# ACTUAL ISSUES OF FORMATION OF PROFESSIONAL COMPETENCES OF FUTURE PROFESSIONALS WHEN STUDDING GOOD PHARMACEUTICAL PRACTICES

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### INTRODUCTION

The formation of competencies of future professionals for the pharmaceutical field, taking into account the relevance and expectations of potential employers, is an important component in the development of educational-and-professional (EPP) and educational-and-scientific programs (ESP) at all cycles of higher education (HE).

For this reason, the meetings of professors and students with employers, among which "Arterium" Corporation – the leading pharmaceutical enterprise in the region, are held systematically at the Lviv Polytechnic National University.

At one of such meetings, in 2016, precisely the employers of "Arterium" Corporation paid attention to the insufficient knowledge level of the Good Pharmaceutical Practices (GPP) complex in the professional training of pharmacy specialists. Employers noted, first of all, it is necessary to carry out the advanced training the newly hired specialists on this topic. For this purpose, the annual cycles of lectures of leading specialists of the enterprise for senior year's students were organized within the framework of the cooperation. The trainees received appropriate certificates, which were taken into account by the employer when considering applications for internships at the corporation, and this, in turn, fostered future employment.

The Scientific and Methodological Commission of the specialty "Pharmacy, Industrial Pharmacy" conducted the all-round analysis of this problem and as results, the revision and updating of existing EPP and ESP of the three cycles system of HE have been conducted.

It should be noted that according to the Cabinet of Ministers of Ukraine (CMU) Resolution No. 266 of 29.04.2015 "On Approval of the list of branches of study and specialties, for the training of higher education applicants" (with amended), the Order of Ministry of Education and Science of Ukraine No. 1151 of 06.11.2015 "On the features of introduction of the list of branches of study and specialties for the training of higher education applicants", a specialty 15.00.01 "Technology of drugs, organization of

pharmaceutical business and forensic pharmacy" was renamed to specialty 226 "Pharmacy, Industrial Pharmacy" (branch of study 22 "Healthcare").

The new specialty was considered related to the specialty 15.00.01 "Technology of drugs, organization of pharmaceutical business and forensic pharmacy". It was licensed in 2016 and implemented at the Department of Technology of Biologically Active Substances, Pharmacy and Biotechnology of Lviv Polytechnic National University for the training of HE applicants by the third (educational-and-scientific) cycle.

Admission for specialty 226 "Pharmacy" (since 2017 – "Pharmacy, Industrial Pharmacy" following amendments to the list of specialties) at the third (educational-and-scientific) cycle study is based on the diploma of HE by the chemical and pharmaceutical specialties and entrance exam results. Accordingly, since 2016, students' admission for the first and second cycles study was carried out by the specialty 226 "Pharmacy" (similarly, since 2017 – "Pharmacy, Industrial pharmacy"). Therefore, these prerequisites have allowed the Lviv Polytechnic National University to develop new EPPs and ESPs for all three cycles of HE and to take into account the expectations of employers.

Our research aimed to summarize the experience on revision the EPP and ESP for the specialty 226 "Pharmacy, Industrial Pharmacy" in Lviv Polytechnic National University and to make the comparative analysis of corresponding educational programs (EP) in Danylo Halytsky Lviv National Medical University concerning the teaching of the GPP complex, that provides formation of certain competencies of future specialists for pharmacy branch.

# 1. The principles of creation of educational-and-professional programs and the system of learning outcomes assessment at the Lviv Polytechnic National University

The unified List of the branch of study, elaborated in Ukraine in 2016, allowed combining the different Lists of branches of study and science. It was based on ISCED-2013 (International Standard Classification of Education) and necessitated the creation of new EPPs for specialties that previously had other names<sup>1</sup>. Such an approach to the implementation of international standards is justified since the classification of education based on ISCED is harmonized with the Standard Industrial Classification of All Economic Activities (SIC), which has become an important condition for

<sup>&</sup>lt;sup>1</sup> ISCED Fields of Education and Training 2013 (ISCED-F 2013), UNESCO Institute for Statistics, Montreal. URL: http://www.uis.unesco.org/Education/Documents/isced-fields-of-education-training-2013.pdf

appropriate training of specialists in relation to labor market needs. The National Standard Classification of Education<sup>2</sup> is a tool for transparency of HE in Ukraine, which is towards integration into the European and international educational space.

The Law of Ukraine "On Higher Education" also provided for a change in the concept of the organization of education: from a teacher-oriented to a student-centered approach, from a process-centered to learning outcomes (LO) approach. It was necessary to standardize not the list of normative disciplines, but the list of graduate competencies and the normative content of training, which are defined as "learning outcomes"<sup>4</sup>. The reform in HE in Ukraine has led to the development of the student-centered learning conception aimed the forming a qualified competitive specialist, capable of the research-andinnovative type of thinking, who needs continuous professional development and has the appropriate skills. The student-centered approach requires direct, meaningful discussion between students, professors, and the administration of the HE institution regarding the design and organization of the training program. The program should provide students with an opportunity to choose courses, create individual educational paths, elective classes. Therefore, it is extremely important that this program should have a flexible structure. The flexible organization of learning, teaching and self-assessment activities, including schedule flexibility, are also important. It is necessary to introduce interactive learning systems into the educational process, to provide the participants of this process with the possibility of self-improvement, self-control of knowledge. independent work with educational materials in the mode and volume that satisfies them, as well as the choice of a rich information base, various ways of communication, including interactive, for solving educational problems and forming the specialists competencies<sup>5</sup>.

Implementation of the Law of Ukraine "On Higher Education" at Lviv Polytechnic National University is carrying out by the development and

<sup>&</sup>lt;sup>2</sup> Національна стандартна класифікація освіти. Національна академія педагогічних наук України. URL: http://naps.gov.ua/uploads/files/sod/NSKO.pdf

<sup>&</sup>lt;sup>3</sup> Про вищу освіту: Закон України від 01.07.2014 р. № 1556-VII. Дата оновлення: 16.01.2020. URL: https://zakon.rada.gov.ua/laws/show/1556-18

<sup>&</sup>lt;sup>4</sup> Koster A., Schalekamp T., Meijerman I. Implementation of Competency-Based Pharmacy Education (CBPE). Pharmacy. 2017. Vol. 5(1). 10–26. DOI 10.3390/pharmacy5010010.

<sup>&</sup>lt;sup>5</sup> Zubin A. Competency and its many meanings. Pharmacy. 2019. Vol. 7(2). P. 37. DOI 10.3390/pharmacy7020037.

Parson L., Childs B., Elzie P. Using competency-based curriculum design to create a health professions education certificate program that meets the needs of students, administrators, faculty, and patients. *Health Prof. Educ.* 2018, Vol. 4, P. 207–217. DOI 10.1016/j.hpe.2018.03.008

approval of internal standards for QA in education, including those concerning the Higher Education Standard (HES) – HES LP 02 "Student-centered learning":

HES LP 02.01. Regulations on the organization of educational process at Lviv Polytechnic National University;

HES LP 02.02. Regulations on the organization of educational process for postgraduate (PhD) students and for Doctor of Philosophy applicants beyond PhD studies at Lviv Polytechnic National University;

HES LP 02.03. Regulations on the academic mobility for applicants of bachelor, master, doctoral and postdoctoral studies and academic staff at the Lviv Polytechnic National University;

HES LP 02.04. Regulations on the organization of students' practical training (PT) at Lviv Polytechnic National University;

HES LP 02.05. Regulations on the organization of the courses teaching in foreign languages;

HES LP 02.06. Regulations on the organization and monitoring of students' independent extra-auditorium learning;

HES LP 02.07. The procedure of organization of study according to student's individual schedules;

HES LP 02.08. Regulations of the student's research work at the Lviv Polytechnic National University;

HES LP 02.09. Regulations on the provision of paid educational services of students learning certain disciplines and other components of the curriculum in excess of the syllabus established at the Lviv Polytechnic National University;

HES LP 02.10. Regulations on the organization of the Ukrainian student's Olympiads at the Lviv Polytechnic National University.

HRS LP 02.11. Regulations on the organization of the Ukrainian competition of the student's scientific projects according to the branch of study and specialties.

Consequently, student-centered learning involves educational methods that shift the focus of education from teacher to student. The principles of student-centered learning are as follows: 1) the teacher should not be a lecturer, but a facilitator of the learning process; 2) he/she provides successful group communication; 3) not so many lectures, but more research, discussions, and projects; 4) application of flip learning, problem-based learning; 5) clickers. The tasks of the EPP/ ESP development team consisted not only creation of training programs, but also solving the following questions: 1) introduction of student-centered learning practices into the educational process; involvement of employers in the development of educational programs (EP); 2) student's participation in the training programs formation; 3) student's choice of subjects; 4) implementation of contemporary quality assurance (QA) practices into the activities of Lviv Polytechnic National University.

Environmental, Social, and Governance (ESG) criteria as QA standards and recommendations in the European Higher Education Area (EHEA)<sup>6</sup> according to the European Association for Quality Assurance in Higher Education (ENQA) provides for student-centered learning and teaching: 1) respect and attention to the diversity of students and their needs, making it possible flexible learning trajectories; 2) the application of different appropriate ways of material's presentation; 3) flexible use of various pedagogical methods; 4) regular evaluation and correction of material supply and pedagogical methods; 5) encouraging students' independence while providing proper mentoring and support from the teacher; 6) developing mutual respect in the relationship between the student and the teacher; 7) proper response to student complaints. Also, teachers should be aware of the available methods of examination and control of knowledge and must receive support in developing their skills in a certain area. Assessment methods, as well as evaluation criteria, should be notified previously. The assessment allows students to demonstrate the level of achievement of the intended LO. Students receive feedback, accompanied, when necessary, with advice on the learning process. If it is possible, more than one examiner measures student learning. The rules of assessment of LO should provide an opportunity to take into account mitigating circumstances. The assessment is applied consistently and fairly to all students and is conducted according to established procedures. There is a formal procedure for student appeals.

An internal system for assessing the quality of education is being formed at the Lviv Polytechnic National University. Student-centered learning is the main element of this system. For example, the involvement of students in the process of QA in an educational system is a fundamental principle of the regulation, and its purpose is an ensuring the requirements and expectations of the educational service seekers (entrants, students, PhD students). Particular attention is paid to the introduction of student-friendly forms and methods of learning, interactivity, mobility and mentoring.

The possibility of identification, quantification, and measuring are important for LO estimation.

The development of EP and systems for LO estimation can be represented as an informational outline of the relationship between elements of the HE system. The informational outline (Fig. 1) can be viewed from different perspectives: as an elements of the websites of HE establishments, including the electronic office of the HE seeker; as an opportunity for the employer to get acquainted with EPP/ESP, syllabus on disciplines, the system of LO assessment and to influence them in a certain way.

<sup>&</sup>lt;sup>6</sup> Standards and guidelines for quality assurance in the European Higher Education Area (ESG). Brussels, Belgium: European Association of Institutions in Higher Education. 2015. 27 p. URL: https://enqa.eu/index.php/home/esg/

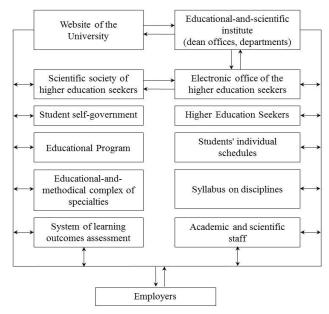


Fig. 1. Information outline of the relationship between the elements of the system of creation of educational-and-professional programs and the system of LO assessment

Also, the procedures for creating students' individual schedules, as well as the possibility of communication between HE seekers within their own partnership and student self-government are clear and transparent.

# 2. Elaboration of the structural-and-logical framework and defining competencies for disciplines at the first cycle study (bachelor program) at Lviv Polytechnic National University

Structural-and-logical framework of bachelor training (the first educational-and-qualification cycle) for specialty 226 "Pharmacy, Industrial Pharmacy" contains 2 selective blocks: "Pharmacy" and "Technologies of pharmaceutical preparations" (Fir. 2–3).

The 2 specializations – 226.1. "Pharmacy" and 226.2. "Industrial Pharmacy" within specialty 226 "Pharmacy, Industrial Pharmacy" have proposed at a meeting of the Scientific-and-methodological commission of the Ministry of Education and Science of Ukraine. Consequently, developed selective blocks are relevant.

We have selected competencies that are formed by the appropriate disciplines (table 1).

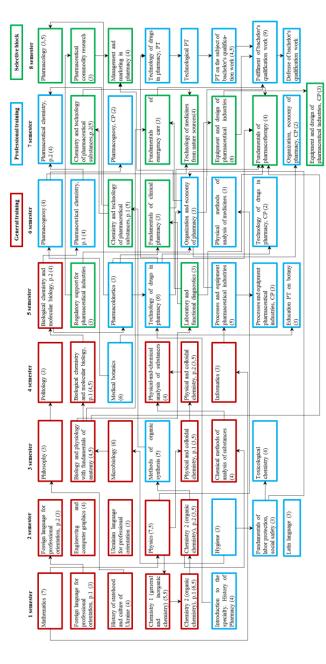


Fig. 2. The structural-and-logical framework of the first cycle study (bachelor program) at Lviv Polytechnic National University (PT - practical training; CP - course project) for specialty 226 "Pharmacy, Industrial Pharmacy", subject block "Pharmacy"

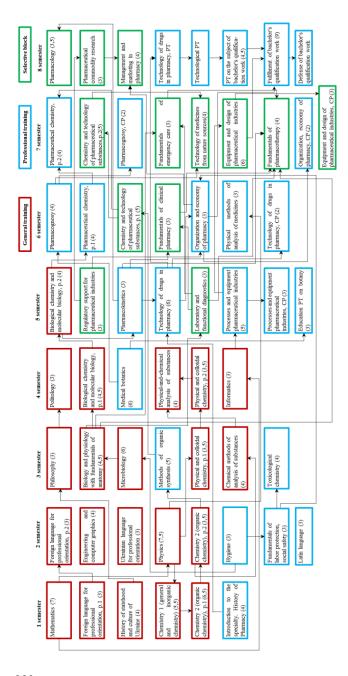


Fig. 3. The structural-and-logical framework of the first cycle study (bachelor program) for specialty 226 "Pharmacy, Industrial Pharmacy", subjects bloc "Technologies of pharmaceutical preparations" at Lviv Polytechnic National University (PT – practical training; CP – course project)

# Competences acquired in learning of separate disciplines

2	Subject	Amount of credits	Competencies (PC – Professional competences; Program outcomes: KN (knowledge), SK (skills)
1	Drugs technology	8 (including course	PC11. Knowledge concerning current methods of quality control of pharmaceutical products.
		project)	project)  FC.28. Ability to analyze raw materials, intermediates products, mushed pharmaceutical products.  project)  KN15. Knowledge of a variety of dosage forms of pharmacy production, the technology of their preparing and application.
			KN21. Knowledge of chemistry and technology of different classes of medicines, requirements for quality of raw materials and final products.
			SK14. Reasonably choose the appropriate method of dosage form manufacturing, be able to make the necessary calculations and make it
2	Pharmacokinetics	33	KN17. Basic knowledge of pharmacokinetics the most important medicines for clinical practice.
			KN30. Knowledge of classification, pharmacological properties, applications, mechanisms of action, routes of administration, absorption, distribution, metabolism, and excretion of drugs, side effects, indications, and contraindications.
			SK16. To apply knowledge of the drug's pharmacokinetics to predict their effects on the human body and prevent side effects.
3	Organization and economics of	5 (including course	PC34. Ability to understand and consider the social, ecological, ethical, economic aspects that influence the formation of (including course rechnical decisions.
	pharmacy	project)	KN18. Knowledge of production, the practical and economic activity of pharmacy enterprises, fundamentals of accounting and reporting of pharmacy enterprises.
			SK17. To create and organize pharmacy enterprises, to provide them with medicines and medical products, to conduct operative accounting and to report on the activity of the pharmacy.
			SK18. Effectively motivate yourself and your subordinates to perform assigned the practical tasks.
4	Physical methods of medicines	c	PC7. Ability to apply knowledge of specific methods of physical-and-chemical studies to identify organic compounds, substances of different classes, including potential medicinal substances.
	analysis		PC11. Knowledge concerning current methods of quality control of pharmaceutical products.
			SK27. To be able to summarize and systematize information on chemical structure, physical properties, methods of obtaining and analyzing novel medicinal substances.
5	Regulatory support for	3	PC23. To demonstrate the accounting record-keeping skills, to know definitions following international requirements and principles.
	pharmaceutical industries		PC24. To identify and perform validation work necessary to confirmation of critical aspects control for specific manufacturing operations.

Ne e	Subject	Amount of credits	Competencies (PC – Professional competences; Program outcomes: KIN (knowledge), SK (skills)
v	Regulatory support for pharmaceutical industries	r	KN4. To have basic knowledge of legislation and reference materials, current standards and specifications, instructions and other documents concerning pharmacy and industrial pharmacy.  KN26. To know the legislation concerning the manufacturing of pharmaceutical products, the main categories of normative documents on standardization process, requirements for their content and composition; general principles of pharmaceutical product quality management, a regulatory framework for good manufacturing practice; plan of works on product and manufacturing certification.
9	Equipment and design of pharmaceutical industries	9 (including course project)	9 PC3. Ability to use regulatory-and-technical documentation necessary for engineering activities in the pharmacy branch and (including course the ability to draw up technical documentation when designing a pharmaceutical production.  Project) PC16. Ability to choose the optimal parameters of the manufacturing processes of medicines (including veterinary, medical-and-cosmetic preparations and preparations of natural raw materials).  PC17. Knowledge about types of equipment for pharmaceutical industries, features of using and principles of operation of different devices.
			PC20. To apply the acquired knowledge and understanding for identification, formulation and solving the problems of the creation and functioning of chemical-and-pharmaceutical industries.  PC23. To demonstrate the accounting record-keeping skills, to know definitions following international requirements and principles.
			PC29. The ability to apply and integrate knowledge and understanding of different engineering disciplines for drawing up a technological-and-equipment scheme of manufacture with automation and supply of energy sources and systems of the utilization of planmaceutical waste from manufacturing facilities.  10.70. The ability to apply basic knowledge of technical, algorithmic, information and computer software for modeling and computer designing hased on the planmaceutical manufacturing miniciples.
			PC35. The ability to manage technological processes and maintain an enterprise quality management system.  KN6. To know the legislative framework that regulates the rules for the organization and management of the manufacturing process at the chemical-and-pharmaceutical enterprises.
			KN16. To know the main devices and processes of pharmaceutical industries (separation, heat transfer, mass transfer, extraction, drying, etc.).  KN24. To know the influence of the main factors on the structure of technological equipment, the characteristics of metals, which was used for malitime activities of anniment for pharmical and advertises.
			when are used to making equipment, types or equipment for excinicar-annequation monoranes.  KN26. To know the legislation concerning the manufacturing of pharmaceutical products, the main categories of normative documents on standardization process, requirements for their content and composition; general principles of pharmaceutical product quality management, a regulatory framework for good manufacturing practice; plan of works on product and manufacturing certification.

Fable 1 (ending)

Amount
of credits
9 SK5. To participate in the organization, research, and modernization of chemical-and-pharmaceutical industries and set (including course tasks for the current repair of production equipment.
project) SK6. To compose technological block-scheme and equipment diagram of chemical-and-pharmaceutical manufacture, to carry out material, technological, thermal calculations for production processes.
SK9. To develop a project of chemical-and-pharmaceutical manufacture, using the legislation and reference engineering-and-technical literature.
SK10. To draw up the technological flowcharts, equipment, and devices, schematic diagrams of technological and construction implementation of manufacture using computer programs.
SK11. To develop a plan for the location of equipment, workplaces, according to legislation and standards, taking into account technology requirements.
SK23. To design new technological schemes for drug manufacturing, perform the calculation for the technical project in the development of new manufactures, to operate, calculate and select equipment for the modernization of technological processes.
SK25. To compose technological regulation for pharmaceutical products, to analyze production situations, to record them and to make decisions on compliance with the requirements of legislation, to certify working places.
PC31. The ability to apply commercial and economic contexts to the design of pharmaceutical industries, to conduct a technical-and-economic evaluation of manufacture or scientific-and-technical development, and to manage and market pharmaceutical products.
PC35. The ability to manage technological processes and to maintain an enterprise quality management system.
KN22. To know the fundamentals principles of organization of chemical-and-pharmaceutical industry, production management; principles of creation, research, registration of medicines; Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) systems, principles of industrial manufacturing of medicines, state system of quality control of medicines, fundamentals of pharmaceutical marketing and foreign economic activity of the enterprise.
SK21. To organize work on creation and registration of chemical-and-pharmaceutical enterprise, to make its development plan; conduct research and industrial manufacturing of medicines; to carry out export-import operations.

An analysis of the content of the EPP by component groups and training cycles was also conducted (table 2).

Table 2

The division of EPP by component groups and training cycles

	Cycle	The volume of academi (cred	ic load for HE ap its /%)	plicants	
№	Cycle training	Mandatory components of EPP	Selective components of EPP	Total	
1	General training cycle	90/38	12/5	102/43	
	Professional training cycle	88,5/37	49,5/20	138/57	
Tota	1	178,5/75	61,5/25	240/100	

# 3. Elaboration of the structural-and-logical framework and defining competencies for disciplines at the second cycle study (master program) at Lviv Polytechnic National University

The training of masters and master of research is carried out for organizational-and-managerial, investment and scientific-and-research activity, for training of teaching and scientific reserve of HE establishments, research institutions in the pharmacy and industrial pharmacy branch, as well as for the manufacture of medicines, their storage, quality control, delivery, distribution, regulation of drug supply, as well as advice, provision of information on medicinal products.

Structural-and-logical framework of master training (the second educational-and-qualification cycle) for specialty 226 "Pharmacy, Industrial Pharmacy" contains 2 selective blocks: "Pharmacy" and "Technologies of pharmaceutical preparations" (Fir. 4–7).

The courses provide the students' competences according to the requirements of the HE standard (table 3).

The results of analysis of the content of the EPP by component groups and training cycles are presented in table 4.

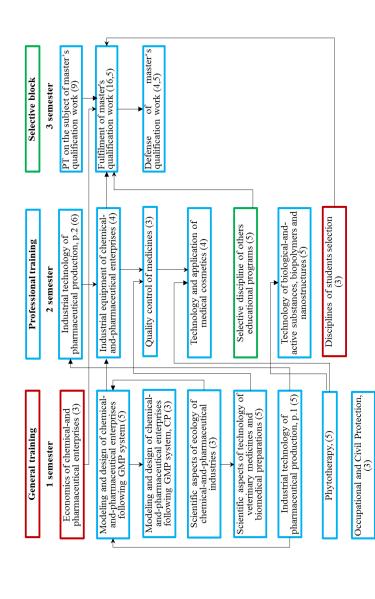


Fig. 4. The structural-and-logical framework of the secong cycle study (master program) for specialty 226 "Pharmacy, Industial Pharmacy", line 01 "Technologies of pharmaceutical preparations" at Lviv Polytechnic National University (PT – practical training; CP – course project)

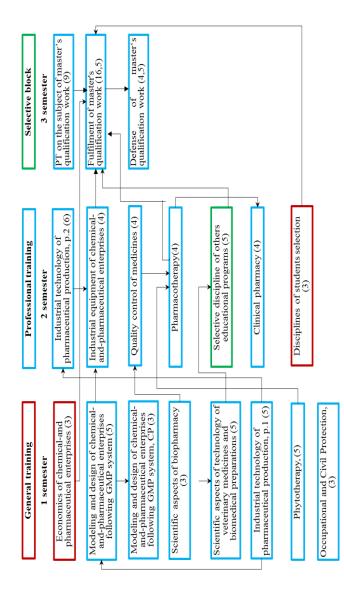
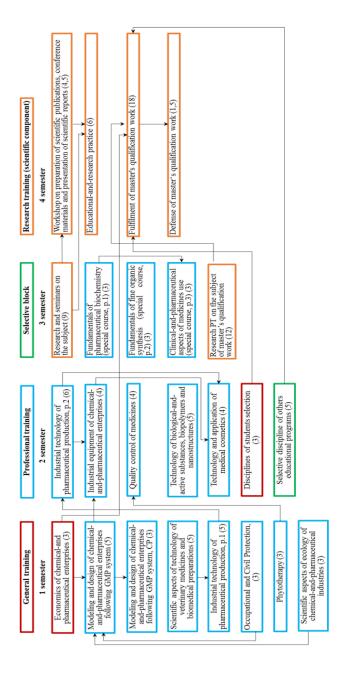
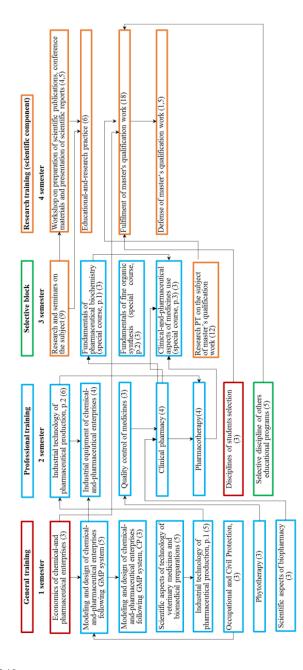


Fig. 5. The structural-and-logical framework of the secong cycle study (master program) for specialty 226 "Pharmacy, Industial Pharmacy", line 02 "Pharmacy" at Lviv Polytechnic National University (PT – practical training; CP – course project)



preparations" at Lviv Polytechnic National University (PT - practical training; CP - course project) Fig. 6. The structural-and-logical framework of the second cycle study (master of research program) for specialty 226 "Pharmacy, Industial Pharmacy", line 01 "Technologies of pharmaceutical



for specialty 226 "Pharmacy, Industial Pharmacy", line 02 "Pharmacy" at Lviv Polytechnic National Fig. 7. The structural-and-logical framework of the second cycle study (master of research program) University (PT – practical training; CP – course project)

Competences acquired in the learning of separate disciplines at the second cycle study

	MP ss of nd nitary	t, the
Competencies (PC – Professional competences; Program outcomes: KN (Gnowledge), SK (skills)	PC14. The current concepts in modeling, scaling and validation of pharmaceutical manufacture following the GMP system.  PC16. The ability to use professionally profiled knowledge of mathematical statistics for statistical analysis of experimental data and mathematical modeling of chemical-and-plaamaceutical processes.  PC17. The ability to use theoretical knowledge and practical skills in the activity and modemization of pharmaceutical enterprises.  PC18. The ability to use theoretical knowledge and practical skills in the activity and modemization of manaceutical enterprise.  KN3. To know the fundamentals principles of design technologies, organization of the projection process, futures of industrial and auxiliary premises planning.  KN4. To know the fundamentals principles of construction design of chemical-and-pharmaceutical enterprises and rules of technological equipment layout.  KN19. To know the classes of fire and explosion hazard of industrial premises and substances, their toxicity, sanitary protection zones, safe working environment for employees of chemical-and-pharmaceutical enterprises.  SK3. To design new technological schemes for medicines manufacturing.  SK4. To observe the issue of building design using standard unified building components and typical standard equipment. SK 16. The ability to design chemical-and-pharmaceutical enterprise following safety rules and GMP standards.	PC3. The ability to develop technological processes and manufacturing methods for new drug substances and medicines.  RC8. The ability to apply knowledge regarding the principles of the introduction of planmaceutical development, the requirements for manufacture, distribution and retail sale and the rational use of medicines.  PC18. The ability to search and use new excipients for the development of various dosage forms.  PC25. The ability to develop new and improve existing technological processes to create low-waste technologies.  KN7. To know of theoretical fundamentals of technological processes of pharmaceutical industries; the current rechnological processes and nethods of manufacturing new medicinal substances and preparations.  KN8. To know the fundamentals of standardization of biopharmaceutical assessment, methods of dosage forms improving, the influence of storage conditions and type of packaging on the stability of medicines.  SK2. To implement measures of GMP and GLP, to carry out export-import operations, to realize marketing work.  SK5. To conduct a step-by-step synthesis of veterinary preparation. to choose optimal parameters of processes, to organize the manufacturing of veterinary preparations.  SK6. To choose alternative ways for obtaining medicines, to organize the production of biomedicines.  SK7. To choose the most optimal method of manufacturing a certain dosage form, to work with technological equipment, legislation, and technical documentation.
Amount of credits	g (including course project)	Ξ
Subject	Modeling and design of chemical-and- pharmaceutical enterprises following GMP system	Industrial technology of pharmaceutical production
Ş	-	2

able 3 (ending)

			Table 3 (ending)
2	Subject	Amount of credits	Competencies (PC – Professional competences; Program outcomes; KN (knowledge), SK (skills)
e.	Industrial equipment of chemical-and-	4	PC21. To know the types of equipment for pharmaceutical industries, features of use and principles of operation of different devices.
	pharmaceutical enterprises		KN9. To know the types and design features of pharmaceutical manufacturing equipment, principles of operation of different devices.
			SK8. To operate industrial equipment.
4	Quality control of medicines	8	PC5. To apply knowledge on specific techniques of physicochemical investigations to identify organic compounds of substances of different classes, including potential medicinal substances.
			PC6. The ability to carry out the qualitative and quantitative analysis of raw materials, intermediates and finished
			pharmaceutical products (including veterinary and medical-and-cosmetic preparations) according to the provided
			INCHIOU.
			PC / To know the procedure of state registration of medicines and the rules for inspection of the manufacturing of
			medicines submitted for state registration.
			PC12. To know the current methods of quality control of pharmaceutical products.
			KN16. To know the fundamentals of the legislation of Ukraine in the field of quality control of medicines.
			SK14. To apply the requirements of the current legislation of Ukraine on quality control of medicinal products at the
			stages of drug manufacturing, preclinical and clinical trials, registration, medication re-registration, transportation,
			storage, and sale.

Table 4

The division of EPP at the second cycle study (master program) by component groups and training cycles

28	Cycle training		The volume of academic load for HE seeker (credits /9/6)		
		Mandatory components of EPP	Selective components of EPP	Total	_
1	General training cycle	3/3	3/3	9/9	_
2	Professional training cycle	64/72	20/22	84/94	_
Total		67/75	23/25	90/100	_

## 4. Elaboration of the structural-and-logical framework and defining competencies for disciplines at the third cycle study (doctoral program) at Lviv Polytechnic National University

At the 2003 conference in Berlin, for the first time, doctoral studies and synergies between the EHEA and the European Research Area (ERA) have been discussed. Whereas the Bologna Declaration referred to two cycles which include all programs of tertiary education ("The second cycle should lead to the master and/or doctorate degree as in many European countries"), the 2003 Berlin Ministerial Communiqué consequently defined doctoral programs as the third cycle.

The third cycle study at Lviv Polytechnic National University includes a broad variety of doctoral phases from pure (doctoral) study programs to fully independent research. These models have various implications for:

- the structure of doctoral studies (free, partially or fully structured);
- the responsibility is taken and the resources invested (e.g. staff and facilities for taught parts of the program) by the home institution;
  - possible links with enterprises and/or professional bodies;
  - the relation of mandatory and optional elements for the doctoral student;
  - the status of the doctoral candidate (student, employee, researcher).

At Lviv Polytechnic National University, the individuals carrying out these projects are not regarded as students but as early-stage researchers/young professionals.

Structural-and-logical framework of philosophy doctor training (the third educational-and-qualification cycle) for specialty 226 "Pharmacy, Industrial Pharmacy" is presented in Fig. 8.

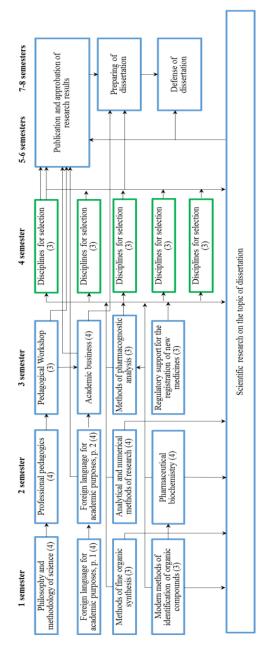
The main competencies that are formed by the appropriate disciplines are presented in table 5.

An analysis of the content of the EPP for the third cycle study by component groups and training cycles was conducted (table 6).

Modernization of professional training through international cooperation and recognition of certificates and assessment of acquired competencies has great importance<sup>7</sup>.

In the period 2016–2020, Lviv Polytechnic National University was a partner of the current agreement with Le Mans University (Le Mans, France) about the double diploma. The travel for students training in master's programs, for PhD students to conduct the research and for teachers to give lectures and passing the training was organized within the framework of the signed agreements on international academic mobility according to the Erasmus + KA1 program with the Lviv Polytechnic National University and the University of Le Mans (Le Mans, France), the University of Opole (Opole, Poland), the University of Toulouse III Paul Sabatier (Toulouse, France), Isa Lille (Lille, France).

<sup>&</sup>lt;sup>7</sup> Pearson, M, Hubball, H. Curricular Integration in Pharmacy Education. American *Journal of Pharmacy Education*. 2012. Vol. 76. P. 204–220. DOI 10.5688/ajpe7610204.



(doctor program) for specialty 226 "Pharmacy" at Lviv Polytechnic National University Fig. 8. The structural-and-logical framework of the third cycle study

# Competences acquired in the learning of separate disciplines at the third cycle of study

2	Subject	Amount of credits	Competencies (PC – Professional competences; Program outcomes: KN (knowledge), SK (skills)
_	Methods of pharmacognostic analysis and quality control of plant raw materials	m	SK3. The ability to demonstrate deep knowledge of pharmacognostic methods of analysis based on analytical regulatory documentation (State Pharmacopocia of Ukraine, State Standards of Ukraine, Specifications of Ukraine); fundamentals of the legislative framework of Ukraine related to the development, registration, manufacturing, quality control and sale of medicinal products, including plant raw materials and products of its processing.  SK4. The ability to conduct scientific researches and to carry out scientific projects using in practice theoretical knowledge related to the identification of medicinal plant raw materials, determining its quality and conducting marketable, phytochemical and biological researches for development new quality control methods or Temporary Pharmacopeta articles. The ability to independently search for new sources of biologically active substances among non-official medicinal plant raw materials, to independently search for new sources of biologically active substances among non-official necticinal plant raw materials, its solate, identify extracts and individual substances and to determine the types of their biological activity.
2	Regulatory support for the registration of new medicines	ю.	PC11. To understand the necessity for state registration of medicines and to know the procedure and futures of functioning of State Drugs List and the procedure for inspection of the manufacturing of medicines submitted for state registration.  PC12. The ability to use the knowledge on the principles of pharmaceutical drug development of various manufacturing types. I aboratory testing, clinical trials, drug registration, requirements for manufacturing, distribution and retail sale and rational use of drugs.  SKS. The ability to create a registration dossier for state registration (re-registration) of medicinal products. Understanding the order of import of unregistered medicines, standard samples, reagents into the territory of Ukraine. The ability to inspect the manufacturing of medicines submitted for state registration.
3	Good Phamaceutical Practices ( GMP, GCP, GLP, GPP, GDP)	en .	PC10. The ability to conduct by the provided method of qualitative and quantitative analysis of raw materials, intermediates and finished products of chemical and planmaceutical manufacture.  SK8. To be able to explain the concept of quality assurance of medicines; to describe the approaches to pharmaceutical development of new drugs; to specify the requirements for preclinical and clinical trials of medicines; to interpret the rules of GMP; to specify the rules of good practice for storage and distribution of medicinal products; to substantiate the principles of pharmaceutical days development; to explain the principles of achieving good manufacturing practice in the manufacture of medicines; to substantiate the role of factors affecting the quality of medicines; to know the legislation concerning registration of medicinal products and discussing in Ukraine.
4	Assessment of quality of medical and planaceutical technologies (quality of drugs, quality of treatment)	m	KN8. To understand the content of term "quality" in medicine and pharmacy; to describe the conception of quality assurance of medicines; to know the main indicators of quality of medical and pharmaceutical technologies; to specify factors that influence the quality of medicines; to describe the principles of rational use of medicines; to understand the principles of quality assessment of medical technologies; to formulate principles of quality assessment of medical technologies.  SKS, To apply the basic indicators of quality of medical and pharmaceutical technologies; to outline the factors that affect the quality of medicines to describe the principles of rational use of medical rechnologies; to outline the factors that affect the medical technologies; to formulate principles of evaluation of quality of medical technologies; to know the main regulations concerning the quality of medical and pharmaceutical technologies; to interpret the results of the evaluation of the quality of medical and pharmaceutical technologies; to improve the quality of medical and pharmaceutical technologies; to implement in practice algorithms for improving the quality of medical and pharmaceutical technologies; to implement in practice algorithms for improving the quality of medical and pharmaceutical technologies; to implement in practice algorithms for improving the quality of medical and pharmaceutical technologies.

able 5 (ending)

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Table 5 (ending)	Competencies	(PC - Professional competences; Program outcomes: KN (knowledge), SK (skills)	KN6. To describe the approaches to pharmaceutical development of new drugs; to know the requirements for clinical and	preclinical drug trials; to use the complex knowledge on methods and techniques of fine organic synthesis for planing the synthesis	of model compounds.	SK7. The ability to conduct a preclinical study of medicines and to analyze the documentation concerning preclinical	investigations. The ability to demonstrate knowledge of the rules of clinical trials of medicines.	SK10. To determine principles for the search of new drugs and scientific approaches to their development; to describe the system	of new medicines examination; to specify sources of information about medicines; to describe the principles for the medicines	introduction into the pharmaceutical market and the use of new drugs; to formulate the tasks of scientific research in the branch of	development of new medicines; to develop the scheme of pharmacological experiment taking into account ethical, deontological	aspects, main indicators of information security; to search and perform analytical work with information on the development and	use of medicinal products.		
	Amount of	credits	3												
	Subject	nafanc	Clinical-and-	pharmaceutical	fundamentals of	medicines	development	(principles of a	search for new	drugs, investigation	of new drugs,	medicines	introduction into	therapeutic practice)	
	2	5	5												

Table 6

The division of EPP for the third cycle by component groups and training cycles

		The volume of academic load f	The volume of academic load for higher education seeker (credits /%)	dits /%)
Cycle training		Mandatory components of EPP	Selective components of EPP	Total
The cycle of disciplines that provide formation the general scientific competencies and universal skills of the researcher	the general the researcher	27/45	3/5	30/50
The cycle of disciplines that provide formation professional competencies	professional	15/25	12/20	27/45
The cycle of disciplines for free choice of the graduate student	aduate		3/5	3/5
Total		42/70	18/30	60/100

Also, at the same period, Lviv Polytechnic National University was a partner of projects of international bilateral scientific and technical cooperation: Ukraine-France M/85-2017, M/113-2018 "Creating sulfurcontaining derivatives of carbocyclic and heterocyclic systems – potential antithrombotic substances" (2017–2018); Ukraine-Poland M/120-2018, M/42-2019 "Derivatives of 9,10-anthraguinone and related carbo- and heterocyclic systems as prototypes for potential antitumor and antifungal substances" (2018–2019). As part of the cooperation agreement between the Lviv Polytechnic National University and the University of Opole (Opole, Poland), training for teachers was organized.

Thus, the analysis of particular directions of work in the process of training specialists for the pharmacy branch shows the important role of services of international cooperation, their direct and tangible influence on the process of formation of a competitive specialist. Internships, practices abroad, other types of academic exchanges contribute to the improvement of competency qualities, tempering of character, personality development of a specialist at different cycles of study<sup>8</sup>.

### 5. The peculiarities of formation of professional competencies on Good Pharmaceutical Practices in the training of specialists at Danylo Halytsky Lviv National Medical University

The development and implementation of GPP standards in the healthcare establishments' activities should be a logical continuation of the strategy of implementation of the Good Practices System in our country, which guarantees the quality of medicines at all stages of their circulation from manufacture to sale for the end consumer. The most important requirement pharmacy professionals involves the support and continuous improvement of their professional activity<sup>9</sup>.

An analysis of the syllabuses of the disciplines, learned by HE seekers in second (master program) and third (doctoral program) cycles study at Danylo Halytsky Lviv National Medical University concerning mastering the future specialists expertise in GPP competencies has demonstrated some problematic issues and unresolved tasks.

At the Danylo Halytsky Lviv National Medical University, the core element of doctoral studies in almost all disciplines for a lot of years was

<sup>&</sup>lt;sup>8</sup> Pittenger, A, Chapman, S, Frail, C, Moon, J, Undeberg, M, Orzoff, J. Entrustable Professional Activities for Pharmacy Practice. American Journal of Pharmaceutical Education. 2016. Vol. 80. P. 57-65. DOI:10.5688/ajpe80457.

<sup>&</sup>lt;sup>9</sup> Гала Л.О. Постійний професійний розвиток фармацевтичних працівників вимога належної аптечної практики. Управління та економіка в фармації. 2016. № 3 (47). C. 24-30.

self-contained research including a scientific dissertation. However, with influences from overseas, a range of innovative doctoral programs have been emerging in response to the changes in society and the challenges of a global labor market.

But, there are no separate disciplines on GPP for HE seekers at the second and third cycles of study. Some competences concerning GPP students acquired at the second (master program) cycle study, when learned disciplines such as "Technology of drugs", "Clinical pharmacy and pharmaceutical care", "Management and marketing in pharmacy", "Organization and economy of pharmacy", "Medicinal Plants Resources Science", "Standardization of medicines" (table 7).

The third (doctoral program) cycle study includes courses, private study, research and writing a thesis. This approach requires a great deal of autonomy and responsibility.

The HE seeker at the third (doctoral program) cycle should: 1) demonstrate knowledge and understanding in the field of research including current specialist knowledge in a limited area of this field as well as specialized knowledge of research methodology in general and the methods of the specific field of research in particular; 2) demonstrate the ability to identify and formulate issues with scholarly precision critically, autonomously and creatively, and to plan and use appropriate methods to undertake a limited piece of research and other qualified tasks within predetermined time frames in order to contribute to the formation of knowledge as well as to evaluate this work; 3) demonstrate the ability in both national and international contexts to present and discuss research and research findings in speech and writing and in dialogue with the academic community and society in general; 4) demonstrate the skills required to participate autonomously in research and development work and to work autonomously in some other qualified capacity.

Accordingly, there are no specific disciplines that are related to the principles of GPP at the third cycle study. Only a few issues of GMP are discussed in elective courses "Technological aspects of pharmaceutical development".

### CONCLUSIONS

The scientific analysis of the state of the problem of the professional training of pharmaceutical branch specialists in terms of GPP at the technical and medical institution on the example of Lviv Polytechnic National University and Danylo Halytsky Lviv National Medical University is carried out.

# Competences concerning GPP acquired in learning of separate disciplines at Danylo Halytsky Lviv National Medical University

Table 7 (continuance)

		Amount	Comnatanciae
Š	Subject	of credits	(PC – Professional competences; Program outcomes; KN (knowledge), SK (skills)
	Technology of drugs	14.5 (including practical training)	SK3. To characterize dosage forms in accordance to the type of disperse system, route of administration, physical state, considering physical and chemical properties of active ingredients and excipients; to determine and prevent the incompatibilities of active ingredients and excipients; to determine and prevent the incompatibilities of active ingredients and medicinal plant material in prescription (physical, chemical, physical-chemical pharmacological); to check single and daily doses of toxic, narcotic, strong active substances and the dispensing norms of narcotic and equivalent to them substances, considering pidyidutal features of a patient (age, body weight, etc.); to weigh, measure and dose various preparations following prescription; to prepare extraction solvents in an appropriate concentration, using different calculations; to stabilize preparations following prescription; to prepare extraction and technological properties of active ingredients and excipients, using suitable agents; to compound various dosage form; to perform sterilization of drug products, considering physical and chemical properties and stability of medicinal substances; to prepare drug products, which are contain toxic, narcotic substances, for dispensing; to write passport of written control for the compounded preparations.  SKI. To choose an optimal technology of dosage form, using a suitable equipment; to select excipients (stabilizers, emulsifiers, prolongating agents, ointment and suppository bases, fillers for tablets, etc.) to produce a drug product; to elaborate technological properties of the manufacture of injection and infusion solutions in the conditions of emterprises and hospital pharmacies; to study technological properties of powders and granulated materials; to perform, preterament and analysis of empholes and containers for injection solutions; to stabilize pharmacettical preparations, considering publical properties of active ingredients and excipients, and agents.
73	Clinical pharmacy amd pharmacut ical care		PC11. The ability to use knowledge of regulatory, legal acts of Ukraine, and recommendations of good pharmaceutical practices in the professional activity.  PC18. The ability to provide rational use of prescription and OTC medicines according to physicochemical, pharmacological characteristics, biochemical, pathophysiological features of a specific disease and pharmacotherapeutic regimens  PC20. The ability to provide counseling and pharmaceutical care when selecting and dispensing medication by assessing the risk/benefit, compatibility, indications, and contraindications based on the patient's health status, taking into account the pharmacokinetic, pharmacochanical pharmaceutical legislation; the main mechanisms of state regulation of pharmaceutical activity; principles of organization of providing pharmaceutical legislation; the main mechanisms of state regulation of pharmaceutical activity in Ukraine; track and elicity state regulation to the population: legal and ethical standards of pharmaceutical activity.  SK11. To Use the legal acts that regulate pharmaceutical activity in Ukraine; track and identify changes and additions to native Ukrainian pharmaceutical legislation; build relationships with patients and physicians in order to meet WHO ethical criteria and good pharmacy practices to promote medicines on the market, minimize abuse and misuse of medicines.
ε.	Manageme nt and marketing in pharmacy	Ø	PC10. To obtain a systematic knowledge of the theoretical foundations of management in planmaceutical marketing PC10. To obtain a systematic knowledge of the theoretical foundations of management management man issues of management, including the essence of modern management theories, subjects and levels of management KN12. Principles, types, oganizational forms and features of entrepreneurial activity in pharmacy, the order of functioning, management of organizations of the planmaceutical industry.  KN13. The mechanism for managing the decision-making process.  SK10. Identify tasks of structural units of pharmaceutical organizations.  SK12. Make the scheme marketing areas of the company.  SK13. Conduct positioning of drugs on consumer preferences.

			(Supple)
_	Wa Cubioet	Amount	Competencies
_	nafanc a	of credits	(PC – Professional competences; Program outcomes: KN (knowledge), SK (skills)
	4 Organizatio	8,5 (including	
	economy of	pracucar training)	PC 16. The ability to ensure proper storage of medicinal preparations and medical devices following GSP in healthcare facilities
	pharmacy		KN1. To know the general principles of pharmaceutical provision of the population, the basic mechanisms of state regulation of pharmaceutical activity
			SK1. To use laws and regulations that regulate pharmaceutical activity in Ukraine and abroad; to provide the information on the material and technical resources of pharmacy.
			SK16. To control storage conditions for starting material in the pharmaceutical entities.
L	5 Medicinal	3	PC19. To develop a holistic view of the current state of plant resources in some regions and the state as a whole, promising medicinal
	Plants		plants, to provide for future professionals a comprehensive knowledge concerning medicinal plants, sustainable use and protection of
	Resources		resources
	Science		KN20. The modern methods for determination of productivity and stocks of wild medicinal plants.
			KN22. Ways of rational use and protection of resources of medicinal plants.
			SK20. To apply knowledge for the sustainable use of plant resources and environmental protection.
	6 Standardiza		PC7. Ability to properly store medicines and other pharmacy products by their physicochemical properties and GSP rules in healthcare
_	tion of		settings.
	medicines		PC12.Ability to use in the professional activity the knowledge of regulatory, legal acts of Ukraine and the recommendations of good
			pharmaceutical practices.
			SK19. Ability to organize and carry out quality control of medicinal products by the requirements of the State Pharmacopoeia of Ukraine
			and good practices, to determine the methods of sampling for the control of medicinal products and to carry out their standardization
			according to current requirements, to prevent the spread of counterfeit medicines
			SK20. Ability to develop quality control techniques for medicinal products, including active pharmaceutical ingredients, medicinal plant
			raw materials and auxiliaries using physical, chemical, physico-chemical, biological, microbiological, pharmacotechnological and
_			pharmaco-organoleptic control methods.

Certain individuality of professional training of specialists in the pharmaceutical industry in the context of the acquirement of professional competencies in GPP based on the analysis of the EPP and ESP was disclosed.

EPP for first (bachelor program) cycle study at Lviv Polytechnic National University consists of 14 general competencies, 35 professional competencies, 62 pieces of knowledges and skills. EPP for second (master program) cycle study involves mastering with 15 general competencies, 28 professional competencies, and 35 pieces of knowledges and skills. 16 general competencies, 8 professional competencies, 20 pieces of knowledges and skills comprise ESP for third (doctoral program) cycle study at Lviv Polytechnic National University. Almost all competencies related to GPP issues.

The logical conclusion of the training of specialists in the field of pharmacy is the discipline "Good Pharmaceutical Practices", which includes the whole range of practices, so it is proposed at the Lviv Polytechnic National University for study at the third (educational-scientific) level.

Unlike Lviv Polytechnic National University, HE seekers at Danylo Halytsky Lviv National Medical University study principles of GPP only at the second (master program) cycle study.

### SUMMARY

As the complexity of the pharmaceutical industry increases a there is an increasing need for suitably qualified personnel. Universities must respond to needs for employers and graduates with the appropriate skills and knowledge to enable the transformation and future growth of this industry. Restructuring educational offerings to focus on graduate attributes, such as analytical and critical thinking, collaboration and problem-solving, creativity, flexibility and self-direction in the context of the pharmaceutical industry facilitates the changes needed for future growth and to the improvement of the pharmacy industry as a whole.

The aim of this article is to provide an overview of the applications of competency based education in the education and training of pharmacists, the process for constructing a competency based pharmacy curriculum, and the potential advantages and challenges associated with its implementation. The formation of competencies of future professionals for the pharmaceutical field, taking into account the relevance and expectations of potential employers, is an important component in the development of educational-and-professional and educational-and-scientific programs at all cycles (bachelor, master and doctoral programs) of higher education. The article present the result of scientific analysis of the state of the problem of

the professional training of pharmaceutical branch specialists in terms of Good Pharmaceutical Practices at the technical and medical educational institution on the example of Lviv Polytechnic National University and Danylo Halytsky Lviv National Medical University. Certain individuality of professional training of specialists in the pharmaceutical industry in the context of the acquirement of professional competencies in Good Pharmaceutical Practices based on the analysis of the educational-and-professional and educational-and-scientific programs was disclosed.

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