
**BIOTECHNOLOGY IN PHARMACY:
THE LATEST TECHNOLOGIES
FOR MANUFACTURING MEDICINES AND ASPECTS
OF BIOPHARMACEUTICAL EDUCATION**

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INTRODUCTION

Modern achievements in biotechnology and bioengineering have opened up new opportunities for industrial pharmacy, resulting in an expansion of the range of medicines available. At the same time, there is a need to create a new specialization, “Pharmaceutical Biotechnology,” for specialty I8, “Pharmacy (by specialization),” in field of knowledge I, “Health Care and Social Welfare.”

The first section of the monograph “Biotechnology in Drug Production (Biopharmacy)” analyzes literary sources on the development of biotechnology in recent years and highlights the achievements of using biotechnology methods in industrial pharmacy. It looks at specific biotechnology and bioengineering techniques and discusses the criteria for the characteristics of traditional medicines and biotechnological preparations. It presents specific medicines obtained using biotechnology methods and indicates the types of pharmacotherapy and diseases for which these medicines are used in medicine.

The second section of the article, “Pharmaceutical Biotechnology as a New Educational Specialization,” substantiates the need for and argues in favor of creating a separate specialization, I8.03 “Pharmaceutical Biotechnology,” within the specialty I8 “Pharmacy (by specializations)” in the field of knowledge I “Health Care and Social Security.”

1. Biotechnology in drug manufacturing (Biopharmacy)

Biotechnology, as an interdisciplinary field of science and production for the creation of new products, including medicinal products (MPs), is based on the use of living organisms, cell cultures, and biological processes.

Biotechnology plays a special role in industrial pharmacy, as it opens up new opportunities for the development of effective and safe medicines¹. It is thanks to biotechnological approaches that it has become possible to obtain

¹ Singh V., Kumar A. Pharmaceutical biotechnology: concepts and applications. Springer, 2020.

new-generation vaccines, recombinant hormones, monoclonal antibodies, and other biopharmaceuticals, which have significantly expanded the arsenal of modern medicine².

Biopharmaceuticals differ from traditional (MP) drugs obtained through chemical synthesis in a number of specific characteristics. The main difference is that traditional drugs are chemically synthesized low-molecular compounds with a relatively simple structure, while biopharmaceuticals are high-molecular proteins or other biopolymers produced by living cells³. This determines their complex spatial organization, high specificity of action, and, at the same time, the complexity of industrial production, special storage conditions, and additional requirements for the transportation of such medicines.

Table 1 presents the characteristics of traditional drugs and drugs obtained using biotechnological methods, which allow structuring the criteria by which these two categories of drugs differ.

Table 1

Characteristics of traditional chemical drugs and biopharmaceuticals

| Criterion | Traditional medicine (chemical synthesis) | Biopharmaceuticals |
|--|--|---|
| Nature | low molecular weight organic compounds | high-molecular-weight biopolymers (proteins, peptides, antibodies, nucleic acids) |
| Structure | simple, easily reproducible chemical structure | complex three-dimensional structure, dependent on production conditions |
| Method of obtaining the medicinal product | chemical synthesis | biotechnological methods using living cells |
| Molecular weight | usually < 1000 | from several thousand to hundreds of thousands |
| Specificity of drug action | often broad, with possible side effects | high specificity to specific molecular targets |
| Stability of medicinal products | more stable, longer shelf life | less stable, sensitive to storage conditions |
| Forms of release of the medicinal product | various (tablets, capsules, suspensions, injections) | mainly injectable forms |
| Methods of administration of the medicinal product | enteral and parenteral | parenteral: injection |
| Examples of medicines | aspirin, paracetamol, synthetic antibiotics | insulin, monoclonal antibodies, recombinant hormones, modern vaccines |

² Walsh G. Biopharmaceutical benchmarks 2018. *Nature Biotechnology*. 2018. Vol. 36, No. 12. P. 1136–1145. DOI: <https://doi.org/10.1038/nbt.4305>.

³ Lagassé H. D., Alexaki A., Simhadri V. L., Katagiri N. H., Jankowski W., Sauna Z. E., Kimchi-Sarfaty C. Recent advances in (therapeutic protein) drug development. *F1000Research*. 2017. Vol. 6. P. 113. DOI: <https://doi.org/10.12688/f1000research.9970.1>.

Thus, with the development of biotechnology and bioengineering, as well as their introduction and widespread use in industrial pharmacy, a new class of drugs has been created that differs significantly from traditional chemical drugs. The differences can be classified according to the following characteristics: nature, structure, and mechanism of action.

Biopharmaceuticals open up new prospects in the treatment of complex diseases, including cancer, autoimmune and genetic disorders, and are becoming an integral part of modern pharmacotherapy.

One of the key areas of biopharmaceuticals is the production of recombinant proteins and peptides, which are used to treat many diseases. To obtain them, producer cells are used – bacteria (*Escherichia coli*), yeast (*Saccharomyces cerevisiae*), or mammalian cells. The technology is based on introducing a gene that codes for the desired protein into the producer cell. This cell then begins to synthesize the protein in large quantities, after which it is isolated and purified.

The most famous example of the application of biotechnology in pharmacy is the production of recombinant human insulin, which replaced animal insulin and became the basis for replacement pharmacotherapy for diabetes mellitus. Growth hormone (for the treatment of pituitary dwarfism), erythropoietin (to stimulate red blood cell production in patients with anemia), and other therapeutic proteins are produced in a similar way.

Monoclonal antibodies (mAbs) are highly specific protein molecules that recognize a specific antigen and are used to treat cancer, autoimmune, and infectious diseases. Their mechanism of action is based on the principle of “targeted” therapy: the antibody binds to a specific target (receptor or protein) involved in the development of the disease and blocks its activity. This allows direct action on the pathological process, minimizing damage to healthy cells. For example, the drug trastuzumab (Herceptin) is used to treat breast cancer, rituximab is used to treat lymphomas and autoimmune diseases, and new antibodies are used for immune therapy of infections⁴.

Biotechnology in pharmacy enables the creation of new drugs based on the use of living organisms, cell cultures, and bioengineering methods. One of the first achievements was the production of recombinant human insulin using *Escherichia coli* in 1978, which marked the beginning of the widespread introduction of genetic engineering into pharmaceutical production⁵. Further development includes the creation of monoclonal antibodies, new-generation vaccines, and therapeutic proteins.

⁴ Ecker D. M., Jones S. D., Levine H. L. The therapeutic monoclonal antibody market. mAbs. 2015. Vol. 7, No. 1. P. 9–14. DOI: <https://doi.org/10.4161/19420862.2015.989042>.

⁵ Гурбич О. Метод машинного навчання для створення нових лікарських речовин із заданими властивостями. Науковий вісник Ужгородського університету. Серія «Математика і інформатика». 2022. Т. 40, № 1. С. 126–145. DOI: [https://doi.org/10.24144/2616-7700.2022.40\(1\).126-145](https://doi.org/10.24144/2616-7700.2022.40(1).126-145).

Modern biopharmaceuticals have also ushered in a new era in vaccine development. Traditional inactivated or live vaccines are gradually being supplemented by innovative technologies: recombinant vaccines are obtained by cloning the gene encoding the antigenic protein of the pathogen into producer cells. An example is the hepatitis B vaccine. DNA vaccines contain plasmid DNA that encodes the antigen; after administration, it is captured by human cells, where the antigen protein is synthesized and forms an immune response. RNA vaccines are a new class of drugs that have been widely used during the COVID-19 pandemic (Pfizer-BioNTech, Moderna). They contain messenger RNA that encodes the antigen and, once inside the cells, ensures the synthesis of a protein that stimulates the immune system.

Gene and cell therapy is a cutting-edge field of biopharmaceuticals aimed at correcting hereditary or severe acquired pathologies. Gene therapy involves introducing functional genes into the patient's cells to replace or correct defective ones. It is used to treat hereditary immunodeficiency conditions and some forms of cancer. Cell therapy involves the transplantation of stem cells or modified immune cells to restore or enhance the body's functions. An example is CAR-T therapy, in which the patient's T lymphocytes are genetically modified to recognize and destroy tumor cells.

CRISPR-Cas9 technology, which allows for precise genome editing, occupies an important place. It has opened up new opportunities for treating hereditary diseases (such as sickle cell anemia) and developing personalized drug therapy regimens.

All current research is focused on creating universal platforms for vaccine development, advancing personalized medicine, and using artificial intelligence to predict the properties of biomolecules and optimize production. It is expected that in the coming decades, biopharmaceutical technologies will become the basis for treating most complex diseases.

Drug manufacturing and delivery technologies (3D printing of drugs) enable the creation of drugs with the correct dosage, combined prescriptions of active ingredients, and controlled release. The first 3D-printed drug, Spritam (devetiracetam), has been approved by the FDA. An overview of the latest 3D printing technologies in industrial pharmacy includes inkjet printing methods, UV curing, materials science, and a drug quality control regulatory system.

Nanotechnology is used when targeted drug delivery is required: lipid nanoparticles (LNPs) have proven effective in mRNA vaccines (such as Pfizer-BioNTech and Moderna), protecting mRNA and ensuring its delivery to the cell. Other methods include the use of liposomes, nanocells, protein nanocells, exosomes, microneedles, enzyme inhibitors, and permeation enhancers to increase bioavailability. Nanotechnology as a carrier for targeted delivery:

nanoparticles can deliver drugs to specific cells, improving efficacy and minimizing side effects. However, there are risks of accumulation in organs (liver, spleen), which can cause inflammation. The use of liposomes, polymeric and lipid nanoparticles for targeted drug delivery is promising. mRNA-based vaccines against COVID-19 have become an example of the successful application of this technology^{6,7}.

Digital twins and machine learning in biopharmaceutical manufacturing—digital copies of manufacturing processes that enable automation, control, and product optimization. At the same time, integration with operators requires collaborative intelligence – a combination of technology and human management^{8,9}. Artificial intelligence (AI) is used for quality control and performance prediction in bioreactors¹⁰.

Machine learning (ML) improves the efficiency of the development and production of bioproducts, including pharmaceuticals, by analyzing large amounts of data, controlling quality, and optimizing technological processes.

Despite significant successes, the biopharmaceutical sector of industrial pharmacy faces a number of challenges: the high cost of developing and manufacturing biological products; the complexity of ensuring drug stability, storage, and transportation (especially for protein drugs and RNA vaccines); the need for strict quality and safety control; limited availability in low-income countries. However, the prospects for the development of biopharmaceuticals are extremely broad¹¹.

Graduates of the Department of Technology of Biologically Active Compounds, Pharmacy, and Biotechnology (TBSFB) of Lviv Polytechnic National University (LPNU) work at leading pharmaceutical and biotechnology companies in Ukraine, such as Enzym State Enterprise (Ladyzhyn), PJSC Enzym Company (Lviv), Arterium Corporation (JSC Kyivmedpreparat, Kyiv; JSC Galichpharm, Lviv), TzOV TECHNOLAB (Lviv), TOV Pharmaceutical Company Biostimulator (Odessa), TOV Pharma Life (Lviv), TOV Ternopharm (Ternopil), LLC NVP YENAMIN (Kyiv), JSC Farmak (Kyiv), as well as in scientific institutions.

⁶ Krammer F. SARS-CoV-2 vaccines: The race is on. *Immunity*. 2020. Vol. 52, No. 1. P. 374–375.

⁷ Hou X., Zaks T., Langer R., Dong Y. Lipid nanoparticles for mRNA delivery. *Nature Reviews Materials*. 2021. Vol. 6, No. 12. P. 1078–1094. DOI: <https://doi.org/10.1038/s41578-021-00358-0>.

⁸ Li Y., Chen J. The role of biotechnology in modern medicine. *Journal of Biotechnology & Biomedicine*. 2021. Vol. 5, No. 2. P. 45–58.

⁹ Leader B., Baca Q. J., Golan D. E. Protein therapeutics: a summary and pharmacological classification. *Nature Reviews Drug Discovery*. 2008. Vol. 7, No. 1. P. 21–39.

¹⁰ Kroll C. A., Schmidt A. Indirect stratospheric moisture increase after a Pinatubo-magnitude eruption can be comparable to direct increase after 2022 Hunga. *Communications Earth & Environment*. 2024. Vol. 5, No. 1. P. 497.

¹¹ Walsh G. *Biopharmaceuticals: Biochemistry and Biotechnology*. John Wiley & Sons, 2018.

The educational base of Lviv Polytechnic provides comprehensive training for specialists in pharmaceutical biotechnology at the bachelor's, master's, and PhD levels, with powerful laboratory, digital, and scientific infrastructure supported by highly qualified teaching staff.

Educational programs (EP) for students at the Department of TBSFB, Lviv Polytechnic National University, are divided into three levels: bachelor's, master's, and PhD (educational and scientific) levels in the following specialties: G21 “Biotechnology and Bioengineering”, I8 “Pharmacy (by specialization),” specialization I8.02 “Industrial Pharmacy”.

EP The educational programs at Lviv Polytechnic National University cover all levels of training from bachelor's to PhD and provide both basic engineering biotechnology competencies and highly specialized knowledge in the field of pharmacy and biotechnology. Particular attention is paid to integration with research activities, preparation for work in the pharmaceutical industry in accordance with GMP standards, as well as international scientific cooperation.

The sequence and diversity of EP implemented by the Department of Technology of Biologically Active Compounds, Pharmacy, and Biotechnology at Lviv Polytechnic National University are presented in Table 2.

Lviv Polytechnic National University covers all levels of education from bachelor's to PhD and provides training in both basic engineering biotechnology competencies and highly specialized knowledge in the field of pharmacy and biotechnology. Particular attention is paid to integration with research activities, preparation for work in the pharmaceutical industry in accordance with GMP standards, as well as international scientific cooperation. The bachelor's degree provides basic engineering and biotechnology training. The master's degree (EPP) develops practical skills in pharmacy and biotechnology. The master's degree (ERP) combines education and scientific training, laying the foundation for a PhD. The Doctor of Science degree is geared toward scientific careers, research activities, and teaching at institutions of higher education.

In order to determine the current status of the availability of specialists with higher education at an industrial pharmaceutical manufacturing enterprise, we processed the database of the human resources department regarding positions for specialists with higher education and the corresponding specialties that grant the right to hold these positions (Table 3).

Since the research was conducted during martial law in Ukraine, we will continue to refer to the aforementioned industrial pharmaceutical company as IPhC-1.

Therefore, specialists with pharmaceutical education are graduates (bachelors/specialists/masters) of the following specialties: “Pharmacy, Industrial Pharmacy,” “Pharmacy,” “Pharmaceutical Technology,” “Industrial

Table 2

EP of the Department of TBSFB, Lviv Polytechnic National University

| Level of Education/ Type of Program | Specialty/Code | Duration of training | Volume/ECTS credits | Program focus |
|--|---|---------------------------------|----------------------------|---|
| Bachelor (EPP) | Biotechnology and Bioengineering (G21/162) | 4 years | 240 ECTS | Biotechnological processes, engineering fundamentals, fundamental and applied disciplines |
| Master's degree (EPP/ONP) | Pharmacy (by specialization) / Pharmacy, industrial pharmacy (I8/226) | 1.5–2 years | 90–120 ECTS | Theory and practice of pharmacy, science, GMP, management, innovation, economics, master's thesis |
| Master's degree (EPP/ONP)) | I8 Pharmacy, specialization I8.02 Industrial Pharmacy | 5–6 years (full training cycle) | 300–360 ECTS | Advanced training in industrial pharmacy, research training, PhD preparation (focus on continuing education in graduate school) |
| Master's degree (ONP archiving program) | Pharmaceutical Biotechnology (8.162.00.01) | 1.5 years | 90 ECTS | Biotechnology in pharmacy, GMP, management, innovation, economics |
| Doctor of Philosophy (PhD) (ONP) | Pharmacy (by specialization) I8/226 Biotechnology and Bioengineering (G21/162) | 4 years (postgraduate studies) | Personalized plan | Preparation of dissertation research, postgraduate studies, scientific career, teaching activities |

Table 3

List of IPhC-1 departments and positions requiring specialized higher education*

| № | Division name | Job title | Higher education in the specialty | Number of positions |
|--|-----------------------------|-------------------------------------|--|----------------------------|
| Key workers in industrial pharmacy | | | | |
| 1 | Ampoule workshop | Workshop manager | Pharmaceutical/Chemical/Biotechnology | 25 |
| | | Master of Change | Pharmaceutical/Chemical/Biotechnology | |
| | | Senior masters | Pharmaceutical/Chemical/Biotechnology | |
| 2 | Tablet packaging workshop | Workshop manager | Pharmaceutical/Chemical/Biotechnology | 11 |
| | | Master of Change | Pharmaceutical/Chemical/Biotechnology | |
| | | Senior masters | Pharmaceutical/Chemical/Biotechnology | |
| 3 | Chemical workshop | Workshop manager | Pharmaceutical/Chemical/Biotechnology | 10 |
| | | Master of Change | Pharmaceutical/Chemical/Biotechnology | |
| | | Senior masters | Pharmaceutical/Chemical/Biotechnology | |
| 4 | Quality Control Department | Head of Quality Control Department | Pharmaceutical/Chemical/Biotechnology | 31 |
| | | Chemist | Pharmaceutical/Chemical/Biotechnology | |
| | | Quality Engineer | Pharmaceutical/Chemical/Biotechnology | |
| 5 | Biological laboratory | Head of the biological laboratory | Biological/Pharmaceutical | 28 |
| | | Biologist | Biological/Biotechnological | |
| 6 | Research Center | Head of the research center | Pharmaceutical/Chemical/Biotechnology | 38 |
| | | Chemist | Chemical/Pharmaceutical/Biotechnology | |
| | | Process Engineer | Pharmaceutical/Engineering/Biotechnology | |
| 7 | Quality Assurance Group | Quality Assurance Team Leader | Pharmaceutical/Chemical/Biotechnology | 14 |
| | | Quality expert | Pharmaceutical/Chemical/Biotechnology | |
| Other categories of employees (support services) | | | | |
| 8 | Customer Service Department | Head of Customer Service Department | Engineering | 75 |
| | | Mechanical engineer | Engineering | |
| | | Power engineer | Engineering | |
| | | Technician | Engineering | |

Продовження таблиці 3

| | | | | |
|----|--|--|---|----|
| 9 | Procurement Department | Head of Procurement Department | Engineering / Economic | 17 |
| | | Procurement Specialist | Engineering / Economic | |
| 10 | Warehousing | Warehouse manager | Engineering / Economic | 7 |
| | | Storekeeper | Engineering / Economic | |
| 11 | Transportation department | Head of the transport department | Engineering | 7 |
| | | Traffic Safety Engineer | Engineering | |
| | | Specialist | | |
| 12 | IT Department | Head of IT Department | Engineering | 8 |
| | | Electronics Engineer | Engineering | |
| | | Programmer | Engineering | |
| 13 | Accounting | Chief Accountant | Economic | 20 |
| | | Accountant | Economic | |
| 14 | Economic Planning Department | Head of Economic Planning Department | Economic | 8 |
| | | Economist | Economic | |
| 15 | Human Resources Department | Head of Human Resources | Management / Economic | 11 |
| | | Human Resources Specialist | Management / Economic | |
| 16 | Legal Department | Head of Legal Department | Legal specialty | 2 |
| | | Lawyer | Legal specialty | |
| 17 | Personnel Training and Development Service | Head of Training and Personnel Development | Management / Pharmaceutical/ Biotechnology/ Economic | 8 |
| | | Specialist in training and personnel development | Management / Pharmaceutical/ Biotechnology / Economic | |

**Explanations for the names of specialties listed in Table 2 are provided below.*

Pharmacy,” new specialty I8 “Pharmacy (by specialization)” specialization I8.02 “Industrial Pharmacy”.

Specialists with a degree in chemistry – graduates (bachelors/specialists/ masters) in the following specialties: Chemistry, Chemical Technologies of Pharmaceutical Preparations, Chemical Technology of Biologically Active Compounds. Specialists with a degree in biology – graduates (bachelors/ specialists/masters) in the following fields: Biology, Biology and Biotechnology, Biology and Biochemistry.

Specialists with engineering education – graduates (bachelors/specialists/ masters) of the following specialties: graduates (bachelors/masters) of the following specialties: Transport Technologies, Applied Mechanics, Electrical Power Engineering, Electrical Engineering and Electromechanics, Computer Science, Computer Engineering, Information Systems and Technologies.

Biotechnology education: graduates (bachelors/specialists/masters) of these specialties now belong to Field of Knowledge G “Engineering, Manufacturing, and Construction,” specialty G21 “Biotechnology and Bioengineering.” There are no specializations, only different EPs such as “Industrial Biotechnology” and “Pharmaceutical Biotechnology”.

Economic education: graduates (bachelors/specialists/masters) in the following specialties: Economics, Business Economics, Economic Cybernetics, International Economics, Finance, Marketing, Management. Legal education: graduates (bachelors/masters) in the specialty “Law.”

Analysis of the data presented in Table 3 shows that the classification of specialty G21 “Biotechnology and Bioengineering” under Field of Knowledge G “Engineering, Manufacturing, and Construction” allows graduates to hold positions that require engineering education. However, in our opinion, the EP “Pharmaceutical Biotechnology” is more specialized and, in terms of content, tends to be closer to specialty I8 Pharmacy (by specializations) and, according to logic, should be a separate specialization I8.03 of Field of Knowledge I “Health Care and Social Welfare.”

2. Pharmaceutical biotechnology as a new educational specialization

The relevance of introducing a new specialization, “Pharmaceutical Biotechnology”, within the framework of specialty I8, “Pharmacy (by specializations)” is based on the fact that industrial production of medicines should be subordinate to one ministry and regulated by the same regulatory and legal acts, and the training of specialists should take place within the framework of one specialty.

The rapid development of biopharmaceuticals has led to the emergence of fundamentally new drugs – recombinant proteins, monoclonal antibodies,

new-generation vaccines, and methods of gene and cell therapy. Traditional pharmaceutical education is focused primarily on chemical synthesis and classical pharmacotherapy and is not always able to provide training for specialists who are proficient in modern biotechnological methods. This creates a need for a new educational specialization, “Pharmaceutical Biotechnology”¹² which combines knowledge of biology, molecular genetics, biochemistry, bioengineering, and pharmacy. The integration of these disciplines will enable the training of highly qualified specialists capable of working in the field of biopharmaceutical development and production¹².

Articles by foreign authors have already discussed approaches to creating a curriculum and educational program (EP) for “Pharmaceutical Biotechnology” and proposed basic and elective educational components (Table 4).

Table 4

Fundamental (core) and applied (elective) educational components of the EP “Pharmaceutical Biotechnology”

| Key educational components | Selective educational components |
|--|--|
| Molecular biology and genetics (<i>structure and functions of genes, methods of their modification</i>) | Technology for the production of biological products (<i>selection of strains of microorganisms or other biological objects used to obtain a specific product; cultivation of these objects under controlled conditions to ensure their growth and reproduction; isolation and purification of the biological product from the obtained biomass, as well as its formation into the final product; quality control of the obtained biological product</i>) |
| Cell biology and cell culture (<i>principles of growing producer cells (bacteria, yeast, mammalian cells)</i>) | Pharmacology of biological products (<i>mechanisms of action and features of the use of biopharmaceuticals</i>) |
| Biochemistry of proteins and peptides (<i>structure, functions, and methods of obtaining therapeutic proteins</i>) | Methods of gene and cell therapy (<i>gene engineering, CRISPR-Cas9, cell therapy (CAR-T)</i>) |
| Microbiology and industrial biotechnology (<i>use of microorganisms in the production of biologically active substances</i>) | Immunology (<i>development of modern vaccines, principles of immune response</i>) |
| Bioinformatics and biostatistics (<i>analysis of biological data, modeling, and forecasting</i>) | Regulatory aspects and bioethics (<i>clinical trials, legal and ethical requirements</i>) |

¹² Mahler H. C., Mäder K., Lee G. Pharmaceutical biotechnology education: Current state and future perspectives. *European Journal of Pharmaceutics and Biopharmaceutics*. 2021. Vol. 163. P. 25–35. DOI: <https://doi.org/10.1016/j.ejpb.2021.03.012>.

The materials we have analyzed indicate that EPP should include fundamental (basic) and applied (selective) educational components, including: molecular biology and genetics (basics of working with genetic material and methods of its modification); cell biology and cell culture (studying the principles of cultivating producer cells); microbiology and industrial biotechnology (using microorganisms to synthesize biologically active substances); biochemistry of proteins and peptides (structure, functions, and methods of obtaining therapeutic proteins); pharmacology of biological products (features of the action of biopharmaceuticals); methods of gene and cell therapy (modern technologies for the treatment of hereditary and oncological diseases); immunology and vaccinology (basics of modern vaccine development); bioinformatics and biostatistics (digital tools for data analysis in biopharmacy); biopharmaceutical production technology (industrial processes, purification, and quality control); regulatory aspects and bioethics (GMP requirements, clinical trials, and ethical standards in pharmaceutical biotechnology).

Fundamental (core) disciplines provide students with basic knowledge of molecular and cellular processes, the structure and functions of biomolecules, as well as methods of data analysis and modeling. They form the scientific basis necessary for understanding the principles of biopharmacy¹³.

Applied (elective) disciplines are aimed at the practical application of this knowledge in the production and control of biopharmaceuticals, the development of new drugs, clinical pharmacology, and compliance with regulatory and ethical standards. Together, these areas form a comprehensive training program for specialists capable of working at the intersection of science and pharmaceutical practice^{14,15}.

Pharmaceutical biotechnology is emerging as an interdisciplinary field that combines pharmacy, biotechnology, and bioengineering. The emergence of a new specialty, “Pharmaceutical Biotechnology”¹⁶ abroad is in line with global trends in the development of the bioeconomy, providing training for specialists in the innovative pharmaceutical industry¹⁶. International experience

¹³ Polakovic M., Stastna M. Biotechnology education in pharmacy: Bridging academia and industry. *Biotechnology Journal*. 2019. Vol. 14, No. 7. P. 1800721. DOI: <https://doi.org/10.1002/biot.201800721>.

¹⁴ Shukla A. A., Thömmes J. Recent advances in large-scale production of monoclonal antibodies and related proteins. *Trends in Biotechnology*. 2010. Vol. 28, No. 5. P. 253–261. DOI: <https://doi.org/10.1016/j.tibtech.2010.02.001>.

¹⁵ European Federation of Pharmaceutical Industries and Associations (EFPIA). *Biopharmaceutical education and skills for the future workforce*. EFPIA Report, 2022.

¹⁶ Hou X., Zaks T., Langer R., Dong Y. Lipid nanoparticles for mRNA delivery. *Nature Reviews Materials*. 2021. Vol. 6, No. 12. P. 1078–1094. DOI: <https://doi.org/10.1038/s41578-021-00358-0>.

demonstrates the active integration of biotechnology into pharmaceutical education^{17,18}.

However, in higher education institutions (HEIs) in Ukraine, this component of education is represented only by the EP “Pharmaceutical Biotechnology,” and its classification under specialty G21 “Biotechnology and Bioengineering” in the field of knowledge G “Engineering, Manufacturing, and Construction” is not entirely appropriate.

In particular, the Pharmaceutical Biotechnology EP is located at Lviv Polytechnic National University, National University of Food Technologies (NUFT), and Igor Sikorsky Kyiv Polytechnic Institute (KPI). Students learn about the technologies used in the production of biopharmaceuticals, regulatory aspects, and quality control. KPI and other higher education institutions have a three-level educational structure: bachelor's, master's (professional/scientific), and doctor of philosophy (PhD). Within the master's program, master's qualification theses are presented in the field of biopharmaceutical production^{19,20}.

We also collected and analyzed foreign experience of higher education institutions in training specialists in biotechnology and bioengineering.

The University of Pécs (Hungary) offers an accelerated PharmD + Biotechnology program that combines pharmaceutical training with biotechnology disciplines, allowing students to earn a PharmD and a BSc in biotechnology in 6 years (instead of 8), with an appropriate laboratory component and a research focus^{21,22}.

The Golden LEAF Biomanufacturing Training and Education Center (BTEC) at the University of North Carolina in the United States provides students and professionals with practical skills in bioprocessing in accordance with GMP standards²³.

Training centers for biopharmaceutical education, such as the Golden LEAF Biomanufacturing Training and Education Center (BTEC) at the University of North Carolina (USA), provide practical training in bioprocesses (production of

¹⁷ Kroll P., Zydney A. L., Pfisterer H. Digital twins and machine learning in biopharmaceutical manufacturing. *Trends in Biotechnology*. 2022. Vol. 40, No. 7. P. 873–885. DOI: <https://doi.org/10.1016/j.tibtech.2022.01.007>.

¹⁸ Norman J., Madurawe R. D., Moore C. M. V., Khan M. A., Khairuzzaman A. A new chapter in pharmaceutical manufacturing: 3D-printed drug products. *Advanced Drug Delivery Reviews*. 2017. Vol. 108. P. 39–50. DOI: <https://doi.org/10.1016/j.addr.2016.03.001>.

¹⁹ Освітньо-професійна програма Біотехнології та біоінженерія [Електронний ресурс]. URL: <https://ipnu.ua/sites/default/files/2021/program/15914/opp-bak-162-2020.pdf>.

²⁰ Ibid.

²¹ University of Pécs. Accelerated Pharmacy and Biotechnology Degree Pathway. International Office, University of Pécs, 2024. URL: <https://international.pte.hu/>.

²² National University of Food Technologies (NUFT). Pharmaceutical biotechnology educational program. 2023. URL: <https://nuft.edu.ua/>.

²³ Walsh G. Biopharmaceutical benchmarks 2018. *Nature Biotechnology*. 2018. Vol. 36, No. 12. P. 1136–1145. DOI: <https://doi.org/10.1038/nbt.4305>.

therapeutic proteins, monoclonal antibodies, vaccines) in accordance with GMP standards^{24,25}. This could serve as a model for Ukraine.

Graduates successfully work in the pharmaceutical industry and research institutions, continue their education abroad, and receive scientific awards²⁶.

We also conducted a comparative analysis of the cost of education, the characteristics of the educational process, and employment opportunities for graduates of EP in pharmaceutical biotechnology/biopharmacy at higher education institutions in Ukraine and European countries, which are presented in Table 5.

Table 5

Characteristics of the EPP “Pharmaceutical Biotechnology/Biopharmacy” at higher education institutions in Ukraine and European countries

| HEI / Country | Name of EP | Level | Average cost of education | Features of training | Employment prospects |
|---|---------------------------------------|--------|---|---|--|
| Lviv Polytechnic National University, Ukraine | Pharmaceutical biotechnology | Master | 55,500–58,200 UAH/year (≈1,550–1,630 €) | Combination of biotechnology and pharmacy; focus on the production of biological products | In pharmaceutical companies, laboratories, educational and scientific institutions |
| Jagiellonian University, Republic of Poland | Pharmaceutical Biotechnology | Master | 2000 €4,000/year (typical for the EU) | English-language program, modern laboratories | Opportunity for internships in the pharmaceutical industry, employment in pharmaceutical and biotech companies |
| University of Vienna, Austria | Biotechnology Pharmaceutical Sciences | Master | 26.72 + 20.70 €/semester (1500€/year) | The program is open to international students, high academic standards, active international projects | Scientific career, work in European biotech companies, opportunity to enroll in a PhD program |
| ETH Zurich, Switzerland | Pharmaceutical Sciences | Master | 1,460 CHF/year (until fall 2025) 4,380 CHF/year from fall 2025 | Among the most prestigious technical universities in the world; very high level of research | International projects, work in pharmaceutical companies and research centers |

²⁴ BTEC. Golden LEAF Biomufacturing Training and Education Center. North Carolina State University, 2022. URL: <https://www.btec.ncsu.edu/>.

²⁵ North Carolina State University [Електронний ресурс]. URL: <https://www.btec.ncsu.edu/>.

²⁶ Langer E. S. Biopharmaceutical industry training and education trends. BioProcess International. 2016. Vol. 14, No. 3. P. 20–27.

Продовження таблиці 5

| | | | | | |
|-------------------------------------|--------------------------------------|--------|--|---|---|
| State University, Germany | Biotechnology/ Pharma | Master | Free even for foreigners (only a semester fee of approximately €300 per semester is payable) | High academic standards, often with no tuition fees, active research activities | Academic career, pharmaceutical companies, biotechnology laboratories |
| University of Helsinki, Finland | Biotechnology/ Pharma | Master | Free for EU/ EEA citizens; ≈ €13,000/ year for foreigners | High academic standards, research orientation, international environment, modern facilities | International pharmaceutical companies, laboratories, and scientific institutions |
| The Karolinska Institute, Sweden | Biomedicine/ Pharmaceutical Sciences | Master | Free for citizens ≈ €15,000/ year (for foreigners) | Global ranking, access to cutting-edge research, integration of science and clinical practice | Prospects in industrial pharmacy, international research |

A comparative analysis of EP in the field of pharmaceutical biotechnology and biopharmacy reveals significant differences between Ukrainian and European universities in terms of tuition fees, level of international integration, and employment opportunities.

In Ukrainian universities (Lviv Polytechnic National University, National University of Pharmacy, Taras Shevchenko National University of Kyiv), tuition fees are low (between €800 and €1,300 per year), which makes the EP accessible to students. At the same time, these programs are inferior in terms of material and technical resources and international integration. However, Ukrainian universities are gradually developing partnerships with European institutions, offering internships abroad, and involving students in scientific research, which increases their competitiveness.

In particular, Lviv Polytechnic National University offers a master's degree program in Pharmaceutical Biotechnology, with an estimated cost of approximately 55-58 thousand UAH per year (approximately €1550–1630). The program requires students to earn 90 ECTS credits and complete a master's thesis, with an emphasis on the integration of biotechnological and pharmaceutical disciplines²⁷.

²⁷ National University “Lviv Polytechnic”. Educational program: Pharmaceutical biotechnology. 2024. URL: <https://lpnu.ua/>.

Universities in European Union countries, in particular Jagiellonian University (Poland), offer master's programs in pharmaceutical biotechnology aimed at international students, which cost an average of €2,000–4,000 per year. An important advantage is the availability of English-language courses and internship opportunities in biotechnology companies²⁸.

At the University of Vienna (Austria), a master's degree in biotechnology and pharmaceutical sciences costs approximately €1,500 per year, making it one of the most affordable programs for international students among EU countries²⁹.

The highest level of scientific research is offered by ETH Zurich (Switzerland), which has a program in pharmaceutical sciences. The cost of tuition is CHF 1,460 (\approx €1,330) per year, but from fall 2025, it will increase to CHF 4,380 (\approx €4,000). Graduates of this university have a competitive advantage in the global labor market, as ETH is one of the ten best technical universities in the world³⁰.

At a number of state universities in Germany and Finland, master's degree programs in biotechnology or pharmaceutical sciences are often free of charge for foreign students, making these countries particularly attractive to Ukrainian students³¹.

Thus, the cost of studying pharmaceutical biotechnology varies significantly: from free programs in Germany and Finland to €4,000 in Switzerland. Ukrainian universities, in particular Lviv Polytechnic National University, offer more affordable programs, but their international integration and involvement in industrial internships needs further development³².

Summarizing the picture, we see that European universities (ETH Zurich, Karolinska Institute, University of Helsinki, German state universities) offer study programs with a strong research component, access to state-of-the-art laboratories, and a high level of international cooperation. At the same time, the cost of education varies from completely free (German state universities) to quite high (14–15 thousand euros per year in Sweden and Finland, up to 4380 CHF/year in Switzerland). This funding policy creates attractive conditions for students from different countries around the world, but at the same time requires significant financial costs from foreign students outside the EU/EEA.

²⁸ Jagiellonian University. Biotechnology and pharmaceutical sciences programs. 2024. URL: <https://international.uj.edu.pl/>.

²⁹ University of Vienna. Master programs in life sciences and biotechnology. 2024. URL: <https://www.univie.ac.at/>.

³⁰ ETH Zürich. Master in Pharmaceutical Sciences. 2024. URL: <https://ethz.ch/en/studies/>.

³¹ DAAD. Study programs in biotechnology and pharmaceutical sciences in Germany. German Academic Exchange Service, 2024. URL: <https://www.daad.de/en/>.

³² Study in Finland. Tuition fees and programs in biotechnology. 2024. URL: <https://studyinfinland.fi/>.

In terms of employment prospects, graduates of European universities have broader opportunities thanks to access to the international labor market and global pharmaceutical corporations. Graduates of Ukrainian universities, in turn, are in demand on the domestic market, especially in the fields of pharmaceutical manufacturing, clinical research, and drug development³³.

Thus, the analysis shows that European universities provide a higher level of research and practical training, but at a significantly higher cost of education, while Ukrainian universities remain more affordable and are gradually integrating into the international scientific and educational space.

The current situation in Ukraine poses significant educational and social challenges and differs greatly from that in European countries due to martial law and mobilization restrictions. While in European Union countries, pharmaceutical education is developing in a stable environment with a predictable labor market and academic mobility for students, in Ukraine, the education system is forced to function in a state of war.

One of the key factors contributing to the decline in the number of students enrolled in pharmaceutical programs is the mobilization of men and women who are subject to military service starting in 2025. This significantly limits opportunities to study abroad and participate in international exchange programs. While European students are free to choose universities and plan their academic careers, Ukrainian youth often face the need to postpone or even interrupt their studies.

At the same time, there is an outflow of Ukrainian youth abroad. A significant proportion of students, especially young women and men who have the opportunity to leave, choose European universities because they offer stability, high-quality educational programs, and no risk of mobilization. This creates an imbalance: the number of applicants to pharmaceutical/biotechnology programs in Ukraine is decreasing, while the proportion of Ukrainian students in EU countries is increasing.

In addition, the low cost of education in Ukraine, which is a competitive advantage, is losing its significance for many applicants due to safety concerns and the desire to obtain a European diploma, which opens up access to the global labor market.

³³ Polakovic M., Stastna M. Biotechnology education in pharmacy: Bridging academia and industry. *Biotechnology Journal*. 2019. Vol. 14, No. 7. P. 1800721. DOI: <https://doi.org/10.1002/biot.201800721>.

CONCLUSIONS

The introduction of the “Pharmaceutical Biotechnology” specialization into the higher education system is an extremely important step. It will ensure the training of a new generation of specialists capable of combining knowledge of biology, chemistry, genetic engineering technologies, and pharmacy to create innovative medicines. This will contribute to the development of the domestic pharmaceutical industry and Ukraine's integration into the global scientific and technological space.

The current situation in Ukraine poses significant educational and social challenges and differs greatly from that in European countries due to martial law and mobilization restrictions.

SUMMARY

The article in the monograph “Biotechnology in Pharmacy: The Latest Technologies for Manufacturing Medicines and Aspects of Biopharmaceutical Education” by authors Fedoryshyn O.M., Krychkovska A.M., Hubytska I.I. is devoted to reviewing the use of the latest achievements in biotechnology and bioengineering in the development of industrial pharmacy. The application of biotechnological methods has not only expanded the range of medicines, but also led to the creation of new high-quality drugs for replacement pharmacotherapy, the treatment of oncological diseases, and other urgent conditions. The article also justifies the need to create a new specialization, I8.03 “Pharmaceutical Biotechnology” for the specialty I8 “Pharmacy (by specialization)” in the field of knowledge I “Health Care and Social Security.”

The main reasons for the decline in the number of pharmacy students in Ukraine are: military registration of men and women and restrictions on mobility during martial law; migration of young people to Europe in search of a safer and more predictable educational environment; the growing value of a European diploma in the international pharmaceutical sector; psychological factors related to the war and uncertainty about the future in Ukraine.

In the long term, these processes may lead to a significant shortage of pharmaceutical personnel, which will negatively affect the development of the pharmaceutical sector in Ukraine's healthcare industry.

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