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Актуальні питання створення нових лікарських засобів: тези доповідей XXIV міжнародної науково-практичної конференції молодих вчених та студентів (20 квітня 2017 р.). в 2-х. т., Т. 2. – Х.: Вид-во НФаУ, 2017. – 413 с.

Збірка містить матеріали науково-практичної конференції молодих вчених та студентів «Актуальні питання створення нових лікарських засобів». Матеріали згруповано за провідними напрямками науково-дослідної та навчальної роботи Національного фармацевтичного університету. Розглянуто теоретичні та практичні аспекти синтезу біологічно-активних сполук і створення на їх основі лікарських субстанцій; стандартизації ліків, фармацевтичного та хіміко-технологічного аналізу; вивчення рослинної сировини та створення фітопрепаратів; сучасної технології ліків та екстемпоральної рецептури; біотехнології у фармації; досягнень сучасної фармацевтичної мікробіології та імунології; доклінічних досліджень нових лікарських засобів; фармацевтичної опіки рецептурних та безрецептурних лікарських препаратів; доказової медицини; сучасної фармакотерапії, соціально-економічних досліджень у фармації, маркетингового менеджменту та фармакоекономіки на етапах створення, реалізації та використання лікарських засобів; управління якістю у галузі створення, виробництва і обігу лікарських засобів; інформаційниих технологій у фармації та медицині; основ педагогіки та психології; суспільствознавства; філології. Для широкого кола наукових і практичних працівників фармації та медицини.

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Topical issues of new drugs development: Abstracts of XXIV International Scientific And Practical Conference Of Young Scientists And Student (April 20, 2017) in 2 vol., Vol. 2. – Kh.: Publishing Office NUPh, 2017. – 413 P.

Book of Abstracts includes materials of Scientific and Practical Conference of Young Scientists and Students «Actual questions of development of new drugs». Materials are groupped according to the main directions of scientific, research and educational work of the National University of Pharmacy. Teoretical and practical aspects of the synthesis of biologically active compounds and development of medicinal substances on their basis; standardization of drugs, pharmaceutical and chemical-technological analysis, the study of raw materials and herbal remedies development, modern drug technology and extemporal recipe; biotechnology in pharmacy, modern advances in pharmaceutical microbiology and immunology, clinical trials of new drugs, pharmaceutical care for prescription and OTC-drugs, evidence-based medicine, modern pharmacotherapy, socio-economic studies in pharmacy, marketing management and pharmacoeconomics during the development, implementation and use of drugs, quality management in development, production and traffi cking of drugs; information technologies in pharmacy and medicine; basics of pedagogy and psychology; social science; philology are presented. For a wide audience of scientists and pharmaceutaical and medicinal employees.

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ORGANIZATION OF THE AUTHORIZED PERSON ACTIVITY AT THE DISTRIBUTION PHARMACEUTICAL COMPANY

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Introduction. In accordance with the national regulations of Ukraine and EU, the Authorized Person (AP) in a pharmaceutical company (PhC) is an employee with a higher pharmaceutical education.

The Authorized Person is responsible for the functioning of the Quality Management System of medicinal products, as well as granting permission for their further implementation.

The rational organization of the AP's activity at the pharmaceutical enterprise is of scientific and practical interest for the reasons that the experience of organizing and regulating their activities at distribution companies in Ukraine and CIS countries is still not enough.

Aim. The purpose of our work is to develop proposals for improving the organization of professional activities of the AP based on a typical distribution pharmaceutical company. The object of research: activities of the authorized person on the example of pharmaceutical distribution company "Venta. Ltd", m. Dnipro, Ukraine (Importer and distributor nationwide. "Venta. Ltd " is occupies a leading position among the top 10 importers of Ukraine: 600 suppliers, 1000 series medications daily, 150 series of direct import of medicines every day).

The Subject of research: methodology of organization and improvement of authorized person activities at the pharmaceutical companies and wholesale sale of medicines.

Materials and methods. The European and Ukrainian legislation in the field of activity of pharmaceutical distributors has been studied and analyzed, in particular the EU Directive on Good Distributive Practices (GDP), the national GDP guidelines (Guidance СТ-Н МОЗУ 42-5.0:2014 Medicines. Good distribution practice), government regulations, orders of the relevant ministries, Licensing conditions for the production and trade of medicines (Постанова КМУ від 30 листопада 2016 р. № 929), Guidance ICH Q10 Pharmaceutical Quality System etc.

Results of the research. Based on the results of our sociological research, we have been identified the main problems associated with the suboptimal organization of the activities of Authorized Persons at large pharmaceutical distribution companies.

Such problems include:

- inconsistencies during the implementation of the incoming quality control of medicines,
- delays in approving suppliers and customers,
- difficulties with signing pharmacovigilance agreements,
- problems with handling claims for quality,
- inadequate results in staff training,
- rather formal approaches to internal audits etc.

In accordance with the regulatory requirements studied and based on studying the experience of domestic distribution company, we concluded that the following functions should be assigned to the duties of the AP:

- ensuring the implementation and operation of the Quality Management System;
- ensuring the proper performance of input and output quality control of medicines;
- licensing activity;
- participation in training and certification of personnel on quality assurance issues;
- complaints management;
- approval of suppliers and customers;
- medicines recall organization etc.

We also developed a draft of the Regulation on the leaders of QMS processes ("process owners"), documented procedure "Document management", SOP "Acceptance and input control of purchased products" etc.

Conclusions. Summarizing the results of the conducted studies, it can be stated that to optimize the work of Authorized Persons at large distribution pharmaceutical companies, it is rational to appoint several authorized persons, in particular those responsible for the:

- functioning of the Pharmaceutical Quality System,
- incoming quality control of medicines and medical products,
- working with complaints,
- pharmacovigilance,
- withdrawal of medicines, etc.

For each of these areas, we have developed a detailed list of functions that can be use in the development of job descriptions and Standard operating procedures (SOP). We have also developed the subject of internal training courses for authorized persons and criteria for a systematic evaluation of their activities.

These criteria can be used for internal certification of Authorized Persons and verification of the effectiveness of training activities.