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PHARMACEUTICAL BIOTECHNOLOGY IN PHARMACY EDUCATION: USA PHARMACY SCHOOLS

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ABSTRACT

Pharmaceutical biotechnology, pharmacogenomics, pharmacogenetics, combinatorial chemistry, in close relation to high-throughput screening technologies, and bioinformatics are major advances that give a new direction to pharmaceutical sciences and education. Biotechnology influenced not only the pharmaceutical science and education but also the practice in pharmacies. The aim of our study was to review the scientific literature on biotechnology inclusion in pharmacy curriculum and to systematize the approaches that the colleges and schools of pharmacy in the United States of America (USA) apply to address this education. For the period 1989-2010 a total of 18 publications satisfying the search criteria were found. The articles were systematized in historical order following the date of publication.

The developments in modern pharmacy practice are taken into account and implemented in the pharmacy curriculum in the colleges and schools of pharmacy in the United States. In 78% of the USA universities this is achieved by integrating biotechnology content in the PharmD curriculum. Together with the development of biotechnology science the educational programs are improving but they still delay providing knowledge, especially for undergraduate students.

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Introduction

During the second half of the 20th century, the pharmaceutical science and practice were extensively shaped by the advances made in chemistry and biology which led to the discovery of new technologies for development of innovative, safer and more effective medicinal products (11, 18). At the beginning of 21st century a large number of new medicinal products were discovered as agents acting selectively on individual tissues or sites within the cells, thus achieving major safety and efficacy benefits. Genetic engineering and related technologies have promoted the development of a range of modern biotechnology medicinal products, jointly termed biopharmaceuticals or biotechnology-based drugs (17).

Biotechnology is an interdisciplinary science applied to living cells with the aim to produce substances and compounds essential to life and human wellbeing. Production methods used in biotechnology are focused on adding, subtracting, multiplying or dividing bio-molecules. In contrast, conventional pharmacy education lays emphasis on production of synthetic molecules in order to treat the symptoms of diseases (10).

Some medical applications of biotechnology for example include isolation of new antibiotics, improvement of insulin production, and development of malaria vaccines, of diagnostic tests for serious genetic diseases (e.g. hereditary cancers, diabetes and Huntington's chorea) and approaches for detection and treatment of AIDS (15). Thus near 25% of all new medicinal products now approved are biopharmaceuticals (17).

Pharmaceutical biotechnology, pharmacogenomics, pharmacogenetics, combinatorial chemistry, in close relation to high-throughput screening technologies, and bioinformatics are major advances that open a new horizon to pharmaceutical sciences and education (16).

Biotechnology influenced not only the pharmaceutical science and education but also the pharmacy practice. In some countries specialty pharmacies have been developed to offer services, medicinal products for individual patients suffering from chronic diseases, or people with acute conditions requiring biotechnological intervention. Such pharmacies are specialized in high-cost, high-risk conditions and deliver services and products directly to patients or institutions. They also work in close cooperation with third-party payers in order to ensure that drugs are being prescribed appropriately, used correctly, and discontinued when no longer needed (5).

As defined by Speedie et. al (13), major areas of impact of biotechnology on pharmacy practice can be identified as dispensing the proteins and proteinaceous medicinal products requiring often new delivery systems and special home health care (most of the medicines are administered parenterally); new medicines classes in the area of immunotherapy; new diagnostic tools based upon monoclonal antibodies or hybridization technology as well as new economic and ethical considerations concerning limited supply and/or increased costs of therapy, the appropriate use of diagnostics, and the role of pharmacy in the distribution and use of biotechnology derived medicinal products.

According to some authors (5), approximately 1% of the population needs a biotech medicinal product, either for acute treatment or for chronic maintenance. Clinical conditions that often require biotechnological intervention are organ transplantations, diabetes, HIV/AIDS, multiple sclerosis, haemophilia, growth hormone deficiency, infertility, hepatitis B and C, cancer etc. (5) Many vaccines and diagnostics are biotechnology derived products.

It is evident that biotechnology has a significant impact on modern pharmaceutical science and practice, as well as on the increasing number of biopharmaceuticals on the market. Biotechnological methods applied in pharmacy science and practice brings hope for new therapeutic interventions not only for diseases that require better treatment, but also for untreatable ones.

These developments in pharmaceutical science and practice call for a paradigm shift in pharmacy education.

The aim of our study was to review the scientific literature on biotechnology inclusion in pharmacy curriculum and secondly, to systematize the approaches that the colleges and schools of pharmacy in the United States of America (USA) apply to address this education.

Materials and Methods

Literature search was done through MEDLINE/PubMed, Scopus database search as well as by Internet-based search with the key words "pharmacy", "biotechnology", "biotechnology pharmaceutical education", and "biopharmaceuticals". For the period 1989-2010 a total of 18 publications satisfying the search criteria were found. We have limited the search only to publications related to North America as European publications will be reviewed in a separate work. The articles were systematized in historical order following the date of publishing.

The information for the curricula of the biotechnology related disciplines included in pharmacy education in USA universities was taken from the universities' websites. In total, 116 pharmacy schools' internet sites were observed and available information was classified according to the following criteria:

- availability of topics named biotechnology in the regular education;
- availability of postgraduate education courses on biotechnology;
- integrated elective or required education on biotechnology topics.

Results and Discussion

Publications devoted to biotechnology in pharmaceutical education

The presence of biotechnology in the pharmaceutical education in North America has been widely discussed in the scientific literature.

In 1989 Stewart and Fleming shared the opinion that the curriculum of students undergoing training in pharmacy should cover immunoglobulins, immunomodulators, growth hormones, targeted drug-delivery systems, and advanced diagnostic techniques that use biotechnology products due to the proliferation of biotechnology-derived products (14).

In her publication "The impact of biotechnology upon pharmaceutical education", Speedie (13) reviewed the professional curriculum of clinical pharmacy, pharmacy administration, pharmacology, medicinal chemistry, pharmaceutics, basic sciences, and continuing education, as well as the research in pharmacy schools, and graduate education. She defined a significant impact of biotechnology on pharmacy practice and education that needs to be more carefully examined. Henkel et al. (6), Block (2) and Hudson (7) have outlined specific curricula implications for undergraduate and graduate pharmacy study derived from the biopharmaceutical industry development that are the pharmacokinetic and physicochemical aspects of biotechnology-derived pharmaceuticals.

Speedie et al. (12) discussed approaches that were taken in incorporating biotechnology-related material into pharmacy curricula in the 90s. The authors identified three models of inclusion of biotechnology material into pharmacy curriculum: integration throughout an entry level PharmD curriculum, a separate biotechnology course, and a course focused on immunotherapeutics which addresses biotechnology issues in that context. An example of integrated biotechnology into the basic pharmaceutical sciences is given with the University of Mississippi where biotechnology is incorporated into numerous courses throughout the curriculum (biochemical foundation of therapeutics, pharmacogenetics, pharmacoimmunology, medicinal chemistry, human physiology and pathophysiology, basic pharmaceutics, pharmacology, patient assessment and therapeutic monitoring, biomedical ethics etc.). The University of Florida College of Pharmacy has developed and implemented stand-alone biotechnology course for the entry level PharmD curriculum. It is an elective course offered during the last semester of the third year after completion of core courses. The University of Texas used the third approach – specialized coursework in immunology, as large percentage of the biotechnology-derived products are related to the immune system, either as immunomodulators, vaccines, or monoclonal antibodies. The course has begun as an elective course and during the following year has become required. Speedie at al. (12) also presented the results of a survey concerning progress made in schools across the USA and perceived barriers to further progress. The survey represented 72 colleges/schools of pharmacy in the USA. The survey results showed that biotechnology-derived products were brought to pharmacy students' attention throughout various subjects such as biochemistry, pharmacology, applied therapeutics, pharmacoeconomics, etc. Some barriers to implementing a biotechnology course in the pharmacy curriculum were identified as "competition with other topics", "lack of teaching

tools" and "lack of information resources". Lack of personnel and administrative support was identified as a tertiary concern.

During 1996, a study was undertaken to assess pharmacists' evaluations of the program on pharmaceutical biotechnology. Out of the 145 total respondents: 93.1% considered the program to be a valuable learning experience; 85.7% considered the method a convenient and time saving means for professional continuing education; and 84.1% indicated that they would recommend the program to a colleague. Pharmacists agreed: 1) that course materials were presented in sufficient detail (94.5%); 2) with the quality of the audio cassettes (95.8%), printed materials (95.8%), and review check tests (81.9%); and 3) with the easy accessibility of an audio cassette tape recorder (95.9%). The importance of up-to-date biotechnology knowledge for pharmacists is confirmed by the development of a distance learning pharmaceutical biotechnology course which provides pharmacists with a practical review of cell molecular biology, recombinant DNA technology, and products developed through pharmaceutical biotechnology (4).

A survey of 52 pharmaceutical faculties/pharmaceutical biotechnology companies in Europe, Asia and America regarding their views about the creation of a satisfactory program of pharmaceutical biotechnology was done in 2001 (3). All participants in the survey were in agreement about the inclusion of pharmaceutical biotechnology courses in undergraduate teaching programs of pharmacy faculties. Most of the responding faculties of Europe and Japan stated that there were pharmaceutical biotechnology courses in their pharmacy curriculum. Respondents from the USA pointed out that pharmaceutical biotechnology courses should be included as 2-3 hrs/week in undergraduate programs as a mandatory course and the 2nd and 3rd years were suggested as the most appropriate initiation time. Most of the respondents suggested a 2-4 hrs/week for the duration of courses while the generally suggested initiation time was the 3rd year of the pharmacy undergraduate program. However, almost 50 % of the respondents suggested that these should be optional.

Biotechnology is often associated with pharmacogenetics and pharmacoeconomics. In 2005 Latif et al. (8) researched the extent and depth to which pharmacogenetics and pharmacogenomics were being taught in pharmacy schools in the USA. A survey was sent to 85 deans at colleges and schools of pharmacy in the USA. The results showed that although most of the surveyed schools provided some instruction in pharmacogenetics or pharmacogenomics and planed to increase it in the coming years; many did not provide the depth recommended by the American Association of Colleges of Pharmacy (AACP). Sixty-eight percent of the sampled colleges and schools planned to increase their pharmacogenomics/ pharmacogenetics instruction during the following 3 years.

Two policy resolutions were passed by 2008, when the AACP House of Delegates recommended greater focus on the advancement of education in biotechnology. The first one focused on the responsibility of pharmacy curriculum to address up-to-date issues related to biotechnology advances in tailored medicine. It discussed specific competencies such as biology, bioengineering, genetics/genomics, proteomics, nanotechnology, cellular and tissue engineering, bio-imaging, computational methods, and information technologies. The second policy concerned faculty development in biotechnology areas and stated that "faculty development programs and collaborative research and teaching strategies should be expanded such that faculty at colleges and schools of pharmacy are prepared to lead and contribute significantly to education and research…" in the abovementioned areas (1).

Another study conducted in 2010 revealed that 69 of 75 (92.0%) colleges out of 109 surveyed reported to be teaching pharmacogenomics within any of their programs, and 67 (89.3%), within their current PharmD curriculum. As discussed by the authors, this was an increase compared with earlier results (8) that 78% of the programs were providing this content in any program, and 39% were providing it in the PharmD curriculum. The main conclusion the authors made was that at the time of their study the majority of the colleges of pharmacy were providing some level of biotechnology instruction within their curriculum, indicating an increased awareness of the need to do so, and thus demonstrating alignment with AACP recommendations about including this material within the PharmD curriculum (9).

Biotechnology in pharmacy curriculum in the USA

There are 115 schools of pharmacy in the USA. Unlike pharmacy education in most EU countries, the schools of pharmacy in the USA offer PharmD programs (leading to Doctor of pharmacy degree). The eligible candidates shall be graduated from a school or college of pharmacy accredited by the American Council on Pharmaceutical Education or recognized by the relevant State Board of Pharmacy, or have completed equivalent education and experience outside the United States, approved by the relevant State Board of Pharmacy. PharmD duration is 4 years. During the two pre-pharmacy years students study general chemistry, general biology, organic chemistry, computers, anatomy, physiology, physics, economics, public speaking, Afro-American history etc.

At the time of the study of Speedy et al. (12) many schools of pharmacy had already made progress in incorporating biotechnology material into their curricula either through individual courses or integration throughout the curriculum.

The results for the studied schools of pharmacy are presented in **Fig. 1**. In 90 universities (78%) biotechnology is incorporated into different topics (**Table 1**). Twenty-two universities (19%) offer a separate biotechnology course. Three universities developed elective biotechnology courses besides the biotechnology topics incorporated in different subjects.

In the universities where biotechnology is integrated in the curriculum, biotechnology-related knowledge is distributed in cellular biology, biochemistry, pharmacogenomics, etc. (**Table 1**).

TABLE 1

Subjects addressing biotechnology

Subject	Content/Subject matter
Biology	Molecular biology terminology. Immunology. Monoclonal antibodies.
Microbiology	Drug-producing microorganisms. Biopharmaceutical products.
Biochemistry	Protein chemistry. Gene expression. Molecular control mechanisms. Biotechnology/hybridization technology.
Genetics	Gene expression. Functional and structural genomics.
Medical devices	Biopharmaceutical products delivering systems: insulin pumps, implants etc.
Pharmaceutical technology	Drug delivery of proteins across membranes. Liposomal drug delivery. Manufacture of biopharmaceuticals. Targeted dosage forms.
Pharmaceutical chemistry	Biotechnology-derived products. Manufacture of biopharmaceuticals. Recombinant DNA and hybridization technologies.
Pharmacology	Biotechnology-derived products. Immunomodulators, trombolytics, blood coagulation factors, insulin products, anticancer drugs, interferons, vaccines, antibodies etc. Molecular mechanisms of biopharmaceuticals' actions. Genes involved in drug response and adverse drug reactions. Personalized medicine.
Social pharmacy and pharmaceutical legislation	Biopharmaceuticals and ethics. Pharmacoeconomics of biopharmaceuticals. Handling of biopharmaceuticals during storage and transportation. Dispensing. Pharmacogenetics. Pharmacovigilance of biopharmaceuticals.

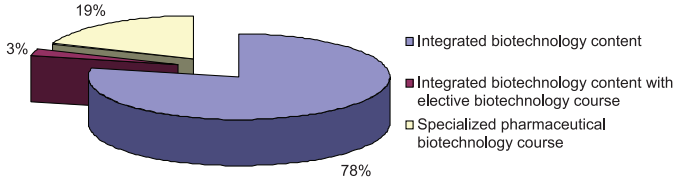

Fig. 1. Content of biotechnology in PharmD programs in the USA.

Topics addressed in cellular and molecular biochemistry include DNA/RNA/protein structure and synthesis, signal transduction pathways, gene regulation, organelle function and regulation, enzyme kinetics, energy catalysis, and bacterial/viral biology and it serves as a foundation for understanding the cellular and biochemical actions of drugs.

Besides the courses on biochemistry and molecular biology, some universities offer a laboratory course on experimental methods of biochemistry and molecular biology with emphasis on problem solving (e.g. Samford University in Alabama). Pharmacogenomics is focused on gene structure, DNA replication, transcription, translation, and recombinant DNA technology used in production of biotechnology-derived medicinal products.

In addition, some universities offer specialized pharmaceutical biotechnology courses in PharmD programs during the professional years (Medical University of South Carolina, West Virginia University, University of Wisconsin-Madison, University of Iwova, Massachusetts College of Pharmacy and Health Sciences, University of Oklahoma, Palm Beach Atlantic University etc.). The pharmaceutical biotechnology course teaches recent developments in the synthesis, structure, and function of biologically active peptides and their relationship to the treatment of disease in man.

Principles of immunology as applied to drug development and utilization with emphasis on immunotherapeutic agents. The specialized combined biotechnology and immunology course at Wilkes University, School of Pharmacy, Pennsylvania, focuses on discussion of non-specific host defence mechanisms and a detailed description of specific immunity. Products that impair artificial active and passive immunity are presented. The concept of biotechnology is discussed together with the currently available immunology-related products of genetic engineering. The various immunological disorders and the immunology of cancer and HIV are discussed. At Ferris State University College of Pharmacy the biotechnology course is combined with a molecular biochemistry course, while at Husson University in Main biotechnology is combined with pharmacogenomics.

In Palm Beach Atlantic University biotechnology content is combined with immunology. This combination provides an overview of infectious organisms, pathogenic mechanisms; antimicrobial agents that are used to treat such infections, mechanisms by which organisms develop resistance, and epidemiologic patterns of common infections. Students are focused on application of biotechnology in creating diagnostic and therapeutic immune agents. In Massachusetts College of Pharmacy and Health Sciences pharmaceutical biotechnology is taught during the second professional year, while in some universities it is taught during the first professional year (Sullivan University in Kentucky).

The third approach is an integrated biotechnology content combined with an elective biotechnology course. As an elective, the Scaggs School of Pharmacy offers a course on bio business for 3rd year pharmacy students. The students analyze start-up proposals, the genesis of the biotech industry, biotech categories and growth strategies, the process of spinning out

viable product concepts from academia, financing techniques, business development etc. In the University of Washington the biotechnology elective course is focused on biomedical ethics and pharmaceutical biotechnology and is taught during the last 4th year.

Available publications on biotechnology education in pharmacy schools and colleges in North America are relatively few but from the historical point of view this education is still developing. In comparison with other subjects in the curriculum, it started relatively recently and from the beginning it was focused on product knowledge, while later was further developed to knowledge on technology processes and product usage. After 2000, the biotechnology developments led to the creation of separated branches of science such as pharmacogenetics and pharmacogenomics that were included in the pharmacists' postgraduate education.

The adequate reflection of recent developments in modern pharmaceutical science and practice driven by biotechnology methods in the pharmacy curriculum is very important to ensure safe and rational use of biopharmaceuticals. Prescribers need to have access to trained pharmacists who can address their concerns and problems. In that way payers and healthcare institutions would be assured that biotech drugs are being used properly and according to the established guidelines and patients and their families would receive updated information on modern effective therapy. Thus, designation of biotechnology as a pharmacy specialty would be beneficial to all concerned parties: payers, health institutions, patients etc. As a general principle, the pharmacy education needs to be shaped to the needs of biotechnology-based pharmaceutical industry and clinical practice. As pharmacists accept the responsibility of dispensing, monitoring, and providing information about the new biotechnology-derived products, they will enhance the rational use of these pharmaceuticals (14).

In light of these considerations, it has been suggested that if pharmacists are to take a significant role in biotechnology applications in pharmacy practice, then schools of pharmacy need to offer a more structured, formalized process of teaching this important topic (8). The developments in modern pharmacy practice are taken into account and implemented in the pharmacy curriculum in the colleges and schools of pharmacy in the United States. In 78% of the USA universities this is achieved by integrating biotechnology content in the PharmD curriculum. Regardless of the approach chosen, future pharmacists are provided with knowledge, skills and attitudes to be more competitive in the health care system, pharmacy practice-related fields, pharmaceutical industry and drug research and development areas related to biotechnology-derived products. Educators have the responsibility to decide how these new directions in the education programs should be implemented having in mind the increasing importance of biotechnology-derived products in pharmacists' daily life.

Conclusions

Together with the development of biotechnology science the educational programs are improving but they still delay to provide knowledge, especially for undergraduate students. The educational model that dominates is more oriented towards inclusion of the biotechnology topics in different disciplines and to a lesser extent, towards providing separate topics. There is still no structured and unified approach to biotechnology education in the observed colleges.

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