Our article is designed to summarize the results of the development of biomedical engineering (BME) as an educational and scientific field over the past decade and initiate a public discussion on the need for legislative consolidation in Ukraine of two components of this field: the engineering and the medical ones. In our previous article [1], we have discussed the "evolution" of BME as an educational field (considering primarily bachelor's and master's degrees in higher education). Now is the time for a detailed consideration of the challenges and prospects of this field in the context of the training of philosophy doctors and doctors of science. Let us note at once that when determining the prospects for the development of the field, we take into account both world experience (primarily — current trends in developed countries) [2–4] and the specifics of healthcare and engineering activities in Ukraine [5, 6].

As a consequence of the latest reform of higher education in Ukraine in 2015 [7], the specialty "Biomedical Engineering" has emerged (for the three levels of higher education: a bachelor, a master, and a philosophy doctor). World and Ukrainian experience shows that the higher the level of higher education, the greater the degree of diversification of the field and its interpenetration with other (related) specialties. The results of admission of applicants to the BME master and postgraduate programs at Igor Sikorsky Kyiv Polytechnic Institute shows that those who are interested in obtaining the appropriate education are bachelor's graduates in the fields of "Chemical and Bioengineering", "Automation and Instrumentation", "Biology", "Medicine". The trend of the last decade is to increase the share of interdisciplinary dissertation research directly related to BME and technology. Related to BME scientific works on the PhD level are performed in the framework of such specialties as "Biotechnology and Bioengineering", "Medical Diagnostics and Treatment Technologies", "Physical and Occupational Therapy", etc.
биоінженерія”, “Технології медичної діагностики та лікування”, “Фізична терапія, ерго-терапія” тощо. Спеціфіка вступу та навчання за відповідними освітньо-науковими програмами дає здобувачам із різною базовою підготовкою можливість безперешкодно оволодівати знаннями з БМІ та проводити такого роду наукові дослідження.

Іншою є специфіка підготовки докторів наук. До сьогодні в Україні не існує відповідної наукової спеціальності. Тому на навіщому кваліфікаційному рівні (доктор наук) наразі наявний весь комплекс проблем, що колись був притаманний рівням бакалавра і магістра [1]. Неподаліко Міністерство освіти і науки України винесло на громадське обговорення проект переліку наукових спеціальностей за галузями науки [8]. В рамках розробленого проекту передбачається уведення нової спеціальності “Біомедична інженерія та технології” у галузі технічних наук. Вважаємо, що такий крок повною мірою відображає сучасні тенденції наукового-технічного розвитку в Україні та світі. Разом із тим наукові дослідження, що ведуться у провідних наукових центрах світу та України й стосуються БМІ, мають не лише технічне спрямування — значна їх частина безпосередньо стосується теоретичної (фундаментальної) медицини. Одними із передових наукових центрів, що проводять такого роду дослідження, є, наприклад, Стенфордський університет, США, та Рейнсько-Вестфальський університет Аахена, Німеччина.

Варто пам’ятати про передумови виникнення БМІ як галузі у США та країнах Західної Європи у середині XX століття та “рушійну силу” цього процесу, якою стали саме лікарі, представники клінічної медицини. В останні два десятиліття в Україні спостерігається загострення таких самих проблем, що були характерні для розвинутих країн півостороніїх: клініцисти, які фокусуються на технологіях діагностики, профілактики та лікування, мають труднощі із формалізацією своєї наукової роботи в контексті наукової атестації. Тому єдиним рішенням цієї проблеми є поширення БМІ як наукової спеціальності також і на галузь медичних наук.

Вважаємо, що нова спеціальность “Біомедична інженерія та технології” (технічні науки) має увібрати у себе такі “старі” [9] спеціальності:

The specifics of admission and training in the relevant educational and scientific programs allow applicants with different basic training to master the knowledge of BME and conduct such research.

The specific of doctors of sciences training is different. To date, there is no relevant scientific specialty in Ukraine. Therefore, at the highest qualification level (Doctor of Science) we observe a whole range of problems that were once inherent in the bachelor and master levels [1]. Recently, the Ministry of Education and Science of Ukraine has brought up for public discussion a project of the new list of scientific specialties [8]. The developed project envisages the implementation of a new specialty "Biomedical Engineering and Technology" in the field of technical sciences. We believe that this step fully reflects current trends in scientific and technological development in Ukraine and the world. At the same time, scientific research conducted in the world and Ukrainian leading scientific centers and related to BME has not only a technical direction — many of them are directly related to theoretical (fundamental) medicine. Some of the leading research centers conducting this type of research are, for example, Stanford University, USA, and the Rhine-Westphalia University of Aachen, Germany.

It is necessary to keep in mind the preconditions for the origin of BME as a scientific field in the United States and Western Europe in the middle of the XX century and the “driving force” of this process — physicians, representatives of clinical medicine. In the last two decades, Ukraine has seen the aggravation of the same problems that were characteristic of developed countries half a century ago: clinicians focusing on diagnostic, prevention, and treatment technologies struggle with formalization of their research in the context of scientific attestation. Therefore, there is only one way to solve the issue — to recognize BME as a part of medical science.

We believe that the new specialty "Biomedical Engineering and Technology" (technical sciences) should include the following "old" [9] specialties:

- Biological and medical devices and systems (technical sciences);
- Transplantology and artificial organs (technical sciences);
- Biomechanics (technical sciences).
• Біологічні та медичні прилади і системи (технічні науки);
• Трансплантологія та штучні органи (технічні науки);
• Біомеханіка (технічні науки).

Нова спеціальність “Біомедична інженерія та технології” (медичні науки) має стати правонаступницею таких “старих” [9] спеціальностей:
• Трансплантологія та штучні органи (медичні науки);
• Біомеханіка (медичні науки);
• Медична та біологічна інформатика і кібернетика (медичні науки).

У рамках висунутої нами концепції наукової спеціальності “Біомедична інженерія та технології” пропонуємо для громадського обговорення формалізоване змістовне наповнення предметної області двох складових нової наукової спеціальності. Пропонуємо використати журнал “Innovative Biosystems and Bioengineering” як майданчик для обміну думками щодо подальшого розвитку БМІ як освітньої та наукової галузі в Україні (пропозиції просимо надсилати на електронну адресу редакції*) чи головного редактора**.

### SPECIALTY PASSPORT

**Biomedical Engineering and Technology** (medical sciences) (project)

**Specialty formula**

The field of theoretical medicine focused on the interaction of medical and biological devices, tools, products, materials, and systems with living organisms, due to physical, chemical and biological effects. The main areas of research are the experimental study of the safety of new medical and biological devices, tools, products, materials, and systems, the study of biological mechanisms of their action and manifestations of undesirable side effects, as well as preclinical study of their effectiveness.

**Research areas**

1. Research of the mechanisms of effect of medical and biological devices, tools, products, materials, and systems on living objects *in vitro* and *in vivo*, including both physiological and pathological processes.

2. Development and improvement of methods for assessing the effect of physical factors, chemicals (toxicity, biocompatibility), artificial and modified biological objects, mediated by the use (application) of medical and biological devices, tools, products, materials, and systems.

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2. Experimental (preclinical) study of safety and efficacy of new medical and biological devices, tools, products, materials, and systems, including determination of the efficiency of treatment regimes (modes), diagnostics, and prevention of pathological conditions on model systems.

3. Development and experimental study of biotechnical and biotechnological systems aimed at the restoration and correction of physiological functions or control (monitoring) of the physiological state of an organism, including methods of metabolic, biomolecular, genetic, cellular, and tissue engineering.

5. Development and experimental study of safety and effectiveness of methods, devices, tools, products, materials and systems designed to protect the human body from the adverse effects of physical, chemical, and biological factors. Obtaining and testing chemical and biological origin materials for the development of artificial organs and their parts.

6. Development of the methods and algorithms for evaluating medical technologies based on the use of new medical and biological devices, tools, products, materials, and systems on the relationship between cost and efficiency, safety, quality of life of the patient in alternative treatment (prevention).

7. Study of mechanical properties and structure of biological macromolecules, cells, biological fluids, soft and hard tissues (bioreology), individual organs and systems of humans and animals in normal and pathology in order to develop methods of treatment, prevention, and diagnosis of diseases.

8. Study of the organization, functioning, development, pathological states of living systems of different levels on the basis of information and cybernetic approaches, including for solving problems of medical diagnostics, forecasting the consequences of diseases, evaluating the effectiveness of medical interventions and technologies.

SPECIALTY PASSPORT

Biomedical Engineering and Technology (technical sciences) (project)

Specialty formula

The field of science and technology that investigates problems related to: creation of new and improvement of existing medical and biological de-
Research areas

1. Research of physical, chemical, and biological bases of construction of diagnostic, preventive, surgical devices, tools, products, materials, systems, and their components.

2. Research and development of new methods and tools for diagnosis, measurement of medical and biological parameters (indicators), as well as development of methods to improve their accuracy and reliability.

3. Research and development of new methods of calculation, design, manufacture, quality management, diagnosis, mathematical and other kinds of modeling of medical and biological devices, tools, products, materials, and systems, as well as methods, tools, and technologies for their maintenance, repair, and operation.

4. Development, research, and optimization of medical and biological life support systems in space flight conditions, as well as in other extreme conditions.

5. Development of methods for processing and registration of medical and biological information. Development and improvement of algorithmic and software methods and means of studying the organization, functioning, development, and pathological conditions of living systems at different levels of organization.

6. Development, research, and optimization of intelligent biotechnical systems, as well as means of biosafety provision (including control and forecasting) based on the achievements of basic medicine, physicochemical biology, bioengineering, and computer technology.
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[9] Order of the Ministry of Education of Ukraine dated September 14, 2011 No. 1057 "On approval of the List of scientific specialties".

7. Development and optimization of schemes for the construction and operation of telemedicine devices and systems.

8. Development of methods, means and research of mechanical properties and structure of living matter at all levels of its organization, in particular movement of biological liquids, heat and mass transfer, stresses and deformations in cells, tissues and organs, mechanical bases of regulation in biological objects.

9. Mechanics technology-driven development of means for research of properties and the phenomena in living systems, the directed influence on them and their protection against the influence of external factors.

10. Development of devices, tools, products, materials, and systems that replace human and animal organs, as well as their individual functions.