal drugs quality in the course of their production process.

In global sense the transition to GMP is systematic and stage-by-stage ensuring drugs quality. This system allows guaranteeing throughout all stages of medicine production that each separate step (stage, procedure) is carried out within the rules and GMP requirements. Experts say, that transition to GMP standards promises double benefit to drugs manufacturers. Firstly, it is an effective advertizing production quality within the country; secondly, it is an opportunity to realize export potential of the state [3].

Introductions of GMP rules in pharmaceutical branch is an expensive cost-based task which demand to carry out full reconstruction of the pharmaceutical enterprise, creation of pure premises, modernization of processing equipment and the new quality system arrangement.

At the present stage, introduction of GMP methodology of the developed countries has become inaccessible for the pharmaceutical enterprises of Kazakhstan because of high commercial services cost of the international experts. Furthermore, a number of problems for the medicinal drugs production arrangement according to features of technological process are interpreted by experts within the technical task. Of course, the problem of technologies confidentiality is also important. Therefore, domestic experts have to possess their own methodology of the pharmaceutical production arrangement for the purpose of medicine production of faultless quality [4].

Due to the above mentioned, there is a question related to development of methodological approaches and arrangement rules of pharmaceutical production according to the international requirements.

Besides, by drawing up methodology of the production arrangement it is necessary to consider such factors, as the premises, equipment, personnel, technology, raw materials, product range, management and marketing which influence the process of GMP introduction in the pharmaceutical enterprises of the Republic of Kazakhstan [5].

For an assessment of reliability of all production elements cycle, detailed preparation and planning of various stages there is a need to adhere to algorithm of the pharmaceutical production arrangement (Fig. 2). All planned work has to be performed in a certain sequence and according to existing normative documents.

Organization of pharmaceutical production is a complex and demanding task that requires knowledge and skills not only in business, information technology, training and a variety of other areas but in the organizational design (engineering).

Designing (Engineering) is among the most important processes for the project, as a result of its implementation is the development of the unique facilities, goods or services [6, 7, 8].

Designing has its own methodology, which includes the structure of the principles and norms of activity, subject, object and its model, methods [9, 10].

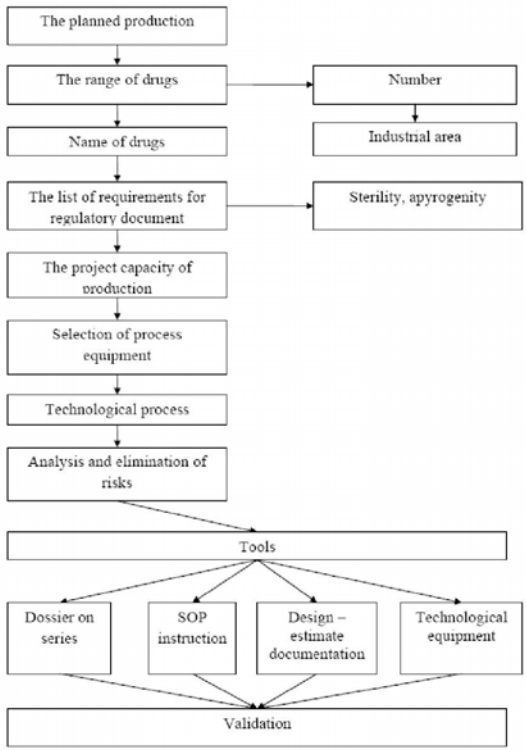

Figure 2. Algorithm of pharmaceutical production organization.

2. Materials and methods

For the designing of the pharmaceutical industry in the Republic of Kazakhstan, we identified the basic principles, which are subdivided into three groups (Fig. 3):

- general principles for the designing of production systems;
- specific principles for the designing of the pharmaceutical industry;
- principles taking into account regional differences.

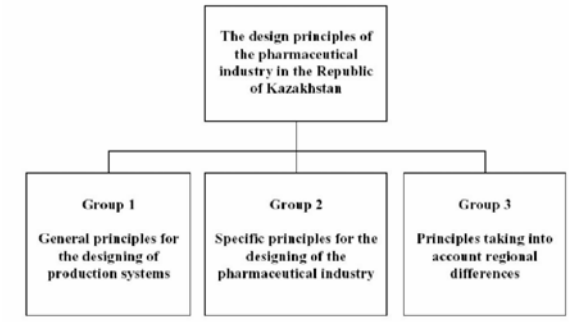

Figure 3. Principles of designing the pharmaceutical industry in the Republic of Kazakhstan

The above principles are closely intertwined in each production phenomenon, are specified in separate regulations of designing pharmaceutical manufactures.

Group 1 principles. General principles for the designing of production systems.

Principle of systems. It suggests that the pharmaceutical industry is a complex, multi-level socio-economic system consisting of interconnected, interacting, balanced in time and space subsystems, which in some external surroundings fulfill the goal set for the system as a whole.

The principle of an object orientation. It is accomplished by constructing tree goals, and using program – based and network planning.

The principle of a phased approach. Planning from general to specific (ie, gradually increasing concretization). Particular problems as possible differentiate and distribute the stages for consistent designing.

The principle of correspondence of production organizational forms to its technical and economic content. It requires the formation of an organizational structure taking into account the features of production processes and conditions of their occurrence.

The principle of urgency. Transformation of random, unstable, disordered structural connections, relationships and the corresponding structures to stable and regulated.

The principle of concentration. Subordination of the individual functions for implementing a single system of function to get the desired effect.

The principle of cyclicity. According to the cyclicity of material world - the structure, the vital cycles of various elements of the production system have the sequence of the stages.

The principle of continuous improvement. According to the law of instability of the production system, the work is needed to increase the level of its organization.

The principle of control. Using the principles of scientific management of lab our.

The principle of integration and coordination. It defines the basic function of a project manager.

The principle of experience. All experience gained in the design process should be recorded and transferred for use in other phases of the designing and organizing projects.

The principle of parallelism. Building a process that enables the simultaneous designing component subsystems, elements, links of the production system.

The principle of digitalization. Involves the use of electronics.

The principle of monitoring changes in the project. All the processes of the project must be carefully controlled.

Quality management principles. The standards of RK ISO 9001-2001 have 8 quality management principles:

a) Customer focus. Organizations depend on their customers and therefore should understand current needs, meet customer requirements and strive to exceed their expectations.
b) Leadership. Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.
c) Involvement of people. People at all levels are the essence of an organization and their full involvement enables organizations to capitalize their ability with benefit.
d) The process approach. The desired result is achieved more efficiently when activities and related resources are managed as a process.
e) System approach to management. Identifying, understanding and managing interrelated processes as a system, promote the efficiency and effectiveness of the organization in achieving its objectives.
f) Continuous improvement. Continual improvement of the organization as a whole, should be regarded as a permanent objective.
g) Decision making based on facts. Effective decisions are based on the analysis of data and information.
h) Mutually beneficial supplier relationships. An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both sides to create value.

The principle of unity of social, economic and technological solutions. It defines the relationship of social factors to the optimization of the economic and technological solutions.

The principle of information sufficiency. It defines the requirements for the information, its accuracy, timeliness, completeness, etc.

The principle of reliability. The property of the production system to maintain stability in the small, within the established standard in time and in space.

The principle of specialization. It is a form of organization of the production process, in which a given workplace, site shop, divisions of the production system is concentrated on production of similar products, as well as the minimum number of manufacturing processes and operations.

The principle of proportionality. It is to quantify the proportionality (combination) of the elements of the production process: the output parameters of the elements of performance, capacity, production (main and auxiliary serving) and coordination of bonds.

The principle of optimality. The design of all the processes for the production of products in a given amount and time and with the greatest economic efficiency and the lowest cost of labor and material resources.

The principle of continuity. Assumes the shape of the production process, in which all of its operations are carried out continuously, without interruption, and all the intermediate components of products continuously move from stage to the operation.

The principle of concentration. It means focusing on perform of certain manufacturing operations for the production of technologically similar products at individual workplaces, sites, in workshops or production company.

The principle of compatibility. Creating unity of appropriate operating elements and their relationships in the organization of the system.

The principle of consistency. Continuous following the implementation of productional (technological) operations.

The principle of competitiveness. Production design, producing products that can compete.

The principle of flexibility. Organization of production, capable of rapidly under certain characteristics of the elements of the production system, to reorganize producing other products, or change any of its components.

The principle of cost-effectiveness of the design. It is important to estimate the real cost of the required design.

Uniflow principle. Building a technological process that excludes "reverse" of the produced products, equipment placement during the process.

The principle of automaticity. The construction of technological process, in which partial processes and the manufacturing process, in general, are performed automatically (mechanisms) for the maximum possible economically and technologically grounded releasing from manual labor.

The principle of ecology. Enforcement of environmental rules and regulations, excluding harmful influence not only on the production processes and wastes on the environment, but also the impact of the environmental situation in the area of locating production on quality of production.

2nd group of principles. Specific guidelines for the design of the pharmaceutical industry.

The principle of standardization (implementation of GMP, ISO guidelines). It involves the use of obligatory conditions, control points, providing the best course of the manufacturing process and output of quality products.

The principle of the quality of medicines. The main principle of GMP is the quality of medicines should be provided with the technology and organization of production so that the products do not meeting the requirements will not be able to appear.

The principle of variance. Compulsory examination of fundamentally valid options of project for creating the pharmaceutical industry.

Principle of integrated designing. Need for a multidisciplinary approach to design pharmaceutical plants.

The principle of cross-contamination. Compliance with regulatory and technical documents, providing technical measures, procedures and precautions during the process to be followed to avoid the risk of cross contamination.

The principle of trained personnel. Production of drugs should be completed with the necessary number of professionals with the proper skills and experience.

The 3^{d} group of principles. Principles that take into account regional differences.

Sufficiency principle of regional resources - natural, labor, financial, etc.

The principle of integration of the economy of the Republic of Kazakhstan to the world market of the EU, CIS, SCO. Establish close cooperative and investment cooperation with the EU, CIS, SCO.

The principle of preserving the ecological balance. It's provides environmental management.

The principle of creating an economically viable industry for the economy of the Republic of Kazakhstan.

The principle of improving the health of the country through the creation of regional pharmaceutical industry.

Since the construction of new pharmaceutical companies is a mega-project of the regional level, so it's necessary to conduct planning for identifying and assessing the various options for the development of pharmaceutical industries [11, 12].

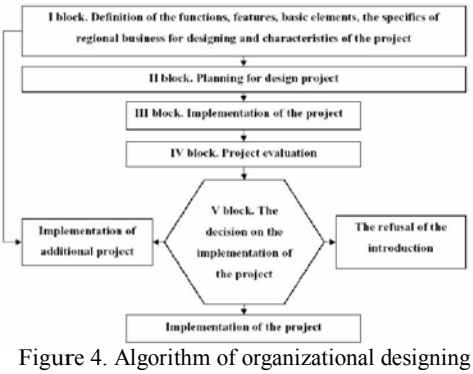

Figure 4. Algorithm of organizational designing pharmaceutical industry

We have developed an algorithm for the organizational design, which is presented graphically in the form of a block diagram (Fig. 4).

3. Results

I block. Definition of the functions, distinctive features, basic elements and methodological approaches, specifics of regional business for designing and characteristics of the project.

1.1. Project functions:

1.1.1. The important functions of designing is to identify these quince of designing pharmaceutical production and evaluation of the selected project variant efficiency of the distinguished investment project.

1.1.2. The second most important function is to decide on the implementation of the project.

1.1.3. Collection of the information necessary for the organizational design of pharmaceutical industry.

1.1.4. Identification of types, the volume of additional work, training and other activities that are essential for the transition from design to large-scale design.

1.1.5. Gaining an experience of designing.

1.2. Distinctive signs of the project:

1.2.1. signs of flexibility and adaptability;

1.2.2. signs of informational, duration and financial limits;

1.2.3. signs of limited size and number of project activities;

1.2.4. signs of involvement of a small number of specialists.

1.3. The main elements of the design:

1.3.1. initial conditions, limitations, and requirements for the design;

1.3.2. sequencing design pharmaceutical plants;

1.3.3. organizational design;

1.3.4. evaluation and selection of an alternate version of the project;

1.3.5. documentation of the project (initial and intermediate - data collection, working out business plan and final - the documentation on adopting the decision for implementation);

1.3.6. types of security planning: informational, program, technical, organizational, legal, methodological, financial.

1.4. The specifics of the regional business of designing. At planning a business it's necessary to take into account the specifics of the regional business. We have identified the following factors of regional characteristics that should be considered in the designing:

- the geographical features of the region (location, scale area, geographical remoteness);
- climatic conditions;

- transport communication in the region;
- the level of socio-economic development of the region.

1.5. Characteristics of the project. The project should have the following characteristics:

1.5.1. Advantage. The project is carried out under conditions of high uncertainty.

1.5.2. Professionalism. The project team should have technical maturity, sufficient experience and knowledge in the designing pharmaceutical industries. The group must reflect in miniature the features and skills required by the project team for large scale designing. Project team or a group of professionals involved in the project must have a high level of professionalism for authoritative apprehending the project results by authorities of organization, potential investors, expert organizations.

1.5.3. The duration of the project. The duration of the project should be at a reasonable time. So continuous performing the project is related to the risk of interest loss from the side of authorities, potential investors.

1.5.4. Realism. The above characteristics must be balanced with the actual conditions of the organization, internal and external environment of the project.

II. block. Planning for design. Planning for organizational designing pharmaceutical industry should contain the following information:

2.1. procedures and agreements;

2.2. training;

2.3. schedule and resources.

2.1. Procedures and agreements. Examples of procedures and agreements which are necessary for carrying out the project and the success of the process are the technical (software) and organizational arrangements (in particular, design and technological solutions, the implementation of the business plan, financial calculations and the examination procedure of the project).

2.2. Training. The types and amounts of necessary types of training are determined for performing the project. Plan and timetable for training should be drafted and approved for this. The resources required for training (the audience and equipment, teachers, professionals and experts), the training must be consistent with the pattern of the project.

When selecting the desired type of training the following factors should be taken into account: qualifications of invited specialists, experts, compliance of training program to characteristics and requirements of specific professional groups; the ability to train local specialists and experts.

2.3. Schedule and resources. To carry out the project the schedule should be developed, including the resources and duration (stages) of the work. Resources include personnel, facilities, training curriculum and finance. Personnel requirements should define concrete specialists, their skills, which are necessary for the successful implementation of the project. Funding must be determined for each type and stage of the design work, such as training, the individual phases of design and use of experts.

III block. The project. Implementation of the project provides for the division of the whole process into consecutive stages, each of which consists of proper stages.

IV block. Evaluation of the project. Results of the project should be assessed according to the evaluation criteria of organizational design guideline for the pharmaceutical industry and select the preferred version of the project.

The assessment of the project management should determine further action by answering the following questions:

- Is it appropriate to implement this project?
- What are the specific features of the project leading to its success?
- What are the specific features of the project leading to its failure?

V block. Adopting the decision on introduction of the project. According to the study, the option of adopting a decision on a specific project should be one of the following:

- Implementation of the project. The project results meet or exceed the expectations of the enterprise. In this case it's necessary to make further large-scaled pharmaceutical production designing– working out technical grounding, then a working draft.
- Performing an additional project. This option is considered in the event that were specific issues requiring clarification. In this case, the implementation of the project should further clarifications. For example, changes and additions on the volume of work in design, goal setting, the size of investments, options, decisions, etc.
- Failure to implement. Option is considered when the results of the project do not meet the criterion, according to organizational design guideline for the pharmaceutical industry.

4. Discussions

Thus, our proposed key measures of state support for the domestic pharmaceutical industry, pharmaceutical manufacturing organization, algorithm of organizing pharmaceutical manufacture and the basic principles of organizational design for

the pharmaceutical industry of the Republic of Kazakhstan will promote to improving the investment climate and product quality, developing competition domestic of pharmaceutical market. Also we developed an algorithm of organizational designing the pharmaceutical industry, which consists of the following units: the definition of the functions, features, basic elements, the specific regional business for the design and characteristics of the project, planning of the design, execution of the project, evaluation of the project, the decision to implement the project.

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