Modern approaches in biotechnology: demands, attainments and perspectives

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As it is known, biotechnology is relatively new science, which develops tempestuously; it is a complex of fundamental and applied sciences, technical equipment, which are aimed at obtaining and using cells of microorganisms, animals, plants, as well as products of their live activity. Recently, more and more often in medical practice preparations of biotechnological origin are used: amino acids, enzymes, vitamins, hormones, antibiotics, etc.

Biotechnological drugs are drugs used for the prevention, treatment and diagnosis of diseases. Active substances in biotechnological products, in contrast to synthetic drugs, have a biological origin. There are significant physico-chemical differences between biotechnological and biological products and chemical drugs, such as lability and complexity inherent to biological and biotechnological products. Such differences require special pharmaceutical and biopharmaceutical quality estimation during the research and development processes.

Analysis as well as features of standardization of biotechnological products includes information on the preparation, chemical structure, physical and chemical properties, also analysis, storage and use of biologically active substances such as amino acids, enzymes, nucleotides, alcohols, organic acids, polysaccharides, hormones, phytohormones, alkaloids, vitamins, antibiotics, etc. that can be obtained in biotechnological production.

The main source for obtaining medicines for biotechnological production are bacteria, yeast, molds, algae, as well as animal and plant cell cultures, those metabolism and biosynthetic capabilities provide the development of specific biologically active substances.

For obtaining medicinal products, biotechnological methods of genetic engineering are also used. Thus, genetically engineered strains of the *E. coli*, yeast that cultivate cells of mammalians and insects are used to produce growth hormone, insulin and human interferon, various enzymes and antiviral vaccines.

The quality of biotechnological products is determined by the choice of technology and manufacturing process. Minor changes in the manufacturing process can have a significant impact on the quality of the drug, so the development of the manufacturing process is of paramount importance for biological products such as vaccines, biotechnological products or derivatives of blood, or therapeutic oligonucleotides, such as DNA vaccines and gene therapy products.

Considering that the number of new biotechnological medicines is constantly growing, as well as the training of highly qualified specialists in biotechnology is necessary for the development of modern industrial pharmacy, the elaboration and creation of new and improvement of the existed manuals on the analysis of biotechnological products are very actual.

The main normative document for all the ways of analysis and standardization of medicinal substances is the State Pharmacopoeia of Ukraine (SPhU), that contains requirements for medicinal products' quality in general pharmacopoeial articles, as well as methods of quality control for medicinal products in individual monographs. The SPhU has a legislative character; its requirements for the quality of medicinal products are mandatory for all enterprises and institutions of Ukraine that produce, store, control and sell pharmaceuticals.

The SPhU demands and provisions are in harmony with the European Pharmacopoeia: the relevant articles of the European Pharmacopoeia are supplemented with requirements that take into account the specifics of the current state of pharmaceutical production in Ukraine. General and individual articles are constructed in the form of two interrelated parts: the European - identical corresponding article of the European Pharmacopoeia (adapted translation of the material) and the national, marked with the letter N, which reflects the national specificity of Ukraine (additional tests, information and other materials). The national part does not contradict the European one, but contains additional requirements (already legislated in Ukraine) for medicinal products manufactured in conditions that are not in compliance with GMP. In the framework of the current pharmaceutical legislation the problem of elaboration of a general guidance which will be valid normative legal act with its provisions and recommendations is also important. This guideline should be followed considered as a harmonized position of the European and World pharmaceutical sector; compliance with its provisions by stakeholders will facilitate the evaluation of registration dossiers in Ukraine, and will assist in conducting research on pharmaceutical development, standardization and certification of biotechnological and biological products. This approach is currently in line with world standards for the application of quality standards in the manufacturing of biotechnological products.

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