RESEARCH ARTICLE

ISSN 2307-9266 e-ISSN 2413-2241

Scientific and Practical Journal
PHARMACY & PHARMACOLOGY

ACTUAL PROBLEMS OF PROFESSIONAL AND PERSONAL DEVELOPMENT QUALIFIED PERSONS RESPONSIBLE FOR QUALITY OF MEDICINAL PRODUCTS FOR HUMAN USE

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Received 3 Aug 2021 Accepted 12 Oct 2021

The aim of the study is to investigate topical problems of the professional and personal development of qualified persons responsible for quality of medicinal products for human use.
Materials and methods. In the period from April 6 to May 10, 2020, an online survey of leading employees in the field of quality assurance of Russian manufacturers was conducted. 176 people took part in the survey; the return of questionnaires was about 17.9%.
Results. From the standpoint of D. Super's theory of professional development, the largest number of respondents was at the maintenance stage, holding their achieved positions (53.2%). All respondents, regardless of age, were motivated for professional development. Most often qualified persons had chemical engineering (27.3%) and pharmaceutical education (22.2%). Most of them had a working experience in 1–2 divisions of the enterprise, and combined the functions of qualified persons with managerial positions (74.5% and 71.9%, respectively). The majority of the qualified persons (86.4%) indicated the sufficiency of the available knowledge and the lack of knowledge on certain issues. Knowledge and skills in the quality risk management, specific GMP issues and statistical methods (59.0%, 49.2 and 44.2%, respectively); communication and interpersonal skills and, in particular, stress management, emotion management and the art of negotiation (49.4%, 41.3% and 40.9%, respectively), were most popular. About 36% of respondents notified the need for the digital economy competencies, while only 5.1% notified the presence of an electronic batch production record at the enterprise. Finally, only half of the respondents (50.5%) had a formal training plan for qualified persons.
Conclusion. This pilot study revealed the need for the revision of the Exemplary Additional Professional Training Program for Qualified Persons and the professional standard, the urgent need for the regulatory body to develop a scheme and principles for the continuous professional development of qualified persons, and showed the direction of further research in this area.
Keywords: qualified person; pharmaceutical company; professional development; medicines; additional vocational training
Abbreviations: GMP – Good Manufacturing Practice; RSC – Royal society of chemistry; CPD – Continuing professional development; CE – continuous education; EAPTP QPs – Exemplary Additonal Professional Training Program for Qualified Persons; Ps – Pharmaceuticals; QCD – Quality Control Division; QAD – Quality Assurance Division; QP – qualified person; PQS – Pharmaceutical Quality System.

АКТУАЛЬНЫЕ ПРОБЛЕМЫ ПРОФЕССИОНАЛЬНО-ЛИЧНОСТНОГО РАЗВИТИЯ УПОЛНОМОЧЕННЫХ ЛИЦ ПО КАЧЕСТВУ ПРОИЗВОДИТЕЛЕЙ ЛЕКАРСТВЕННЫХ СРЕДСТВ ДЛЯ МЕДИЦИНСКОГО ПРИМЕНЕНИЯ

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Получено 03.08.2021 Принята к печати 12.10.2021

For citation: Zh.I. Aladysheva, N.V. Pyatigorskaya, V.V. Belyaev, N.S. Nikolenko, E.I. Nesterkina, S.A. Loseva. Actual problems of professional and personal development of qualified persons responsible for quality of medicinal products for human use. *Pharmacy & Pharmacology.* 2021;9(5):410-422. **DOI:** 10.19163/2307-9266-2021-9-5-410-422

Для цитирования: Ж.И. Аладышева, Н.В. Пятигорская, В.В. Беляев, Н.С. Николенко, Е.И. Нестеркина, С.А. Лосева. Актуальные проблемы профессионально-личностного развития уполномоченных лиц по качеству производителей лекарственных средств для медицинского применения. *Фармация и фармакология.* 2021;9(5):410-422. **DOI:** 10.19163/2307-9266-2021-9-5-410-422

Научно-практический журнал
ФАРМАЦИЯ И ФАРМАКОЛОГИЯ

ОРИГИНАЛЬНАЯ СТАТЬЯ
DOI: 10.19163/2307-9266-2021-9-5-410-422

Цель. Изучение актуальных проблем профессионально-личностного развития уполномоченных лиц по качеству производителей лекарственных средств для медицинского применения.
Материалы и методы. В период с 6 апреля по 10 мая 2020 года был проведен онлайн-опрос ведущих сотрудников в области обеспечения качества российских производителей. Участие в опросе приняло 176 человек, возврат анкет составил около 17,9%.
Результаты. С позиций теории о профессиональном развитии Д. Сьюпера наибольшее количество респондентов находилось на этапе поддержания, сохранения достигнутых позиций (53,2%). Все респонденты вне зависимости от возраста мотивированы на профессиональное развитие. Наиболее часто уполномоченных лиц имели химико-технологическое (27,3%) и фармацевтическое образование (22,2%). Большинство имели опыт работы в 1–2 подразделениях предприятия, а также совмещали функции уполномоченных лиц с руководящими позициями (74,5% и 71,9%, соответственно). Большинство уполномоченных лиц (86,4%) указали достаточность имеющихся знаний и нехватку знаний по отдельным вопросам. Наиболее востребованными оказались знания и умения по управлению рисками для качества, специфические вопросы GMP и статистические методы (59,0%, 49,2% и 44,2%, соответственно); коммуникативные и межличностные умения и, в частности, управление стрессом, управление эмоциями и искусство переговоров (49,4%, 41,3% и 40,9%, соответственно). Около 36% респондентов отметили потребности в компетенциях цифровой экономики, и при этом только 5,1% отметили наличие на предприятии электронного досье на серию. И наконец, всего лишь у половины респондентов (50,5%) имелся формальный план обучения уполномоченных лиц.
Заключение. Данное пилотное исследование выявило необходимость пересмотра примерной дополнительной профессиональной программы повышения квалификации уполномоченных лиц и профессионального стандарта, острую необходимость разработки регуляторным органом схемы и принципов непрерывного профессионального развития уполномоченных лиц, а также показало направление дальнейших исследований в этой области.
Ключевые слова: уполномоченное лицо по качеству; фармацевтическое предприятие; профессиональное развитие; лекарственные средства; дополнительное профессиональное обучение
Список сокращений: GMP – Надлежащая производственная практика; RSC – Королевское химическое общество Великобритании; CPD – Непрерывное профессиональное развитие; CE – непрерывное образование; ДПП УЛ – Примерная дополнительная профессиональная программа повышения квалификации уполномоченных лиц; ЛС – Лекарственные средства; ОКК – Отдел контроля качества; ООК – Отдел обеспечения качества; УЛ – Уполномоченное лицо по качеству; ФСК – Фармацевтическая система качества.

INTRODUCTION

The personnel professional development, especially that of key employees, is considered the most important element of the enterprise management and one of the conditions for the success of their activities [1-9]. Depending on the theoretical approaches to the study of this process, different definitions are used. From the point of view of psychologists, “professional development is a change in the psyche in the process of mastering and performing vocational, educational, labor and professional activities” [1]. From the standpoint of acmeology, this is “the process of actualizing the potential of an individual and achieving the highest forms of professionalism” [7]. Many researchers emphasize the idea that the basis of professional development is self-development as “the process of transforming one’s own life into an object of practical transformation in connection with the requirements of a professional activity, leading to creative self-realization in the profession” [10], self-directed learning and self-esteem [11, 12].

From the standpoint of sociology, professional development can be described as a process of socialization of an individual with the meaning of their organization activities, the need for respect and consideration of opinions when making decisions [13]. The Royal Society of Chemistry of Great Britain (RSC) defines continuous professional development of a chemist as the responsibility of individuals to systematically maintain, improve and expand knowledge and skills to ensure professional competence throughout their working life (career)[1]. The Irish Pharmaceutical Society, in its Professional Development Models report, emphasizes that continuing professional development (CPD) is a self-directed process that allows professionals to develop and deepen a wide range of knowledge, skills and motivations consistent with their current and future work activities. The need to separate continuing professional development (CPD) and continuous education (CE) is also highlighted. Under CE, it is suggested to consider structured educational experience (planned training) and practical activities in the postgraduate period in order to improve and expand knowledge, skills and competencies. As a self-governing process, CDP involves the specialists’ determination of their educational and other needs, an assessment of the achievement of current goals and objectives of their development. CE is one of the components of professional development[2].

[1] The Royal Society of Chemistry – Continuing Professional Development. Available from: https://www.rsc.org/cpd/
[2] Pharmaceutical Society of Ireland Review of International CPD Models. Final report. – PSI, Dublin Ireland, 2010. Available from: ttps://www.thepsi.ie/Libraries/Education/PSI_International_Review_of_CPD_Models.sflb.ashx.

The research of the professional development problems is aimed at finding approaches and methods to improve the management of an organization, in particular, the management of personnel and their professional training, both internal (corporate) and external; psychological and personal aspects, a staff motivation. The problems of national schemes for attestation (accreditation) of specialists in regulated professions (medical and pharmaceutical specialists, aviation specialists, teachers and lecturers, etc.) and their effectiveness for ensuring the life and safety of the population are also investigated.

For a drug manufacturer, professional development of the personnel, in particular, a qualified person (QP), as well for other regulated professions, this is also a prerequisite for carrying out production activities. Thus, in the Rules of Good Manufacturing Practice (GMP) which are in force in the Russian Federation and in the Eurasian Economic Union (EAEU) states parties, Appendix 16 explicitly states: "Qualified persons must maintain their qualifications up to date in the light of scientific and technological progress and take into account changes in the management system quality related to products, the compliance of which with the established requirements is confirmed by an qualified person". In EU GMP, there are similar requirements[3]. Therefore, professional development issues are not only the responsibility of an qualified person, but should be also included in the scope of the pharmaceutical quality system of the enterprise. The considered professional group in our country is characterized by a structural development, when the most competent employee is selected to perform these functions [5].

Requirements for the qualified person's qualifications have been established by regulatory legal acts, since this person is personally responsible for the release of a series of medicinal products into civilian circulation and is often forced to make up difficult decisions in the conditions of uncertainty. Thus, the legislation determines that "the following specialists are allowed for certification: the ones who have at least 3 years of experience in the field of production, or quality assurance, or quality control of medicines and completed higher education in one of the following areas – chemical, chemical-technological, chemical pharmaceutical, biological, biotechnological, microbiological, pharmaceutical, medical". Qualified persons must also undergo training in 12 chemical, biomedical and pharmaceutical disciplines, or when receiving higher education, or as a part of additional professional training[4]. Similar requirements are established in all the countries of the Eurasian Economic Union[5] and are available in all the countries of the European Union[6]. The main labor actions of qualified persons when confirming the compliance of each batch of a medicinal product and releasing the batch into civil circulation, are indicated in GMP[7]. The description of the labor functions, knowledge and skills of the qualified person can be found in the professional standard "Expert on manufacturing pharmacy in the field of Pharmaceutical Quality Assurance". It was approved by the Order of the Ministry of Labor of Russia dated 05.22.2017 No.429n (Labor function B / 05.7 Evaluation of the batch production record of a medicinal product with registration of a decision on release into circulation)[8]. There is an exemplary additional professional training program of advanced vocational training for qualified persons, approved by the Ministry of Health of Russia[9]. Thus, the state participates in the formation of the personnel potential of the pharmaceutical industry, although, as in other industries, according to experts, it is not very effective [14].

[3] [1] Order of the Ministry of Industry and Trade of Russia of June 14, 2013 No. 916 (as amended on December 18, 2015) "On the approval of the Good Manufacturing Practice Rules" (Registered at the Russian Ministry of Justice on September 10, 2013 No. 29938). [2] Rules of Good Manufacturing Practice of the Eurasian Economic Union, approved by the Decision of the Council of the Eurasian Economic Commission dated 03.11.2016 No. 77. [3] EudraLex – Volume 4 – Good Manufacturing Practice (GMP) guidelines.

[4] [1]. Order of the Ministry of Health of the Russian Federation "On Approval of the List of Documents Submitted by a Certified Qualified Person of a Manufacturer of Medicines of a Member State of the Eurasian Economic Union, Stages of the Procedure and Procedure for Making Decisions on Certification of Qualified Persons of Manufacturers of Medicinal Products for Medical Use in accordance funds approved by the decision of the Council of the Eurasian Economic Commission of November 3, 2016 No. 73 "On the procedure for certification of qualified persons of drug manufacturers." No. 73 "On the Procedure for Attestation of Qualified Persons of Medicinal Products Manufacturers. [3] Federal Law "On the Circulation of Medicines" dated 12.04.2010 No. 61-FZ.

[5] Agreement on uniform principles and rules for the circulation of medicines within the Eurasian Economic Union dated December 23, 2014.

[6] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

[7] [1] Order of the Ministry of Industry and Trade of Russia of June 14, 2013 No. 916 (as amended on December 18, 2015) "On the approval of the Good Manufacturing Practice Rules" (Registered at the Russian Ministry of Justice on September 10, 2013 No. 29938). [2] Rules of Good Manufacturing Practice of the Eurasian Economic Union, approved by the Decision of the Council of the Eurasian Economic Commission dated 03.11.2016 No. 77. [3] EudraLex – Volume 4 – Good Manufacturing Practice (GMP) guidelines.

[8] Order of the Ministry of Labor of Russia dated May 22, 2017 No. 429n "On the approval of the professional standard" Specialist in industrial pharmacy in the field of quality assurance of medicines "(Registered with the Ministry of Justice of Russia on July 20, 2017 No. 47480).

[9] Order of the Ministry of Health of Russia dated January 22, 2014 No. 37-n "On the approval of exemplary additional professional pharmaceutical education programs" (Appendix No. 2) (Registered with the Ministry of Justice of Russia on April 18, 2014 No. 3203).

ОРИГИНАЛЬНАЯ СТАТЬЯ
DOI: 10.19163/2307-9266-2021-9-5-410-422

Despite rather a long period (almost 8 years) of the formation of the professional group in Russia considered in this article, and the importance of the qualified persons' professional development for the health of the population, no publications on the professional development of qualified persons of Russian drug manufacturers and related issues, had been found. Therefore, **THE AIM** of the described pilot study was to investigate the current situation in this area.

MATERIALS AND METHODS

The study of relevant problems of qualified persons' professional and personal development was carried out by a questionnaire method. A broad educational need was investigated both in the professional knowledge and skills described above, which belong to the category of "hard-skills", and universal competences (over-professional skills, skills of the 21st century, etc., soft-skills) that qualified persons should have as highly qualified specialists [15–17]. In this study, the structure of universal competencies given in the "Target Model of Competencies 2025", was used[10].

The questionnaire included 42 questions related to various aspects of this professional group's work in our country, as well as problems of professional development, socio-demographic and professional factors influencing it. Depending on the position from which professional development is considered, various factors affecting it are distinguished. They are external (regulatory requirements and recommendations), internal (work with personnel in the organization, financial and procedural opportunities, etc.). Very importantan factors are personal (professional potential, motivation, personal goal-setting, etc.); socio-demographic (gender, age, social status, education) and psychophysiological (psychophysiological potential, goal commitment, a sense of mastery, interpersonal interaction); social and professional (the content of the profession, ways of performing professional tasks, professional experience) and socio-economic (the level of wages, the demand for certain professional knowledge and skills, "professional success", etc.) [2–4, 8, 18–20].

When developing the questionnaire, the provisions of regulatory legal acts related to the qualified persons' professional development, were taken into account[11]. 27 people with knowledge of qualified persons' work took part in checking the readability and clarity of the questionnaire.

The survey was conducted online by Sechenov University in cooperation with the National Chamber of Pharmacy from April 10 to April 30, 2020. The questionnaires were sent by email to potential respondents (982 people, 48 constituent entities of the Russian Federation, more than 300 enterprises). 176 people took part in the survey; respectively, the return of questionnaires was about 17.9%. All respondents are acting qualified persons or have performed functions of qualified persons in the past (96% and 4%, respectively). Most of the respondents are female (86.2%), have been working at pharmaceutical enterprises for more than 10 years (72.6%).

RESULTS AND DISCUSSION

The resulting sample includes employees of various sizes enterprises, producing various dosage forms (Fig. 1).

According to the modified theory of D. Super, the respondents are at different stages of professional development [3, 5, 21]:

1) at the stage of stabilization, consolidation and promotion – 26.6%;

2) at the stage of maintaining, keeping the achieved positions – 53.2%;

3) at the stage of declining professional and social activities – 20.2%.

It should be notified that no unwillingness to study and develop professionally in the age groups in the range of 40-60 years, which should have been expected from the literature, have been revealed [2, 3]. On the contrary, all respondents, regardless of age, are motivated for professional development.

The distribution of qualified persons by vocational education is shown in Fig. 2. The most common are chemical engineering (27.3%) and pharmaceutical education (22.2%).

Slightly more than a third of survey participants (37.5%) have work experience in only one department: quality control department (QC), quality assurance department (QA) or a production unit; 36.9% have experience in two divisions (the combinations of the aforesaid plus a regulatory division), the rest have experience in three or more divisions; 71.6% of the respondents are heads of enterprise structural divisions or occupy even higher administrative positions. These data make possible to conclude that a combination of horizontal (a change in the professional and functional activity areas) and vertical (advancement in the organizational and managerial hierarchy) directions, is characteristic for the professional and official development of qualified persons [5].

When asked about the sufficiency of knowledge

[10] Butenko V, Polunin K, Kotov I, Sycheva E, et al. Russia 2025: from personnel to talents. The Boston Consulting Group, 2017: 70 p. Russian
[11] The Royal Society of Chemistry – Continuing Professional Development. Available from: https://www.rsc.org/cpd/

ISSN 2307-9266 e-ISSN 2413-2241

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PHARMACY & PHARMACOLOGY

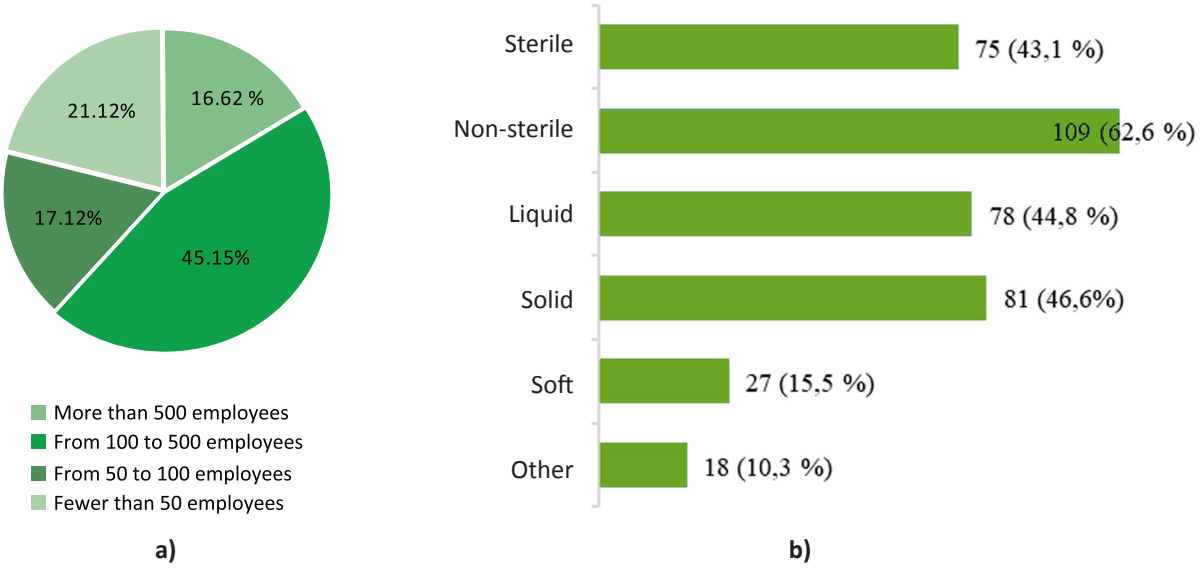


Figure 1 – General characteristics of qualified persons who took part in the survey
Note: a) distribution of respondents by enterprise size; b) dosage forms produced by the enterprises where the respondents work

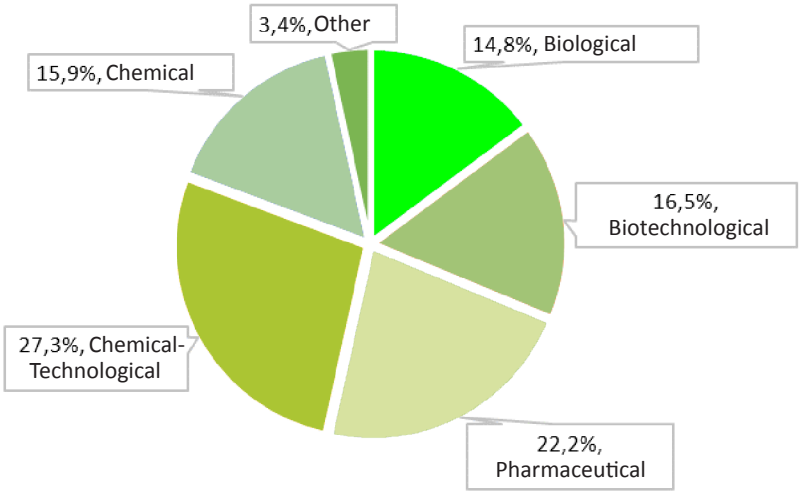


Figure2 – Distribution of respondents by vocational education

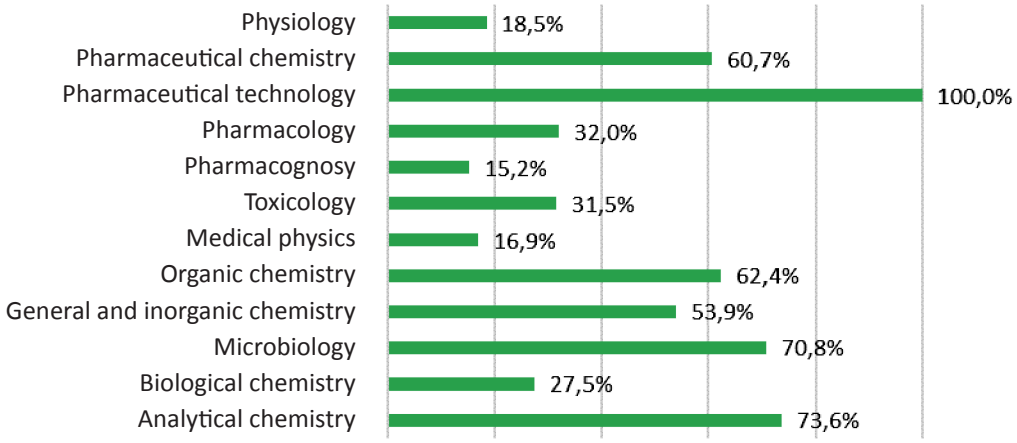


Figure 3 – Use of knowledge of compulsory subjects in qualified persons' practical activities

ОРИГИНАЛЬНАЯ СТАТЬЯ
DOI: 10.19163/2307-9266-2021-9-5-410-422

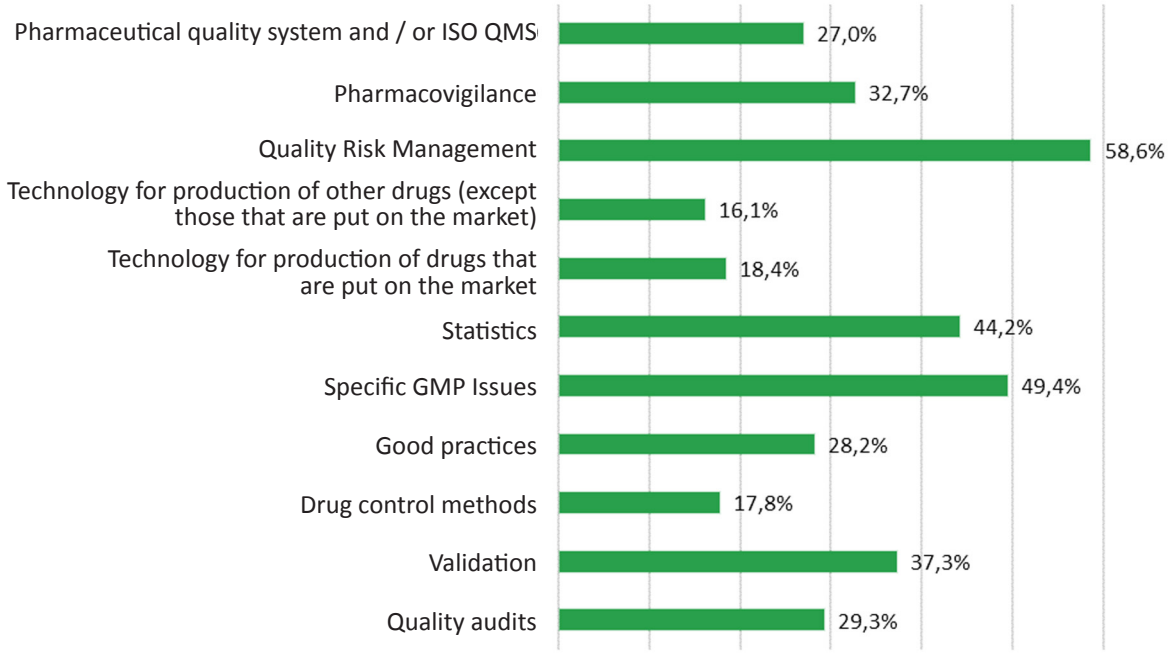


Figure 4 – Qualified persons' need for training in various professional competencies (hard skills)

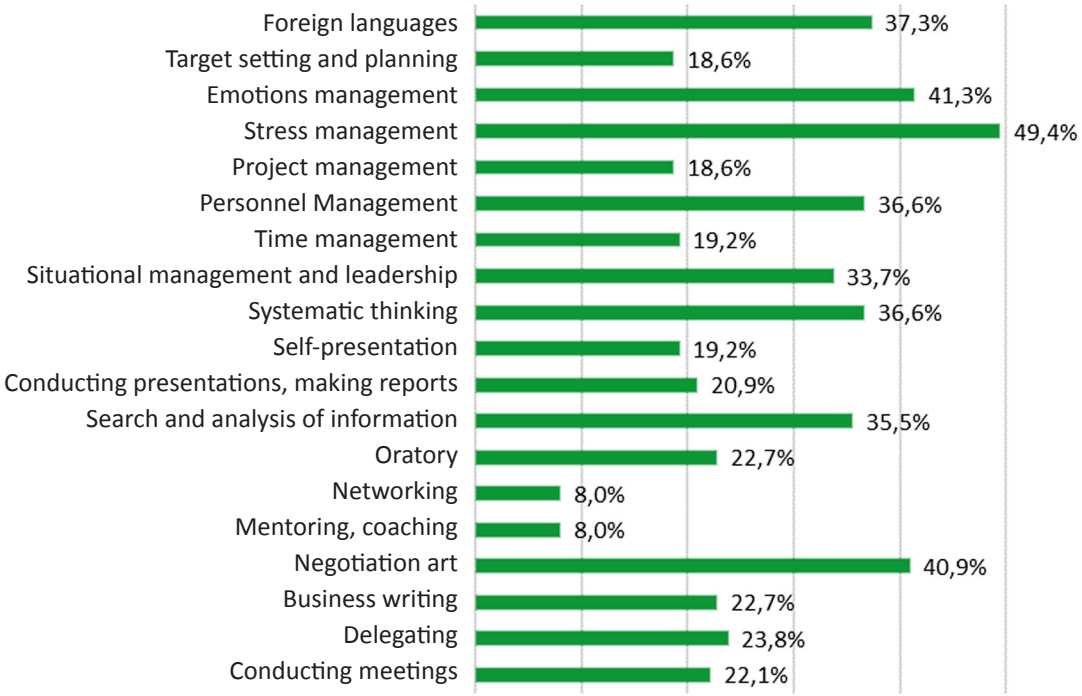
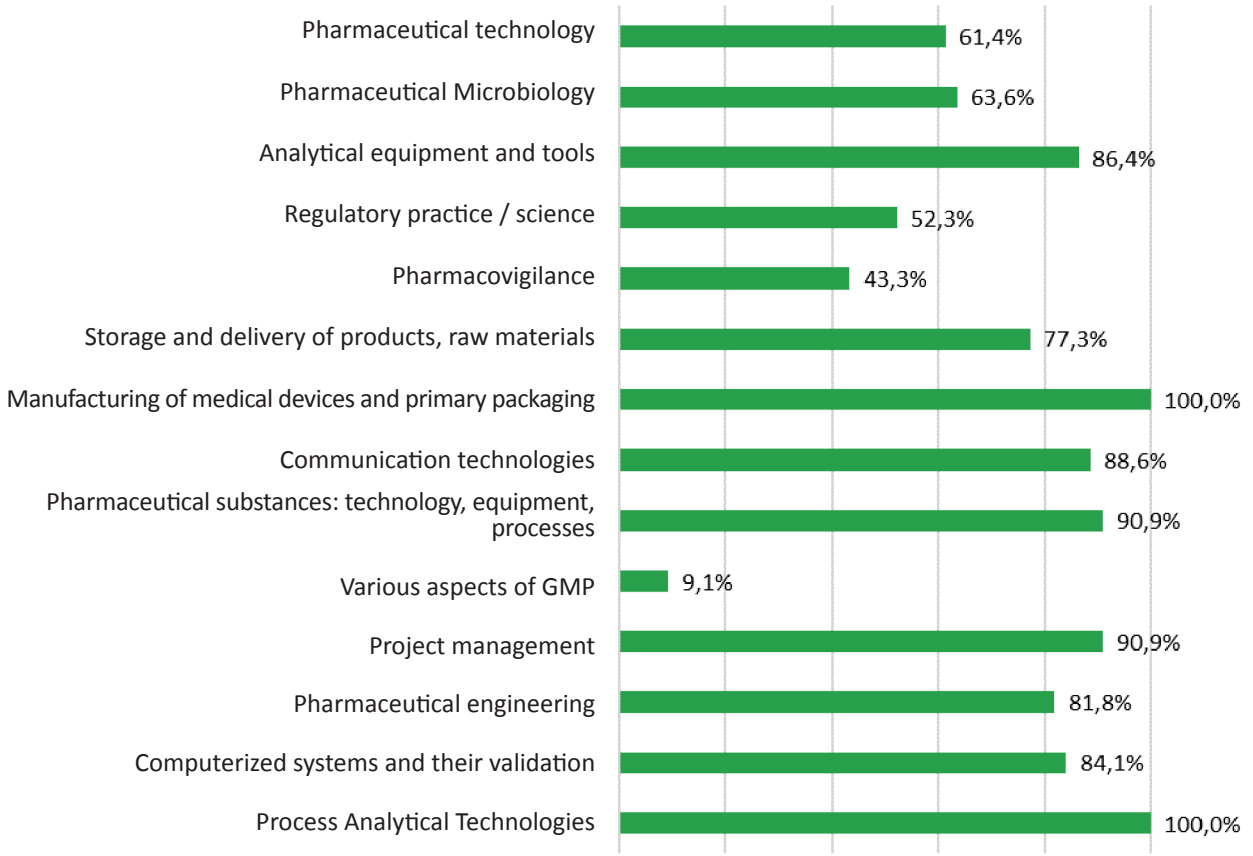


Figure 5 – Qualified persons' need for training in various universal competencies (soft skills)



Figurer 6 – Topics not presented in qualified persons' external and internal training programmes in 2018–2021
Note: according to reports on professional activities in Term 1, 2021

to perform the functions of qualified persons, only 9% of the respondents answered unequivocally in the affirmative. This group included people with different kinds of education, but mainly with biotechnological and chemical-technological ones (50.0% and 31.2%, respectively), at different stages of professional development, but with an equally long experience of work at pharmaceutical enterprises (100% – more than 10 years). Even fewer respondents (4.5%) indicated that their education is insufficient to perform the discussed functions. This group was also dominated by persons with chemical-technological education (62.5%), which is explained by a great number of qualified persons with this kind of education in the obtained sample, as well as by a great number of profiles (directions) of educational programs in chemical technology, many of which do not include study of industrial pharmacy problems. Only 14.6 percent of the respondents indicated that their knowledge is sufficient to perform the functions of qualified persons, but at the same time, they still notified the presence of an educational need for both professional and universal competencies. The data obtained practically coincide with the data of the survey carried out in 2012: 71.2% of employers and 100% of the surveyed specialists in the pharmaceutical industry noted the need to acquire new knowledge in order to fulfill their official duties [22]. In general, these data show, on the one hand, the effectiveness of the regulatory requirement for qualified persons' mandatory professional development once every 5 years[12] (their knowledge is updated and there are no significant gaps in the current knowledge). On the other hand, the obtained data show the need to optimize the content of the above-mentioned additional professional programs and, indirectly, the fact that enterprises do not allocate sufficient resources for the professional development of qualified persons.

The data on the use of knowledge on the disciplines compulsory for studying by qualified persons in professional practice, are shown in Fig. 3. Noteworthy is rather a small number of qualified persons using knowledge of pharmacology (32.0%); the largest percentage of them are persons with pharmaceutical education (40.4%). These results can be explained, first, by the time period when the survey was conducted (2020): the requirements for the compulsory study of pharmacology and other disciplines described above, by qualified persons, although established in 2016, came into effect on the territory of our country only in 2021. Second, these results can be explained by the absence of this and other biomedical disciplines in engineering and natural science educational programs.

To answer the question about the required profes-

[12] Resolution of the Government of the Russian Federation of 06.07.2012 No. 686 "On approval of the Regulation on licensing the production of medicines".

ОРИГИНАЛЬНАЯ СТАТЬЯ
DOI: 10.19163/2307-9266-2021-9-5-410-422

sional (hard skills) and universal (soft skills) competencies, the respondents were offered an open list of knowledge and skills with the ability to indicate additional competencies that had not been included in the questionnaire. The data obtained are shown in Fig. 4 and 5.

The most popular were knowledge and skills in quality risk management (58.6%), which is explained by their almost widespread use in GMP-regulated organizations. It should be notified that these results coincide with the data of the authers' 2020 survey on the industry practice of quality risk management in the Russian pharmaceutical industry, in which 59.0% of the respondents emphasized the lack of specialists with competence in quality risk management [23]. Quite a lot of respondents also notified the need to study specific GMP issues (the narrow issues highlighted in the annexes of the rules and various guidelines) and statistical methods (49.2% and 44.2%, respectively). The authors were unable to determine any significant correlations in the identified educational needs with socio-demographic and professional factors. This need was not influenced by qualified persons' vocational education, age and work experience in the pharmaceutical industry, the nature of products and the size of the enterprise, the number of qualified persons at the enterprise, the position held and work experience in various divisions of the enterprise (QCD, QAD, etc.). The least popular were knowledge and skills in the field of drug production technology and pharmacopoeial analysis (18.4 and 17.8%, respectively). In the group that indicated the presence of such an educational need, there was a fairly large number of respondents with education in the field of natural sciences (38.0%), which, in the authors' opinion, is explained by the absence of pharmaceutical technology and pharmacopoeial analysis in educational programs in biology and chemistry. The authors did not find any correlation with other socio-demographic and professional factors. The identified educational needs of qualified persons with the Exemplary Additonal Professional Training Program for Qualified Persons[13] (EAPTP QPs) – manufacturers of medicines for medical use, were compared. The modules "Pharmaceutical development and production of dosage forms", "Pharmaceutical analysis and quality control of medicines", "Development and production of pharmaceutical substances" turned out to be the least demanded or the most studied out of 10 modules of the program (less than 20% of respondents). Taking into account the current requirements for the compulsory mastering of 12 biomedical and pharmaceutical disciplines, the EAPTP QPs modules related to these issues should be shortened or eliminated. At the same time, the expansion and deepening of the content of such modules as "Quality Management System of a Pharmaceutical Enterprise", "Statistical Methods Used in a Pharmaceutical Enterprise" are definitely required. It is also necessary to include a module on the basics of pharmacovigilance in EAPTP QPs, and to highlight the issues of validation in an independent module at a pharmaceutical enterprise. Since the survey was conducted among the acting Qualified Persons, it may be necessary to have two Exemplary Additonal Professional Training Programs of Qualified Persons at different levels (beginners' and advanced).

The most demanded professional knowledge and skills identified during the questionnaire, are also indicated in the list of knowledge and skills necessary to perform labor function B / 05.7. It is entitled as "Evaluation of the batch production record of a medicinal product with registration of a decision on release into circulation)[14]: a pharmaceutical quality system, quality audits, quality risk management, methods of statistical quality management, mathematical statistics used in assessing the results of tests and validation performed, principles of validation of technological processes and analytical methods, qualifications of premises and equipment, engineering systems. At the same time, only 26.1% of respondents carefully studied this professional standard, and other 38.6% have just looked it through.

Thus, the identified educational needs of qualified persons in terms of professional knowledge and skills indicate the shortcomings of the Exemplary Additonal Professional Training Program for Qualified Persons, the need for an even closer connection between the EAPTP QPs and the corresponding professional standard, as well as the insufficient skills of qualified persons and drug manufacturers to assess their educational and other needs, and plan professional development using professional standards. It can be also argued that the impact of professional standards on the content of advanced professional education, professional programs, including the ones for qualified persons, is not the same as expected by the regulatory body in the field of education[15]. According to the regulation on federal state control (supervision)[16], the work of the organizations carrying out activities in the field of advanced professional education (APE), is not a subject of a federal state control (supervision) and is carried out by the constituent entities of the Russian Federation within the framework of licensing control. Herewith, that does not include the

[13] Order of the Ministry of Health of Russia dated January 22, 2014 No. 37-n "On the approval of exemplary additional professional pharmaceutical education programs" (Appendix No. 2) (Registered with the Ministry of Justice of Russia on April 18, 2014 No. 3203).

[14] Order of the Ministry of Health of Russia dated January 22, 2014 No. 37-n "On the approval of exemplary additional professional pharmaceutical education programs" (Appendix No. 2) (Registered with the Ministry of Justice of Russia on April 18, 2014 No. 3203).

[15] Order of the Ministry of Labor of Russia dated May 22, 2017 No. 429n "On the approval of the professional standard" Specialist in industrial pharmacy in the field of quality assurance of medicines" (Registered with the Ministry of Justice of Russia on July 20, 2017 No. 47480).

[16] [1] Letter of the Ministry of Education and Science of Russia dated 09.10.2003 No. 06-737 "On additional professional education", [2] Methodological recommendations for the development of basic professional educational programs and additional professional programs, taking into account the relevant professional standards, approved by the Minister of Education and Science D.V. Livanov 01/22/2015 No. DL-1 / 05vn.

assessment of the content of APE programs. Therefore, the assessment of educational programs is solely the responsibility of qualified persons and a pharmaceutical enterprise (for example, on compliance with GMP, professional standards and the Exemplary Additonal Professional Training Program for Qualified Persons, identified educational needs of qualified persons). Unfortunately, there was no significant improvement in the situation with APE in the field of industrial pharmacy in comparison with the authors' assessment carried out in 2012 [24].

In general, the most demanded universal competencies among qualified persons were communicative and interpersonal skills from the group of socio-behavioral skills, and, in particular, stress management and emotions management (49.4% and 41.3%, respectively). These data can be explained by qualified persons' working conditions, including relations with other structural divisions of the enterprise: almost two or three respondents from this group (67.3%) reported the presence of conflict situations in the performance of their professional functions (in the entire sample obtained there are less than 58% of them). This, in our opinion, explains the demand for the art of negotiations (40.9%). It should be notified that these skills are also specified in the discussed professional standard, but are absent from the Exemplary Additonal Professional Training Program for Qualified Persons.

The average demand (about 20–22% of respondents' answers) for managerial competencies (conducting meetings, delegating, business writing, etc.) practically coincided with the number of respondents combining the functions of qualified persons with the functions of the top administrative head (29.2%). Although, in general, the number of respondents in managerial positions (the head of a department, laboratory or production site and higher positions) was 71.5%, which can be explained by both the presence of a hidden educational need of qualified persons and the absence of the employer's need to develop managerial skills among middle managers. Moreover, there is no correlation between the educational need for managerial competencies and the size of a pharmaceutical company.

It was also impossible to identify socio-demographic and professional factors that determined a small number of respondents who indicated the need for training in mentoring (coaching) and networking (8% each). Most of the qualified persons who took part in the survey are, probably, not involved in the system of internal personnel training, or are not sufficiently informed about the composition of these competencies, and the lack of the need for networking training is associated with a high degree of closeness of Russian enterprises, the lack of qualified persons' culture of collaboration in the domestic pharmaceutical industry. On the other hand, the data obtained correlate with the results of the carried out survey of employers and pharmaceutical industry professionals in 2012 [22]. Then the competences in teaching and educational activities, including mentoring, were listed among the most popular (6 points out of 10 possible), and, perhaps, their demand by employers led to the following result: for example, such training at the majority of enterprises is included in corporate educational programs. Rather a small number of respondents (35.5%), who indicated the presence of educational needs for the search and analysis of information, was also unexpected. On the one hand, it can indicate a fairly high level of digital literacy among qualified persons (in 2012, this competence was among the most demanded – 7.2 points out of 10 possible). On the other hand, it can be caused by the absence of a real need of employers for these competencies of their employees due to the low speed of digital transformation of the Russian pharmaceutical industry. For example, only 5.1% of respondents indicated that the evaluation of the batch production record is electronically maintained at the enterprise. There is also no state attention to the formation of digital economy competencies among graduates of educational programs in chemical technology, pharmacy, biology, medicine: within the framework of the Federal Target Program "Personnel for the Digital Economy" it is believed that only graduates of chemistry and biotechnology programs develop two or more such competencies[17]. The authors believe that more substantive and in-depth research is required to unambiguously assess the situation and understand the factors influencing the development of the competencies of the Federal Target Program in digital economy.

A practice analysis of planning qualified persons' professional development at Russian pharmaceutical enterprises showed that only half of the respondents (50.5%) have a formal training plan for qualified persons', while only 34% of them undergo formal internal certification, which indicates employers' lack of attention to the problems of qualified persons' professional development. To analyze the contents of plans, topics, forms and modes of teaching qualified persons, 60 reports on professional activities reviewed by the Expert Group of the Sechenov University Attestation Commission for the certification of qualified person – manufacturers of medicines for medical use of the Ministry of Health of Russia (hereinafter the "Expert Group"), were studied. All the reports were submitted to the Expert Group in the first half of 2021 and, according to the new template, included training data for the reporting period (i.e., for the last 3 years)[18]. In half of the reports, there was no mention of the past internal training (53.3%), which was confirmed by the data of the carried out survey. In 72.9%

[17] Decree of the Government of the Russian Federation of June 25, 2021 No. 997 "On approval of the Regulation on federal state control (supervision) in the field of education."

[18] Order of the Ministry of Economic Development of Russia dated January 24, 2020 No. 41 "On Approval of Methods for Calculating Indicators of the Federal Project" Personnel for the Digital Economy "of the National Program" Digital Economy of the Russian Federation " and more core competencies of digital competencies).

ОРИГИНАЛЬНАЯ СТАТЬЯ
DOI: 10.19163/2307-9266-2021-9-5-410-422

of reports, internal training related to the implementation of the EAEU GMP Rules at the enterprise. Of the 32 people who indicated the presence of internal training, only half (16 people) indicated that they underwent it annually. All the qualified persons who applied for certification in the Expert Group (hereinafter referred to as "applicants") underwent external training, and 80% – in addition to the advanced training program developed by the Exemplary Additonal Professional Training Program for Qualified Persons, studied at educational webinars on certain issues of GMP Rules, registration of medicines in the EAEU, validation and qualifications at a pharmaceutical enterprise. About one third of the applicants underwent external training not more frequently than 5 years, 20% – from 3 to 5 years, and the rest – almost every year. The data on the topics of internal and external training are shown in Fig. 6. Most often, Supplementary Programmes for Qualified Persons were trained in various aspects of the GMP Rules, more than half of these Programmes studied pharmacovigilance (56.7%, almost equally in internal and external training), regulatory practice / science (47.7%). There was practically no training in process analytical technologies, the production of medical devices and primary packaging, the technology for the production of pharmaceutical substances, project management, and others (Fig. 6). No correlation either with the size of the pharmaceutical company and the types of products manufactured, or with socio-demographic and professional factors, has been found. In general, according to the reports on the professional activity of the qualified persons, the results of the analysis of training coincided with the trends identified during the survey.

Currently, EAEU GMP Appendix 16[19] aimed at harmonizing it with the similar GMPEC text, is being revised. In the current EU version of this annex, there is a requirement that qualified persons should prove their continuous learning in relation to the type of product, technological processes, technical innovations and GMP changes (the term "continuing" is used in the EAEU draft). The volume of continuing education required, and the type of training acceptable by the regulator, and the type of training evidence, have not been clearly defined. At the same time, in other documents related to qualified persons, for example, in the UK, recommendations on how to ensure the fulfillment of the requirements under consideration, can be found.

Professional development activities are a condition for qualified persons' annual renewal of the membership in a trade union (a prerequisite for qualified persons' certification in the UK). The members of the society send a short report on professional activities to the secretariat. They reflect the maintenance of 12 professional competencies defined by this society, and 5 types of educational activities determined by the Science Council of Great Britain[20] and are randomly checked (the qualified persons' certification was examined in detail in this country [24]). This approach was also used in the template for the annual report of qualified persons' RSC on continuing professional development: the Supplementary Programme is recommended to correlate the following types of professional development with professional activities and performance of office duties, and attach the relevant evidence:

– on-the-job training (performing the functions of a staff internship / student internship manager, developing training proposals, writing reports);

– professional activities (participation in a professional society, mentoring);

– formal training (writing scientific and popular scientific articles / documents, additional professional training);

– self-study (reading magazines, reviewing books and articles);

– other (intellectual volunteering, social activities).

The following examples are indicated as evidence in the template: certificates and testimonies, training materials, reports, a list of studied publications, reviews.

The UK Qualified Persons' Code of Practice has an entire professional development[21] section that details the GMP and professional society requirements discussed above. Additionally, recommendations are given on the procedure for fulfilling the GMP requirements on preliminary training in case of significant changes in qualified persons' labor functions. For example, these can be: changing / expanding the range of medicinal forms released into circulation); when moving to a new place of work and when returning to the activities of qualified persons' after a break: the presence of a training plan approved by the management, which indicates the identified gaps in knowledge and skills and the required training with a time schedule.

As the foregoing example shows, the choice of form(s) and matter(s) of professional development falls on qualified persons themselves. On the other hand, the presence of qualified persons' professional development is a GMP requirement, and, accordingly, is included in the complex of actions of a pharmaceutical company to comply with all established requirements. Therefore, in the authors' opinion, the presence of clear criteria for assessing the adequacy of professional development, established by the regulatory body in the field of assessing the compliance of an enterprise with GMP requirements, by analogy with the regulation and organization in our country and

[19] Orlov VA. An overview of the main innovations in the new version of Appendix No. 16 to GMP rules – "Requirements for confirmation by an qualified person of the conformity of a series of products for the purpose of its release". Available from: https://gilsinp.ru/?wpfb_dl=369

[20] The Science Council Continuing Professional Development. Standards for Registrants. Available from: https://sciencecouncil.org/web/wp-content/uploads/2021/01/Updated-CPD-Standards-for-Registrants.pdf

[21] Qualified Person involved in the manufacture of pharmaceuticals. QP Code of Practice. Available from:https://www.rsc.org/globalassets/09-careers/personal-professional-development/practising-scientists/qpr/qp-code-of-practice-2018.pdf

in the world of continuous medical and pharmaceutical education [25, 26], would have had a significant positive impact on the current situation.

This pilot study did not set the task of identifying the industry practice of organizing internal personnel training, including the methods used in it, which are widely considered in the literature, and assessing their effectiveness [3,4, 12, 27–29]. The study did not investigate the main barriers that hinder qualified persons' professional development, such as lack of time and heavy workload, lack of technical or financial possibilities or doubts about the effectiveness of this process, misunderstanding of the continuous professional development concept [30, 31]. All these problems require a further study.

CONCLUSION

Professional development is the responsibility of qualified persons themselves, as well as the responsibility of the pharmaceutical company. The guidelines for planning professional development are the requirements of the legislation of the country in which qualified persons operate, and other requirements on which their admission to professional activities depends. The professional and official development of qualified persons in our country is characterized by a combination of horizontal (change in the professional and functional areas of activities) and vertical (advancement in the organizational and managerial hierarchy) directions.

The analysis of the open training needs identified in the course of the study, showed that a revision of the Exemplary Additonal Professional Training Program approved by the Ministry of Health of Russia in 2014, is required to improve qualified persons' qualifications of medicines for medical use manufacturers, an update of the professional standard in order to take into account the 2025 (or similar) competency model, and also the competencies of the digital economy.

The identified problems indicate the urgent need for the regulatory authorities to develop schemes and principles for the professional development qualified persons. These will ensure the compliance of individuals and enterprises with the new requirements for this professional group, which are planned to be introduced into Appendix 16 of the Rules of Good Manufacturing Practice of the EAEU, including criteria for CPD of qualified persons, forms and mechanisms for confirming and obtaining the required evidence.

All the foregoing indicates that the problems of qualified persons' professional development are very relevant and require further research, including those identified in this article.

FUNDING

This study did not receive any support from outside organizations.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHORS' CONTRIBUTION

Zhanna I. Aladysheva – idea, research design development, consultation at all research stages, article writing; Natalya V. Pyatigorskaya – research planning; consultation on the conduct of all study stages, article writing; Vasily V. Belyaev – literature analysis, article writing, consultation on research planning and data processing; Natalya S. Nikolenko – data processing, bibliography formalization; Ekaterina I. Nesterkina – consultation on the conduct of separate study stages; Sofya A. Loseva – data processing, bibliography formalization.

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ОРИГИНАЛЬНАЯ СТАТЬЯ
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