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НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

TOPICAL ISSUES OF NEW MEDICINES DEVELOPMENT

МАТЕРІАЛИ
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Topical issues of new medicines development: матеріали XXVII Міжнародної науково-практичної конференції молодих учених та студентів (8-10 квіт. 2020 р., м. Харків). – Харків: НФаУ, 2020. – 494 с.

Збірка містить матеріали науково-практичної конференції молодих учених та студентів «Topical issues of new medicines development», які 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 й обігу лікарських засобів; інформаційних технологій у фармації та медицині; основ педагогіки та психології; суспільствознавства; філології. Також у Збірці опубліковані матеріали учасників Всеукраїнського конкурсу студентських наукових робіт зі спеціальності «Фармація, промислова фармація» Для широкого кола наукових і практичних працівників фармації та медицини.

Book of Abstracts includes materials of Scientific and Practical Conference of Young Scientists and Students «Topical issues of new medicines development». Materials are groupped according to the main directions of scientific, research and educational work of the National University of Pharmacy. Theoretical 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. Also in book there are published material ob All-ukrainian contest student scientific work on speciality “Pharmacy, Industrial Pharmacy” For a wide audience of scientists and pharmaceutaical and medicinal employees.

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Вельмишановні колеги!

Вже понад двадцять років поспіль у квітучі та сповнені особливого весняного настрою квітневі дні Національний фармацевтичний університет проводить традиційну студентську конференцію, яку сьогодні знаємо під назвою «Актуальні питання створення нових лікарських засобів». Дні студентської науки були започатковані іще раніше – у 60-х роках минулого століття. Тож серед усіх традицій, якими багатий наш колектив, підтримка прагнення молоді до наукового пошуку була і залишається однією з пріоритетних. І завдання це – щоб у науку приходили завзяті за здібні студенти – надважливе, що яскраво продемонструвало нам сьогодення.

Серед вихору проблем, з якими повсякчас стикається людство, і які загострилися у році 2020-му, бачимо, як потрібні світу науковці, й особливо – вчені, які працюють у фармацевтичній сфері, розробляють нові ліки та вакцини, ті, чиє покликання – рятувати життя та оберігати здоров'я людства. Й ось шлях до таких необхідних винаходів та відкриттів починається уже сьогодні, в інститутах, академіях та університетах, де студенти мають змогу проводити свої перші наукові дослідження та демонструвати їх широкому загалу.

Національний фармацевтичний університет пишається тим, що попри всю складність ситуації, попри те, що ми вперше проводимо нашу традиційну конференцію дистанційно, до збірки тез XXVII Міжнародної науково-практичної конференції молодих вчених та студентів «Актуальні питання створення нових лікарських засобів» увійшло 385 робіт науковців із 5 країн світу. Адже це є свідченням того, що науковий пошук не зупиняється, що так багато є талановитої молоді, яка пов'язує своє майбутнє із фармацією у всій її багатогранності, а значить – безумовною є надія на краще та впевненість у тому, що всі перешкоди будуть подолані.

Тож нехай успішною та багатою на здобутки буде наукова доля кожного студента, який сьогодні робить перші кроки в науці! Сміливо та натхненно прямуйте вперед, знаючи, що Alma mater завжди підтримає вас, адже Національний фармацевтичний університет – на вашій стороні, на стороні здоров'я!

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ОРГАНІЗАЦІЯ НАВЧАННЯ ПРАЦІВНИКІВ З ПИТАНЬ УПРАВЛІННЯ РИЗИКАМИ ДЛЯ ЯКОСТІ НА ФАРМАЦЕВТИЧНОМУ ПІДПРИЄМСТВІ

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Ефективне функціонування будь-якої організації, насамперед, визначається ступенем розвитку її персоналу. За умов сучасного швидкого старіння теоретичних знань, умінь та практичних навичок спроможність організації постійно підвищувати фаховий рівень своїх працівників є одним із найважливіших факторів забезпечення конкурентоспроможності її на ринку, оновлення і зростання обсягів надання послуг.

Одним з обов'язкових для виконання положень стандарту ISO 9001 є визначення необхідного рівня компетентності персоналу підприємства та постійне його забезпечення і підвищення. Висока компетентність кожного з членів колективу організації є не лише "виробничою" умовою, а й вагомим стимулом для плідної праці, адже саме постійний розвиток особистості підвищує задоволеність своєю працею, дозволяє займати поважне місце у колективі, передбачає кар'єрне зростання тощо.

Надважливий аспект знань та умінь персоналу фармацевтичної організації – це ризик-орієнтоване мислення та володіння методами визначення, аналізування й оцінювання ризиків для якості продукції з метою їх мінімізації чи повного усунення. Ці компетенції – важлива складова загального портрету фахівця у фармацевтичній сфері галузі охорони здоров'я, адже мова йде про надто специфічну продукцію – лікарські засоби. Ризики, притаманні розробці, виробництву, контролю й реалізації ліків мають бути повністю відомі й контрольовані. Відповідно, навчання працівників фармацевтичного підприємства (ФП) елементам ризик-менеджменту є важливою складовою загального процесу навчання.

Виходячи з вищенаведеного, основною метою нашої роботи була розробка пропозицій щодо навчання персоналу згідно із вимогами стандартів ISO серії 9000 та положеннями Належної виробничої практики (GMP) на базі вітчизняного ФП.

Мета навчання персоналу ФП полягає у:

- підтримці необхідного рівня компетентності працівників;
- підвищенні конкурентоспроможності організації завдяки знанням, професійному досвіду та ефективним методам організації праці;
- створенні сприятливих умов для кар'єрного росту та самореалізації на основі мотивації й професійної підготовки;
- підвищенні рівня професійної кваліфікації працівників;
- збільшенні ефективності праці;
- підготовці персоналу до ротаційного переміщення тощо.

Основну роль у розвитку конкурентоспроможності персоналу відіграє навчання персоналу, тому що воно є джерелом підвищення рівня професійної компетентності працівників, способом прискорення адаптації співробітників до роботи в організації й методом забезпечення більш глибокого розуміння ними стратегічної мети і організаційної культури підприємства. Все це безпосередньо впливає на підвищення їх індивідуального рівня конкурентоспроможності. Саме тому підприємство має сприяти розвитку найманих працівників. Здатність персоналу підприємства навчатися і розвиватися швидше за своїх конкурентів є джерелом його соціальних, стратегічних і економічних переваг у майбутньому. Успішний розвиток персоналу вимагає використання конкретних заходів, спрямованих на формування й активізацію його знань, можливостей і поведінкових аспектів, які мають враховуватися при виборі кадрової стратегії,

обґрунтованої кадрової політики, а також реалізуватися в проектах розвитку персоналу з використанням сучасних методів і механізмів.

Чинником забезпечення конкурентоспроможності персоналу є попередня професійна перевірка знань нового персоналу, яка виступає головним інструментом ефективного управління кадрами і ключовим моментом сертифікації кадрів вже на етапі відбору та підбору кадрів. Проведення регулярної перевірки знань не тільки нового персоналу, але й постійного дозволить визначати пріоритети розвитку працівників, прогнозувати і планувати їх кар'єру, таким чином, сформувати й підтримувати у працівників мотивацію до розвитку необхідних підприємству компетенцій, що, без сумніву, буде сприяти зростанню конкурентоспроможності підприємства.

За результатами наших досліджень були запропоновані види професійного навчання та розроблено документовану процедуру "Управління персоналом" стосовно навчання й діагностики знань персоналу на ФП яка містить опис всіх стадій процесу навчання у графічній і текстовій формі. Також були розроблені СОП "Оцінка якості внутрішнього навчання", програма внутрішнього навчання персоналу на прикладі програми для майстрів виробничої дільниці та програма внутрішнього тестування персоналу на знання загальних вимог GMP до процесів виробництва лікарських засобів. Реалізація пропозицій сприятиме підвищенню рівня професійної компетентності працівників на ФП. Здатність підприємства навчатися і розвиватися швидше за своїх конкурентів є джерелом його соціальних, стратегічних і економічних переваг.

УПРАВЛІННЯ РИЗИКАМИ ЯКОСТІ У ФАРМАЦЕВТИЧНІЙ ГАЛУЗІ

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Актуальність: Управління ризиками якості (УРЯ) – це загальний і тривалий процес мінімізації ризиків для якості продукції протягом свого життєвого циклу для того, щоб оптимізувати його користь та збалансувати ризик. Принципи УРЯ ефективно широко використовується у різних галузях.

У фармацевтичній промисловості процес управління ризиками для якості законодавчо почався з включення в 2008 р в структуру Керівництва GMP ЄС, як 20-го додатку. Далі Настанова ICH Q9 «Управління ризиками для якості» з 2008 р. увійшла в якості додатку № 20 до Національної настанови з GMP (СТ-Н МОЗУ 42-4.0:2010 «Лікарські засоби. Належна виробнича практика»), а у 2011 р. набула чинності окрема Настанова СТ-Н МОЗУ 42-4.2:2011 «Лікарські засоби. Управління ризиками для якості (ICH Q9)», яка також була введена в частину 3 Настанови СТ-Н МОЗУ 42-4.0:2011 «Лікарські засоби. Належна виробнича практика», гармонізованої з настановою з GMP ЄС.

Мета: Дослідження загальної концепції управління ризиками для якості в діяльності фармацевтичних підприємств.

Матеріали та методи: Процес оцінки ризику повинен здійснюватися шляхом аналізу, виявлення та оцінки ризику, а плани УРЯ повинні бути переглянуті після їх подальшого контролю. Реалізація УРЯ забезпечує задокументовані, чіткі та відтворювані методи для здійснення етапів процесу УРЯ, засновані на сучасних знаннях про оцінку ймовірності, серйозності та іноді виявлення ризику. Використовуючи інструменти УРЯ, фармацевтична промисловість та регулятори можуть оцінювати, контролювати, повідомляти та переглядати ризики. Ефективна реалізація УРЯ може сприяти кращим і обґрунтованим рішенням, що може надати регуляторам більшу впевненість у здатності компанії боротися з можливими ризиками.

Висновки. Ефективний підхід УРЯ може надалі забезпечити високу якість лікарського засобу для пацієнта шляхом виявлення та контролю потенційних проблем якості під час розробки та виготовлення.

Використання УРЯ може покращити прийняття рішень, якщо виникне проблема якості. Ефективна реалізація УРЯ може сприяти кращим і обґрунтованим рішенням, що може надати регуляторам більшу впевненість у здатності компанії боротися з можливими ризиками.

АНАЛІЗ ТЕМПІВ ТА ПЕРСПЕКТИВ ВПРОВАДЖЕННЯ СИСТЕМ ЕКОЛОГІЧНОГО МЕНЕДЖМЕНТУ В УКРАЇНІ

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Актуальність: Останніми роками в світі гостро стоїть питання відновлення екології, збереження її теперішнього стану або, принаймні, зменшення негативного впливу людини на неї. Офіційні та громадські організації всього світу намагаються вирішити це питання різними методами, від пропаганди зменшення використання пластику і заохочення сортувати відходи до відкритих конфліктів з підприємствами, що негативно впливають на навколишнє середовище. Такі конфлікти і інші негативні процеси є небажаним явищем в бізнесі.

Однак, на жаль, питання збереження екології досі не вирішене і навряд чи вирішиться так швидко, як цього бажає світ. Тому є актуальним пошук шляхів, що будуть вести до вищеназваної мети. Ця проблема змусила організації по всьому світу звернути увагу на розроблений у 1996 році стандарт ISO 14001. Цей стандарт встановлює вимоги до екологічного менеджменту з метою збільшення екологічної ефективності бізнесу, що має процеси виробництва, утилізації відходів тощо.

Стандарт ISO 14001 є одним з лідерів за популярністю впровадження організаціями в світі. Аналітичні дані від ISO вказують на те, що з 2013 року в світі з'явилась тенденція на активну сертифікацію організацій за ISO 14001, що висловлює бажання підприємств оптимізувати свій екологічний менеджмент (рис.1)

Рис. 1. Кількість сертифікованих систем екологічного менеджменту (на підприємствах 184 країн світу).

Таким чином, на кінець 2018 року було зафіксовано майже 310 тисяч отриманих сертифікатів у 184 країнах світу.

В лідерах за їх кількістю знаходяться Китай, Японія, Іспанія, Італія та Велика Британія (табл. 1). Найбільше сертифікатів на СЕМ (системи екологічного менеджменту) видано в сферах будівництва, виробництва транспорту і металопродукції (табл. 2).

Таблиця 1. Топ-5 країн за кількістю отриманих сертифікатів відповідності вимогам ISO 14001

№ з/п	Країна	Кількість сертифікатів	Кількість дільниць
1.	Китай	136 715	137 935
2.	Японія	19 131	40 097
3.	Іспанія	12 198	28 020
4.	Італія	15 118	26 978
5.	Велика Британія	11 201	21 809

Таблиця 2. Передові галузі (усього 39) за кількістю сертифікованих організацій на відповідність вимогам ISO 14001 у світі

№ з/п	Сфера	Кількість сертифікованих організацій
1.	Будівництво	53 978
2.	Виробництво транспорту	27 722
3.	Виробництво і переробка металопродукції	26 880
4.	Електроніка, точна механіка, оптика	26 211
5.	Інжинірингові послуги	19 009

Зважаючи на темпи і кількість виданих сертифікатів на СЕМ в світі, українські підприємства також повинні розвиватись і впроваджувати у себе не тільки ISO 9001, а і ISO 14001. Такі вимоги диктує світовий розвиток бізнесу і промисловості, і відповідність міжнародним стандартам дає можливість бути впевненим в якості ведення процесів, готових товарів та послуг.

Мета: Проаналізувати темпи впровадження систем екологічного менеджменту в Україні та перспективи щодо зростання кількості сертифікованих організацій.

Матеріали та методи: Для збору інформації та проведення дослідження були використані офіційні дані Міжнародної організації зі стандартизації (ISO) і Державної служби статистики України, з метою отримання найбільш точних і актуальних офіційних даних щодо динаміки сертифікації за ISO 14001 і показників витрат підприємств на екологію.

Отримані результати: За кількістю сертифікатів, Україна займає далеко не перші сходинки в відповідному світовому рейтингу. Станом на 2018 рік на території країни зафіксовано більше ніж 200 сертифікатів на СЕМ, переважно в сфері машинобудівництва, харчової промисловості, будівництві, електротехніки ти виробництві металопродукції (табл. 3).

Таблиця 3. Передові галузі за кількістю сертифікованих організацій на відповідність вимогам ISO 14001 в Україні

№ з/п	Сфера	Кількість сертифікованих організацій
1.	Виробництво транспорту	30
2.	Харчова промисловість та виробництво тютюну	28
3.	Будівництво	27
4.	Електроніка, точна механіка, оптика	26
5.	Виробництво і переробка металопродукції	23

Безумовно, в масштабах країни, а тим паче, світу, це дуже низька кількість сертифікатів. Для порівняння, використаємо досвід сертифікації за ISO 14001 західних сусідів – Польщі. Офіційні дані свідчать про 2309 зафіксованих сертифікатів станом на кінець 2018 року. Тобто, спостерігається відставання України приблизно в 10 разів за цим показником.

Однак, разом з тим, треба зауважити, що витрати на екологію, згідно Держстату, зростають. Згідно офіційним даним, витрати на екологічний аспект діяльності (поводження з

відходами, очищення небезпечних викидів в атмосферу тощо) на кінець 2018 року, порівняно з 2017 роком, зросли на 18%. Це свідчить про те, що український бізнес рухається за світовими тенденціями і звертає увагу на управління екологічними питаннями своєї діяльності.

Висновки: Таким чином, можна констатувати, що Україна намагається слідкувати світовим тенденціям і вимогам. Темпи сертифікації за ISO 14001 зростають, однак дуже мінливими і обережними темпами. Аналізуючи статистику забруднення навколишнього середовища в Україні і витрат на збереження екології, потрібно відзначити, що українські організації, як і суспільство в цілому, готове вчитись екологічному менеджменту не тільки в аспекті менеджменту організацій, а й в побутових питаннях. Окрім того, можна виявити підготовку до сертифікації та ймовірну готовність до отримання сертифікатів на СЕМ, для забезпечення не тільки якості готової продукції та менеджменту в цілому, а і для підтримання іміджу і відповідності вимогам зарубіжних ринків.

УПРАВЛІННЯ ПРОТОКОЛАМИ ЗА ДОПОМОГОЮ QR – КОДУВАННЯ У СИСТЕМІ ЗАБЕЗПЕЧЕННЯ ЯКОСТІ ФАРМАЦЕВТИЧНОГО ДИСТРИБ'ЮТОРА

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Вступ. Вимоги до управління протоколами на паперовому носії або в електронному вигляді, що слід вести під час виконання кожної операції з дистрибуції, регламентуються у Постанові КМ України № 929 від 30.11.2016 «Про затвердження Ліцензійних умов провадження господарської діяльності з виробництва лікарських засобів, оптової та роздрібної торгівлі лікарськими засобами, імпорту лікарських засобів (крім активних фармацевтичних інгредієнтів)» (далі – ЛУ) та СТ-Н МОЗУ 42-5.0:2014 «Настанова. Лікарські засоби. Належна практика дистрибуції» (далі – GDP).

Управління протоколами під час дистрибуції фармацевтичної продукції сприяє подальшому наданню доказів досягнутих результатів, виконаних робіт, відповідності вимогам законодавства України та результативного функціонування системи управління якістю (далі – СУЯ) на підприємстві.

Мета: Метою є запропонування метода QR – кодування в управлінні протоколами, що додатково забезпечить їх доступність, актуальність, збереження та ефективне управління в усіх процесах СУЯ і прийняття обґрунтованих управлінських рішень, заснованих на об'єктивних та достовірних даних.

Матеріали та методи. В якості інформаційної бази досліджень нами використані нормативні документи, що нормують функціонування СУЯ фармацевтичного дистриб'ютора – ЛУ та настанова GDP, профільні стандарти ISO та інші джерела інформації з використанням методу порівняльного аналізу та практичного досвіду.

Отримані результати. Для реалізації процедури управління електронними версіями протоколів за допомогою QR – кодування, які утворюються методом фотокопіювання оригіналу паперового протоколу, у внутрішню документовану процедуру СУЯ фармацевтичного дистриб'ютора необхідно врахувати наступні рекомендації:

1. Необхідно у кожну документовану процедуру СУЯ вносити розділ «Документація, що стосується даної процедури» та у даному розділі описувати процес та наводити інформацію про розподіл документів (що стосуються певного процесу СУЯ), між відповідальними особами та

місця їх архівування. Такий розділ рекомендовано оформлювати у вигляді таблиці, приклад якої наведено нижче.

Таблиця 1. «Документація, що стосується даної процедури»

№ з/п	Вид документу	Форма документа	Статус	Місце основного збе-рігання	Назва папки / посилання на директорію КЦС[1]	Назва файлу[2] для архівування у сховищі КЦС[1]	Відповідальна особа за зберігання
1	Перелік документів СУЯ (Додаток А)	П	О	ОФ	SOP-4.002		УО
		Е	Ф	КС	https://RECORDS/DOCUMENTATION/SOP-4.002	Версія №*X* від *ДД.ММ.РРРР* р. (СОП-4.002_02_А)	УО

[1] – Корпоративне сховище цифрової (електронної) інформації, що має певний ступінь захисту.
[2] – Назва файлу має містити точну назву, як указано у прикладі. Текст за курсивом має заповнюватись співробітниками, що архівують електронну копію у сховище.
П – Паперовий. Е – Електронний.
О – Оригінал. Ф – Фотокопія.
ОФ – Офіс.
КС – Комп'ютеризована система.
УО – Уповноважена особа.

2. QR – кодуванням позначається:

- Шлях розміщення затверджених робочих форми протоколів у корпоративну сховищі цифрової (електронної) інформації, що має певний ступінь захисту та доступні тільки для визначених користувачів;

- Місце для архівування (посилання на директорію корпоративного сховища цифрової (електронної) інформації, що має певний ступінь захисту), що зазначена у Таблиці 1. «Документація, що стосується даної процедури».

Згенеровані QR – коди для затверджених робочих форм протоколів та місця для їх архівування у корпоративне сховище цифрової (електронної) інформації рекомендується оформлювати у вигляді таблиці та наносити на зворотному боці останньої сторінки документованої процедури СУЯ (наприклад за допомогою самоклеючого стікера), якою затвердженні данні протоколи або використовувати іншій зручний метод для користувачів. Приклад такої таблиці наведено нижче.

Таблиця 2. Інформація з QR – кодами

Назва протоколу	QR – код для завантаження[1] робочої форми	QR – код для архівування електронної копії заповненого протоколу	Назва файлу[2] для архівування у сховищі
Перелік документів СУЯ (Додаток А)			Версія №*X* від *ДД.ММ.РРРР* р. (СОП-4.002_02_А)

[1] – За QR – кодами дозволяється тільки завантаження робочої форми на комп'ютер для подальшого заповнення.
[2]- Назва файлу має містити точну назву, як указано у прикладі. Текст за курсивом має заповнюватись співробітниками, що архівують електронну копію у сховище.

Висновки. Процес управління протоколами у СУЯ фармацевтичного дистриб'ютора, відіграє важливу роль для доказу досягнутих результатів інших процесів СУЯ. Відповідно до вимог GDP, дистриб'ютори повинні зберігати протоколи не менше п'яти років, а якщо висуваються додаткові вимоги, то такий термін збільшується.

Для своєчасної доступності протоколів, їх швидкого пошуку, найчастіше протоколи фотокопіюють та переміщують до комп'ютеризованих систем або інші електронні сховища. Але часто спостерігається ситуація, коли відсутня точна інформація про місця архівування та назви протоколів, що може викликати плутанину у персоналу.

Тому одним із методів управління протоколами СУЯ, нами запропоновано:

- вносити в документовані процедури розділ «Документація, що стосується даної процедури» для строгої регламентації порядку роботи з протоколами;
- закодувати QR – кодом шляхи завантаження затверджених робочих форм протоколів та шляхи їх архівування у корпоративне сховище цифрової (електронної) інформації.

Вищезазначені методи зменшують ризик помилки персоналу, що працює з протоколами з подальшим фотокопіюванням та архівацією. Ці методи також можливо враховувати при проведенні валідації комп'ютеризованих систем, що приймають участь у процесі управління протоколами.

THE RESEARCH OF PSYCHOLOGICAL CLIMATE IN ORGANIZATIONS OF PHARMACEUTICAL PROFILE

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Introduction. Currently, the problem of the psychological climate in the team is very relevant in conditions of economic instability and low motivation of workers to work. Accordingly, this entails a high turnover rate, which in turn is harmful to the activities of pharmaceutical enterprises, if highly skilled workers often quit, respectively, a high turnover rate signals a threat to the stability and integrity of the organization and is associated with significant costs. Therefore, theorists, social psychologists, personnel specialists, internal communications specialists – and company leaders are increasingly thinking about how to improve the socio-psychological climate in the team. However, despite the relevance, this problem is still virtually unexplored from a modern point of view. The relationship between the effectiveness of the organization and its socio-psychological climate is the most important problem for company executives. Therefore, it is so important to know the components of the socio-psychological climate of the organization and their study. A favorable socio-psychological climate is the result of the systematic work and activities of managers, managers, psychologists and all employees of the organization.

Aim. The aim of the study is to analyze and evaluate the socio-psychological climate in the team. After the formulation of the goals and objectives of the study, it is necessary to choose the method by which data will collected. We recommend a questionnaire survey as the most effective method of collecting data in medium and large teams, which, subject to conditions, provides a high guarantee of the sincerity of answers.

Materials and methods. Methodology for assessing the psychological atmosphere in a team (according to A. F. Fidler) is use to assess the psychological atmosphere in a team. It is based on the method of semantic differential. The technique is interesting in that it allows anonymous examination, and this increases its reliability. Each extreme value is assignee a number of points: the extreme negative – 8, the extreme positive – 1. Then all the indicators are ads, and based on the value of the sum,

the atmosphere is evaluate in the team. The minimum total score is 10, which is an indicator of the positive atmosphere in the team; the maximum is 80, respectively, an indicator of the negative atmosphere. Based on all private assessments, an average value is calculate that will characterize the atmosphere in the team.

	1	2	3	4	5	6	7	8	
Friendliness									Hostility
Consent									Disagreement
Satisfaction									Dissatisfaction
Productivity									Unproductive
Heat									Cold
Cooperation									Inconsistency
Mutual support									Malevolence
Passion									Indifference
Entertaining									Boredom
Success									Failure

Results and discussion. The study of the socio-psychological situation at the enterprise includes several stages of work.

The first stage is preparatory. At this stage, the goals and objectives, volumes and terms of the study, responsible for organizing and conducting the assessment procedures, are identifies and agreed. Also at this stage, the final model for studying the socio-psychological situation at the enterprise is former and approve.

The next, second stage is research, during which diagnostic measures and procedures are carrier out in a number of areas:

1. The study of the representations of employees about the state of affairs in the organization.

The result is a characteristic of employees' social perceptions about various aspects of the organization’s life; determining the degree of employee awareness of the state of affairs in the organization and identifying the overall attitude (positive or negative) in relation to what is happening; a comparative analysis of employee perceptions and managers' perceptions of the state of affairs in the organization; description of available social and psychological resources and potential threats to the effective activities of employees.

2. The study of social – psychological climate in the team.

The result is the determination of the degree of favorable psychological atmosphere in the team; identification of areas of psychological tension in the team; determination of team cohesion at the value level; identification of employees' ideas about the goals of the organization and its unit; identification of personal goals of employees and their consistency with the goals of the organization (unit).

We conducted a survey of two teams of 15 people and established point values for evaluating the above parameters. The results of the questionnaire indicate the prevalence of positive traits among the teams: mutual support, friendliness, cooperation and a number of negative traits: boredom and failure. That shows a low interest in the activities of the enterprise.

3. The study of the level of satisfaction with the conditions of activity.

Study of employee motivation for activities.

The result is a study of the degree of satisfaction with working conditions; the study of employee perceptions of the motivating factors present in the organization; the study of the system of motivators in terms of their importance for effective activity; study of the orientation of group motivation.

4. The study of the role structures of the team.

Result: assessment of each employee, obtaining a concentrated and statistically significant opinion of the team about a specific person. Assessment of a group of employees as a whole.

One of the important stages of the study is the analytical stage. In its course, a generalization and analysis of the final results takes place.

The formation of conclusions and recommendations occurs in the following areas:

1. Does the organization (unit) have sufficient social and psychological resources to change and achieve its goals?

2. What are the limitations and potential for effective individual and group activities of the team as a whole?

3. What socio-psychological factors affect the increase (decrease) in personnel efficiency?

4. Under what conditions will the collective potential be realized to the maximum extent?

5. How and in what areas is it necessary to develop a system of managerial influences to optimize the activities of the enterprise (unit)?

At the final stage, they summarize the diagnosis and research.

Conclusions. A favorable socio-psychological climate is a condition for increasing labor productivity, satisfaction of workers, work and the team. Socio-psychological climate arises spontaneously. But a good climate is not a simple consequence of the proclaimed mottos and efforts of individual leaders. This is the result of systematic educational work with team members, the implementation of special events aimed at organizing relations between managers and subordinates. The formation and improvement of the socio-psychological climate is a constant practical task for managers of any rank. Creating a favorable climate is not only responsible, but also creative, requiring knowledge of its nature and means of regulation, the ability to provide a reliable situation in the team's relationship.

DEVELOPMENT OF MEASURES TO INCREASE THE COMPETENCE OF INTERNAL AUDITORS OF PHARMACEUTICAL QUALITY SYSTEMS

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Introduction. In addition to expanding product range and technical modernization, many pharmaceutical companies' management aims to improve the quality management system (QMS). One of the important processes of QMS is internal audit, the development of which is given considerable attention. Audit directly affects the quality of the implementation of all processes of the organization, as a consequence - the quality of products. The competence of the auditors depends on the value of the audit results, as well as the attitude to the quality issues by the staff. Audit confidence depends on the auditors' competence. The auditors should demonstrate:

- proper personal qualities;
- ability to apply professionally knowledge, skills and experience in conducting the audit;
- depending on the audit program, the organization must always determine the required level of competence of all internal auditors.

So, components of the auditor's competence are the professional knowledge, personal qualities required, experience and skills.

Aim: to substantiate the relevance, to analyze and to offer a rational approach to training of internal auditors of the quality management system based on a pharmaceutical company.

Research objectives:

- an overview of the ISO 9001 and 19011 standards;
- defining the necessary knowledge, skills and personal qualities that quality auditors should possess;

- identifying effective approaches, methods and tools for the training of the internal auditors;
- development of a set of proposals for training and control of competence of the internal auditors of a pharmaceutical company.

Object of research: quality management system of a manufacturing pharmaceutical enterprise. Subject of research: the process of internal audits training.

Materials and methods. To carry out our research, we carried out studies on the provisions of ISO 9001 and ISO 9000 as part of an overall management system based on the quality risk analysis approach needed to create, implement, operate, monitor, review, maintain and improve of QMS.

Results and discussion.

Professional auditor's knowledge and skills:

- knowledge, understanding and ability to interpret ISO 9001 and all industry requirements;
- knowledge and ability to audit in accordance with the provisions of international standard ISO 19011;
- ability to generate ideas to improve and optimize organization and product processes.

Our auditor selection conditions are:

- profile education (e.g. "Quality, Standardization and Certification")
- internship (minimum 2 internship audits);
- experience (at least 2 years in quality);
- honesty, openness, sociability, impartiality, diplomacy, receptivity;
- analytical thinking;
- ability to clearly formulate thoughts.

When planning auditor training, we consider it necessary to determine:

- objectives and requirements of the organization for the audits of QMS;
- substantiation of training needs;
- purpose and scope of training;
- target groups of selected applicants;
- learning methods, content of training courses;
- person responsible for training.

Required resources for the implementation of the curriculum:

- training schedule (duration, timing and main stages of training);
- training procedures (for teachers);
- methodical materials, visual aids;
- knowledge diagnostic tools (criteria and methods developed to evaluate the learning outcomes and performance appraisal of auditors).

We have developed the training program for internal auditors, focused on 50 hours of lectures and 40 hours of practical training. The training program contains test assignments on the materials of lectures and practical lessons necessary for the diagnosis of mastering the material.

Conclusions. It is proved that proper training of internal auditors makes the audit process really effective, and a comprehensive analysis of the QMS is truly valuable for senior management. The directions and stages of auditor training are suggested. Recommended topics and types of classes. Examples of tasks and methodology for diagnostics of auditors' competence are developed. The universal training program for internal auditors has been prepared.

UPDATE OF IMPLEMENTATION OF ENERGY MANAGEMENT AT UKRAINIAN ENTERPRISES

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Relevance: The basis of the modern mechanism for improving the competitiveness of enterprises is an innovative model of economic development. The most important factor influencing the competitiveness of products is the share of the energy component in the cost of production. Reducing energy consumption leads to increased profitability and competitiveness of the enterprise. Energy efficiency is addressed through energy management.

In order to activate energy saving processes, the concept of the energy management system (CENM) was widely developed. World experience shows that the introduction of an efficient CENM service in an enterprise that implements the ISO 50001 Standard "Energy Management Systems: Requirements with Operations Manual" can provide an annual reduction in the cost of fuel and energy resources of about 10-15%.

Objective: To analyze the relevance of the implementation of energy management systems in Ukraine and the prospects for increasing the number of certified organizations.

Materials and Methods: Official data from the International Organization for Standardization (ISO) and the State Statistics Service of Ukraine were used to collect information and conduct the survey in order to obtain the most accurate and up-to-date official data on the dynamics of ISO 50001 certification.

Materials and Methods: The experience of European countries shows that implementing energy efficiency policies requires changes at the level of management decisions through the implementation of energy management systems in accordance with ISO 50001 "Energy management systems – requirements and guidelines for application". The state energy efficiency policy should cover all spheres of the national economy – from the regional to the national economy of the country and coordinate administrative, legislative and financial measures to stimulate the economy. Increasing the level of energy efficiency of an industrial enterprise is a task of paramount importance due to the requirements of modernization of the economy, the acceleration of scientific and technological progress, the requirements of socio-economic development, the need to improve the state of the environment. The implementation of the energy efficiency policy is achieved by reducing the energy consumption of industrial products, increasing the use of renewable energy sources and energy conservation. Achieving a significant energy-saving effect is possible provided that not only technical solutions are implemented, but also a more sophisticated energy-saving management mechanism, the energy management system, is applied.

The modern concept of energy management stimulates the emergence and development of metrological support and regulatory and methodological preparation of control, accounting, analysis of energy efficiency, leads to a significant expansion of rights and increase the responsibility of energy services of the enterprise, dramatically enhancing their impact on the efficiency of use of all types of energy resources . As practice shows, despite the significant benefits that can be gained from the implementation of CENM at enterprises, organizations and institutions, there has been no significant promotion of CEN implementation in Ukraine. This is due to the fact that there are many different barriers to the implementation of CEN, including:

- misunderstanding by management of the importance of energy conservation;
- financial unwillingness of enterprises to introduce SEnM;
- the need to reorganize the enterprise structure at the stage of CEN implementation;
- the lack of energy-saving policies;
- lack of incentive system for company personnel;

- insufficient support from management;
- Insufficient awareness of staff about CEN implementation;
- lack of sufficient venture required metering energy consumption.

The main economic benefits of implementing energy management system in the enterprise, providing attractiveness and capitalization growth companies):

- organizational effect (increase of company management): efficient management of energy consumption; improving the production cycle; improving the overall control of the company and optimizing all business processes;
- financial effect (cost optimization company): improving the financial performance of the company through direct savings of energy resources; increase of financial transparency of the company; guarantees of investment in energy-saving projects;
- Reputational effect (to support the image and reputation of the company): the image attractiveness of the company implementing the energy efficiency policy in the eyes of business partners, the population and the authorities; the company's reputation for being successful in improving its energy efficiency.

However, it is necessary to take into account the fact that the formation and development of CENM in enterprises may cause costs related to:

- the need for external expert advice;
- additional education of specialists;
- creation of energy management department;
- further development and maintenance of internal documentation;
- creation of additional means of energy monitoring;
- development, demonstration and dissemination of various information materials on the achieved results of activity of enterprises in the field of energy management, etc.

Activities in the field of energy management should be undertaken by enterprises based on the following principles:

- priority power management;
- «transparency» of the results of energy saving (energy-saving availability performance indicators of the company for all stakeholders);
- wide coverage (involvement of employees of all levels and positions in the energy management activities with clear definition of their subordination and responsibility);
- prevent environmental impact;
- continuous improvement of results of energy saving activities and improvement SEnM;

The company, which has established and built a high-quality work SEnM gets a unique opportunity to improve the production cycle, timely most effective energy saving measures, constantly getting out of these measures in the form of financial gain.

Conclusions: The ISO 50001 standard today is the generally recognized basis for ensuring the integration of energy efficiency into management practices. With the introduction of ISO 50001, companies have been granted access to a single, harmonized standard for the implementation of an enterprise-wide energy-saving system that includes a logical and consistent methodology for identifying and implementing improvements in energy-efficiency and energy efficiency.

CLASSIFICATION OF QUESTIONS USED TO OBTAINING INTERNAL AUDIT EVIDENCE FOR PHARMACEUTICAL QUALITY SYSTEMS

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Introduction. In accordance with GMP EC requirements, self-inspections (internal audits, IA) should be systematically conducted to evaluate the effectiveness and suitability of the pharmaceutical quality system (PQS) at manufacturing and distribution pharmacist companies (PC).

According to previous studies, it was established the main reason for the low IA effectiveness is found to be the lack of professionalism of the auditors, which is reflected in, for example, the lack of a constant ability to conduct interviews, analytical monitoring of staff work, proper audit evaluation and interpretation of different work situations. Poll-related issues include the focus of such an effective audit method only on finding non-compliance with specific regulatory requirements, but not on determining the functioning of the individual process and PQS as a whole. Often, when auditors conducting the questions, they are of a formal nature and are closed-ended questions. In addition, auditors ask questions not only about the audit object identified in the plan, but also about other activities performed in the unit. At the same time, it is known that the focus of the IA is not on the functioning of the PQS processes, but rather on the activities of the units complicates and slows down the audit procedure and increases the risks of failure to achieve the audit objectives.

Aim. The purpose of the study was to analyze approaches and develop suggestions for interviewing staff in conducting IA to collect the evidence needed to make objective, impartial audit decisions.

Materials and methods. The basis for the study were sources of scientific literature of foreign and domestic scientists, ISO 9000 standards, the regulatory framework of the pharmaceutical field of health care related to the functioning of PQS, as well as the results of own studies on the analysis of the IA process on PC. The methods of empirical research were used in the work: systematic-analytical, sociological questioning, comparative analysis, structural-logical modeling.

Results and discussion. Most often, the following methods are used when conducting audits:

- analyzing of documented information;
- interviewing employees at the audited entity;
- observing the activities of the staff at the audited entity.

Interviewing is the most applicable audit method that, unfortunately, is not given proper attention. Based on the results of our research, we find that it is advisable to conduct the interview at certain stages.

It should be noted that conducting a productive interviews involves a certain order of the questions. The process-oriented questions allow you to trace the actual implementation of the PDCA methodology within each audited process. During such an audit, it is possible to evaluate the implementation of all phases of the PDCA cycle - from planning to taking action to improve the process.

At the stage of auditing the planning process, it is advisable to address the process manager with a question. The questions should relate to the distribution of responsibilities and powers among the contractors, maintaining the required level of professional training, awareness of the documented procedures, availability of necessary resources and other aspects.

It is known that any questions of the auditors can have a psychological impact on the interlocutor, so the auditor should be tactful and ask questions of a neutral nature. Audit evidences are considered to be objective only if they are supported by the relevant facts. Otherwise, such evidence is subjective and therefore cannot be used by the auditor to make a decision and report.

It is proved that during the audit it is necessary to use the question-request form: "Could you (show, demonstrate, explain, justify)…., please?". In this case, the interlocutor will not feel pressure from the auditor, and the format of the audit will be open and friendly.

We offer a classification of questions that can be used during IA PQS. Therefore, by its focus, the questions can be divided into:

- main - used to find out the subject of communication; focus on specific audit topics;
- additional - used to detail the interlocutor's answer when the answers to the basic questions are too short.

In turn, it is suggested to divide the additional questions into:

- reminders (help to flesh out the answer),
- clarification (help to disseminate information about the subject of the interview),
- control (used to confirm the collected facts).

Control questions are often revealing when auditors identify differences between actual actions and the documented requirements of an audited entity. It is also a good practice to use detailed questions to confirm the collected data and sources of information. The scheme of classification of audit questions is shown in Fig. 1.

The choice of one type of question depends on the specific purpose of the interview and the situation in which it is conducted. In most cases, it is advisable to ask questions that will be answered and provided with explanations (open-ended questions). Questions that require short yes or no answers (closed) are often uninformative, especially during internal audits.

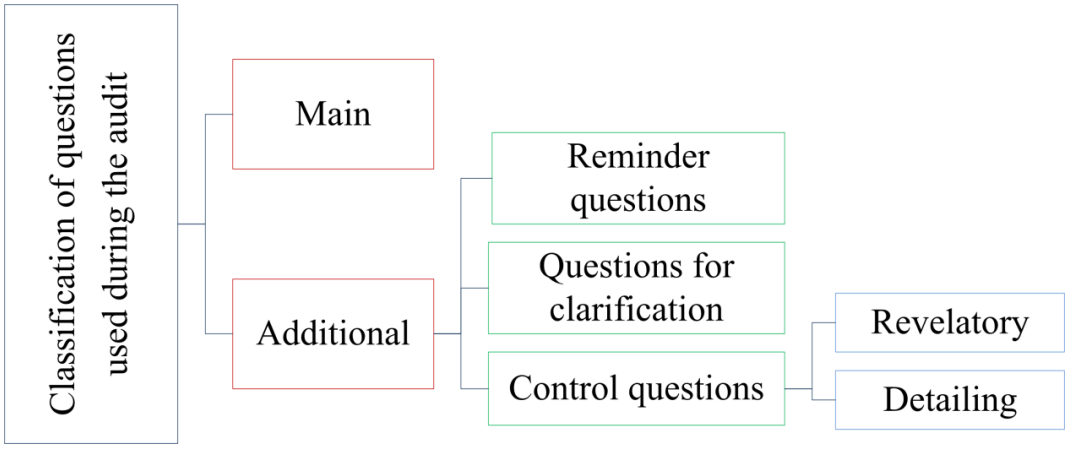

Fig. 1. The classification of questions used during the audit

Choosing the right question formulation is crucial to achieving the goal of the interview.

Conclusions. It is argued that the interview, as a key method of conducting PQS audits, are an important tool for collecting and interpreting audit certificates. In addition, conducting the interview requires careful preparation of appropriate documentation and auditors' competence regarding the audit process and criteria.

It is proven that following the recommendations in practice saves time for preparing and conducting audits; specify the subject matter of the audit and expand the amount and content of the information recorded during the audit; it is better to prepare the auditors and obtain more useful audit results.

In the future, we plan to develop a set of applied recommendations for the organization of audit activities on PC.

THE PROBLEM OF STANDARDIZING THE QUALITY OF SERVICES IN THE FIELD OF AESTHETIC MEDICINE IN UKRAINE

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Introduction. The market of cosmetic procedures is constantly developing, and the demand for fashion trends gives rise to the development of new equipment, new rejuvenation techniques and procedures.

The regulation of cosmetology (cosmetology activity) in the national legislation of Ukraine has no unambiguous answer. When considering the legal regulation of cosmetology, it is necessary to determine what cosmetology services can be considered as medical practice and questions, whether a doctor or a "beauty specialist" can engage in cosmetology activities..

Aim. The aim of this study is to analyze the state regulation of cosmetic services in Ukraine

Materials and methods. The following methods of research were used: the review of literature data and generalization of the material, methods of analysis and synthesis, marketing, system, logical-structural and comparative analysis, forecasting and programming.

Results and discussion. Cosmetology can be divided into aesthetic and medical. Aesthetic cosmetology includes hygienic, decorative cosmetics, makeup. Aesthetic cosmetology can be provided in various beauty salons, beauty parlors, salons, centers, spas. National Classifier DK 009: 2010 "Classification of Economic Activities" does not give independence to this type of economic activity as cosmetic activity. Aesthetic cosmetology is included in class 96.02 "Hairdressing and other beauty treatment", which includes hair washing, trimming and trimming, styling, dyeing, toning, curling, straightening hair and similar services provided for men and women, as well as shaving and beard trimming, face massage, manicure and pedicure, makeup and more. Aesthetic cosmetology activities do not require a license or any other special permits.

Medical cosmetology includes preventive, diagnostic and therapeutic (which in turn can be divided into conservative and surgical). National Classifier DK 009: 2010 "Classification of economic activities" for medical cosmetology has established the following classes:

- 86.21 "General medical practice" - medical advice and treatment in the field of general medicine provided by general practitioners;

- 86.22 "Specialized medical practice" - medical consulting and treatment in the field of special medicine by specialist doctors and surgeons

- 86.90 "Other health care activities" - activities for the protection of human health, which are carried out not in hospitals or doctors or dentists; activities of nurses, midwives, physiotherapists or other paramedical staff in the field of hydrotherapy, therapeutic massage, homeopathy, manual therapy, acupuncture, etc. These activities can be performed in clinics that operate in firms, schools, nursing homes and other non-hospital organizations but have their own counseling centers with patient reception facilities. Such activity must be carried out with the appropriate license.

The current legislation of Ukraine does not contain a definition of "cosmetology assistance", ie any intervention can be considered as a "cosmetology service". To provide cosmetic services, it is necessary to comply with a number of regulatory requirements, which can be divided into two groups:

• the issue of choosing the legal form of a legal entity or work as an individual entrepreneur, the issue of the organization of paperwork, taxation, submission of necessary reports, etc .;

• issues related directly to the provision of cosmetology services, which depend on the person providing such services, the place of their provision, the nature of the cosmetic services.

In cases where cosmetology services are non-invasive, ie aesthetic cosmetology, the regulatory regulation of such activities is carried out based on the general requirements of the civil legislation for the provision of services. Including cosmetology the Law of Ukraine «On Consumer Protection» covers services.

If cosmetology services are related to invasive interventions and / or other types of medical practice (medical cosmetology), it is necessary to comply with the legislation of Ukraine governing medical practice in medical practice. Medical business activities are carried out only based on a license and in accordance with both the special legislation and the Licensing conditions for conducting business activities in medical practice.

Conclusions. Today, the cosmetic industry of Ukraine faces difficult questions. On the one hand, the rapid growth of demand for cosmetic services and cosmetic products establishes a high level of profitability, but also a high level of competition. On the other hand, state regulation of both cosmetics and cosmetic services in Ukraine is under development and raises the question of developing standards for products and activities in the field of cosmetology. State regulation of this industry in Ukraine requires improvement and development of standards harmonized with European legislation, both for perfume and cosmetics, and for beauty salons.

At the same time, the management of cosmetic salons should be aware that the desire to constantly improve their activities, to increase their rating in comparison with competing organizations, is impossible without the introduction of a quality management system in the operation of the cosmetic salon.

Certification for compliance with the requirements of ISO 9001:2015 is recommended, but the implementation of quality management system in the institution is actually a mandatory task for every manager who wants to achieve excellence, reduce workplace inconsistencies, ensure a systematic and continuous growth of the organization.

INTERPRETATIVE PHENOMENOLOGICAL ANALYSIS (IPA) IN THE FOOD COMPLEX

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Introduction. On the face of intense competition, every business requires constant hard work aimed at improving consumer satisfaction.

Catering contributes to reducing the time spent on cooking, the more rational use of food, and provides the population with a balanced diet. In addition, there is an urgent need for an enterprise to comply with standards and legislation.

Catering is one of the most important spheres of economic and economic activity of a person. This industry, on the one hand, contributes to reducing household spending on food preparation, more rational use of food and provides the population with balanced food, and on the other hand, visiting catering facilities is a form of leisure organization and, thus, contributes to improving quality. their lives. Ensuring balanced and rational nutrition for children at the place of study and adults at their place of work is a necessary factor for the reproduction of a healthy population. Public catering is characterized by a variety of types and classes of enterprises whose main purpose is to meet the diverse needs of the population.

The goals of catering establishments vary depending on the type of enterprise and the contingent served, some intended to satisfy both physiological and cultural needs for nutrition and organized rest, others – only for nutrition. In recent years, there has been a positive trend in the development of catering services, which has been largely influenced by the increase in the standard of living of the population. This has resulted in an increase in the share of household spending on food outside the home. The intensification of competition in the market of catering services has led to the necessity of introduction of new management methods, formation of effective pricing policy, development of business development strategy, as well as creation, support and development of competitive advantage of each individual enterprise. The transition to market relations and the development of a market economy have changed the

conditions in which catering companies operate and the factors that influence their development. In addition, the lifestyle and the mentality of the visitors became different. According to the analysis of the existing legislation governing catering, the bulk of the documents was adopted in the 1990s. and solved the problems of transition. However, many regulations are still in force today, without reflecting existing realities. As a result, the methods of economic and administrative regulation, as well as the methods of organizing the activities of catering, have largely remained the same.

Aim. Development of measures to improve the quality of work with consumers in the food complex.

Materials and methods. As materials of research and development used the regulatory documentation mentioned above. Standards and legislation regarding catering establishments. Interpretative phenomenological analysis (IPA).

Results and discussion. In order to develop measures to improve the quality of work with consumers at Gastropab, the importance of indicators and customer satisfaction of cafe services was investigated, the difference between the importance of quality of service between a regular visitor and a one-time customer was explored, as well as the difference between gender groups.

A questionnaire was developed to determine the level of customer satisfaction

The questions are answered in the form of a 5-point scale, consisting of 3 parts.

A common part that implies gender, age, regular visitor or not.

Valuable part: quality of food, sanitary conditions, quality of service, price, interior. Each metric was asked to rank on two metrics: the importance of the metric and the satisfaction with that metric.

154 visitors to the cafe were interviewed.

The results showed that 41.6% (n = 64) were male and 58.4% (n = 90) were female. The average age was 21.52 years, and the majority (81.8%) in the age group was between 20 and 25 years (n = 125). Respondents who visited the cafe less than twice made up about 60% (n = 85).

Averages and standard deviations are perceived as important to customers and a level of satisfaction with each of the five quality attributes.

The level of satisfaction with each of the five quality attributes for regular and one-time customers has been investigated. It also examines the value for men and women and the level of satisfaction with each of the five quality attributes.

Conclusions. Problems identified: Quality of food – needs constant attention, customers are perceived as a necessary condition.

Sanitary conditions are not very important for clients, but HACCP is required by law.

Quality of service – an organizational problem, needs to be addressed through reforming approaches to organizing activities. is perceived as a necessary condition.

Price is an economic problem, we have not considered it, but we need to constantly work on it.

Interior – the problem is not very important for the customers and is well maintained.

INTRODUCTION OF QUALITY MANAGEMENT SYSTEMS AT COSMETICS PRODUCTION ENTERPRISES.

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Introduction. One of the priority directions of reforming the cosmetic industry in the current conditions of development of the Ukrainian economy is the introduction of a quality assurance system at all stages of the product life cycle. Ukraine's cosmetic industry is characterized by high prospects of

competitiveness and import substitution, ensuring that compliance with EU standards is a necessary requirement for its effective promotion on the domestic and foreign markets.

The production of cosmetics is a promising direction for the development of the Ukrainian economy, as in recent years it has shown a steady upward trend in the pace of industrial production and sales. Also, the cosmetic industry of Ukraine is characterized by high prospects of competitiveness and import substitution, which is why ensuring compliance with EU standards is a necessary requirement for the effective promotion of its products in the domestic and foreign markets. The resolution of this issue depends first and foremost on the proper legislative provision of the process of circulation of the cosmetics in accordance with the requirements of European standards and the establishment of a national system of technical regulation of the circulation of cosmetic products as a whole.

Aim. The purpose of the study is to analyze the problems of implementation of quality management systems (QMS) at domestic enterprises for the production of cosmetics and identify promising areas of this activity.

Materials and methods. As information materials used scientific publications, domestic and foreign legislative base on the regulation of circulation of cosmetics, electronic databases of the State Register of Medicines of Ukraine, weekly "Apteka" and "Compendium", the results of their own research. Methods applied: analytical, comparative, content analysis and generalization of information.

Results of the research. The primary stage of the work was the study of the results of the activities of domestic industrial enterprises for the production of cosmetics. Statistical information of the State Statistics Service of Ukraine on the activity of economic entities in the given economic activity was analyzed. Investigated the dynamics of the number of enterprises working in the field of cosmetics, as well as studied the dynamics of production and sales of individual products of industrial enterprises in the cosmetic industry for 2010-2018.

According to the results of the analysis, it can be noted that during the period under review, the number of enterprises operating in the field of industrial production of perfume and cosmetics has doubled. Production volumes of cosmetic products in 2018 increased to 24.1 thousand tonnes, which is almost 2 times higher than in 2017. Sales of perfume and cosmetic products also increased to almost 4,0 UAH million in 2018.

The analysis of regulatory documents regulating the circulation of cosmetic products in Ukraine, shows that the requirements for its quality and safety do not meet international standards, obsolete regulatory and technical documents continue to apply to most cosmetic products. The current regulatory framework does not provide for the regulation of the basic processes of creation, research, registration, the process of post-marketing control of cosmetic products. The requirement of sanitary and hygienic expertise regarding the circulation of shortcuts does not meet world standards. As a result of the absence of a modern legal framework, a slow progress is being made in the process of implementing the requirements of the QMS in the activity of economic entities engaged in the industrial production of cosmetic products. At the same time, the problems of quality assurance, safety and efficiency of the cosmetic products depend on the level of technical regulation of the industry and, first and foremost, require the application of the quality assurance system at all stages of its life cycle. Given the specificity of the modern cosmetic market, in which high consumer demand is used multifunctional cosmetic products that are able to actively influence the physiological processes of the skin, we consider it appropriate at all stages of circulation of the short circuit to take into account their aforementioned specificity. The scheme of the life cycle of the CP specifies the features of their stages of circulation and takes into account the feasibility of introducing processes for the control of their quality, safety and efficiency throughout the product turnover cycle.

Project Resolution of the Cabinet of Ministers of Ukraine "On Approval of the Technical Regulation for Cosmetic Products" (TR), which sets requirements for quality and safety of cosmetic products on the Ukrainian market in accordance with European standards, has been repeatedly published on the official website of the Ministry of Health of Ukraine for public discussion (16.06.2017, 17.07.2019). 23.01.2020 the next version of the draft document is available on the Ministry of Health of Ukraine website

for public discussion. The analysis of the draft document showed the necessity of its certain addition in order to comply with European standarts and current tendencies of development of the cosmetic industry. In particular, it is recommended that the requirements for state market surveillance be specified, that the competent authority take the necessary measures to prohibit or restrict the making available on the market of cosmetic products or them from sales within the limits of inconsistencies made by the responsible person.

In order to effectively implement the Regulation, the question arises of the implementation of its requirements in Ukraine, namely: the creation of a sectoral domestic regulatory framework, the adaptation of documents and the identification of competent organizations that will monitor their implementation. We have proposed a set of actions for the effective implementation of the TR, namely, the development of a draft resolution of the Cabinet of Ministers of Ukraine on the plan of measures for its implementation, development and approval of by-laws, which regulate the procedure for the implementation of the main statements of the TR and the like. Thus, a complex of multi-vector management actions is required for the implementation of the TR, which requires the uniting of efforts as authorized state bodies, industry non-governmental organizations and participants of the cosmetic market as a whole.

Conclusions: The economic perspective of the products of the domestic cosmetic industry for the national economy of Ukraine is demonstrated. The imperfections of the national legislative framework governing the circulation of the cosmetics in the domestic consumer market and the need to reform the cosmetic industry as a whole have been established. The process of reforming the domestic cosmetic industry requires the introduction of QMS throughout the cycle of circulation of cosmetic products, taking into account its specific features at the current stage of development. The issue of implementation of QMS, in particular, in the activities of industrial enterprises of the industry, is the key to ensuring the proper quality, safety and efficiency of the cosmetics in accordance with the requirements of TR. However, it is obvious that the level of application of QMS in the activity of the Ukrainian cosmetic industry does not correspond to the world experience of effective management, which is one of the reasons for the imperfection of the standardization system of domestic cosmetic products. According to our estimates, it is the use of modern models of QMS at all stages of the vital activity of cosmetic products that can improve its competitiveness and become a catalyst for the further development of the domestic cosmetic industry as a whole. In view of the above, it is promising to continue working on the development of regulatory documents that regulate the standardization of cosmetic products, taking into account the experience of international technical regulation and the features of the development of the modern cosmetic market. The introduction of effective management through the use of QMS at all stages of the cosmetic products should ensure a systematic modern approach to the standardization of products and increase its competitiveness in the context of European integration of Ukraine as a whole.

THE PROCESS OF SECUREMENT THE QUALITY OF MEDICAL DEVICES AT THE STAGE OF THEIR IMPORTS IN THE TERRITORY OF UKRAINE

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Introduction. The issue of correct realization of the order of importation of medical devices with the purpose of their further introduction into circulation in the territory of Ukraine is becoming more urgent today. The results of such of realization depend on the preliminary analysis of the provisions of the legislation, which require committing complex actions to taken to resolve the legal relations between the parties and provide for the need for the executor to have specialist knowledge and experience.

Aim. The aim of our research began to study the normative support for the process of importing medical devices and develop instructions for their import into the territory of Ukraine in accordance with European standards.

Materials and methods. To achieve this goal, we use research the regulatory basis. The first of all, it is necessary to examine the Technical Regulation on Medical Devices, approved by the Resolution of the Cabinet of Ministers of Ukraine of October 2, 2013 № 753, № 754, № 755.

Results and discussion. For regulation of legal relations in the sphere of production and circulation of medical devices, the normative fixing of their basic provisions is required. It should be provided exclusively by the state, as is accepted in all countries of the world.

The legislative and regulatory technical documentation for medical devices must be constantly improved and updated in a timely manner to replace outdated quality indicators in line with needs today . Due to the fact that the EU directives on the circulation of medical devices have already been updated, a similar update will take place in Ukraine in the coming years.

The system of technical regulation in Ukraine is notably different from what is understood by standardization, certification or conformity assessment in Europe and in developed countries. The foreign producers who do not have their authorized representatives in Ukraine, in fact, avoid liability for the supply of substandard and dangerous products.

This is due to the fact that the organizational structure of the state control in Ukraine does not meet the requirements of the EU Regulation 882/2004 on the official state control body, which should cooperate with the European safety authorities of both food and medical products, and ensure effective coordination and cooperation between the established controlling bodies. This will avoid duplication of control functions between central government bodies authorized by the state.

The procedure for importing medical devices for the purpose of putting into circulation in the territory of Ukraine can be divided into the following main stages:

- Appointment of an authorized representative in Ukraine.
- Regulation of intellectual property issues (if necessary).
- Completion of the conformity assessment procedure.
- Resolve distribution issues
- Customs clearance of imports of medical devices.
- Advertising and promotion (if necessary)
- Analysis of the circulation of medical devices.
- Representation of the manufacturer's interests.

Accordingly, in order to determine whether the product belongs to the category of medical devices or not, the Ukrainian conformity assessment body will use the relevant European documents. The basic guideline is the delineation and classification of public regulation for medical devices. Version 1 of April 19, 2018.

Imports of medical devices into Ukraine must first be subject to a technical conformity assessment procedure and a Certificate of Conformity must be obtained. Depending on the risk class of the product and some other factors, there are 4 schemes of the following procedure:

1. Self-declaration.
2. Test parts product.
3. Audit of the quality management system.
4. Recognition of EU certificates.

In most cases, certification in Ukraine is equally compulsory for domestic manufacturers and importers, largely without taking into account foreign certificates of conformity previously obtained. Although there are many specific instruments for regulating the circulation of imported goods. To implement some of them, Ukraine has acceded to international agreements, simplifying the existing method of certification and building a system that is harmonized with European requirements.

Conclusions. The having read the regulatory basis for the process of importing medical devices and instructions for their import into the territory of Ukraine, it should be noted that the norms of circulation of medical devices are confirmed by a clear approach of state regulation in this field and revealed a number of inconsistencies in the regulatory framework, which need to be paid attention and introduced with European standards.

OPTIMIZATION OF THE INTERNAL AUDIT PROCEDURES AT A PHARMACEUTICAL ENTERPRISES

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Introduction. Functioning of the Quality Management Systems (QMS) at the any pharmaceutical companies requires mandatory systematic internal audits.

The more effectively the internal audit is performed, the more effective is the quality management system of the organization.

Given the important importance of quality assurance of medicines, the issue of audits for domestic pharmaceutical companies is particularly relevant.

A large number of domestic pharmaceutical companies do not pay due attention to audits, often performing them formally or not taking care of their performance.

Aim: identify the roles and analyze current approaches to conducting internal audits of the quality management systems of drug companies, in compliance with ISO 9001 and GMP requirements, and develop application suggestions for optimizing the audit process of the research object.

Research objectives:

- analyzing of the regulatory requirements for internal audits of QMS;
- studying the experience of audits on the basis of pharmaceutical companies;
- developing of the proposals for optimization of the main stages of the audit process for their implementation on the pharmaceuticals companies.

Object of research: quality management system of a manufacturing pharmaceutical enterprise.

Subject of research: the process of internal audits of QMS.

Materials and methods. To carry out our research, we carried out studies on the provisions of ISO 9001 and ISO 9000 as part of an overall management system based on the quality risk analysis approach needed to create, implement, operate, monitor, review, maintain and improve of QMS.

Results and discussion.

Often, the following are not available at Ukrainian pharmaceutical companies:

- the methodology for evaluating the performance of the audit process and the relevant eligibility criteria;
- rules for asking questions in questionnaires (audit checks);
- rules and criteria for the systematic assessment of the competences of internal auditors and experts involved;
- application of PDCA methodology and others.

Critical audit elements we have identified:

- Audit planning and preparation of audit reports within the PDCA cycle.
- Selection of the audit team.
- Developing questionnaires and maintaining other audit documents.
- Professionalism of auditors.

– These elements of the audit process are governed by the Documented Procedure (DP), which is included in the annexes to the master's work.

It is proposed to regulate the audit process in terms of PDCA methodology:

– Development of internal audit programs and procedures, preparation of an audit team (Plan).
– Program Implementation (Do).
– Audit Data Collection and Evaluation (Check).
– Improvement of audit procedures (Act).

Suggested phases of audits:

– planning of the audit program (formation of groups, distribution of responsibilities and authorities, development of audit schedules etc.);
– performing the audit procedures (filling in the forms of meetings, check-lists, protocols for recording of nonconformities (comments, recommendations), drawing up reports, corrective action plans etc.);
– evaluation and analysis of the implementation of the audit program (completion of forms of assessment of auditors, forms of evaluation of audits performance);
– improvement of the audit process by taking corrective and preventive actions in the framework of audit procedures.

The documented procedure for performing the audit process includes:

– description of the inputs and outputs of the audit process;
– description of all phases of the PDCA audit cycle;
– performance indicators of the audit process;
– on-site audit algorithm etc.

Considerable attention is given to the preparation of questionnaires: the value of the audit results depends on the correct formulation of the questions directly.

To motivate the auditors, we have developed a form of assessing the quality of their work by 14 indicators (carried out after each audit). The assessment is carried out by the Chief Auditor or the Deputy Director of Quality.

Conclusions.

Our approaches have already been partially tested in the internal audits. Following the audits, a report was prepared, a discrepancy statement, comments and recommendations were prepared, and a corrective action plan was developed.

DEVELOPMENT OF A SET OF PROPOSALS FOR IMPROVING OF A SERVICE QUALITY FOR PHARMACY VISITORS

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Introduction. The pharmacy's efficiency implies compliance with current quality management concepts and Good Pharmaceutical Practice (GPP) requirements. At the same time, the quality of pharmaceutical services must meet not only state standards, but also consumer expectations.

Today, competition between pharmacies is very serious, so improving customer service is a necessary and important condition for maintaining business.

Aim. Development of a program for optimizing of a typical pharmacy activity to improve of pharmacy service quality and increase competitiveness. The subject of our research is a pharmacy quality system processes that ensure quality of service and customer satisfaction.

Materials and methods. Scientific professional publications, statistical information, current legislation of Ukraine. Methods of comparative and historical analysis. The main tasks of the research: to study the regulatory framework governing the activities of pharmacies in Ukraine; to analyze the provisions of GPP; to investigate the activities of pharmacies and identify potential areas for further development; to develop a program of measures to improve the activity of the pharmacy institution.

Results and discussion.

Basic requirements for modern pharmacy establishments are:

1) providing and maintaining a high level of competence of pharmaceutical personnel;

2) promoting the rational use of medicines and providing the highest quality pharmaceutical services to pharmacy visitors;

3) regulation and documentation of all important processes and operations.

At present, the problematic aspects of the activity of domestic pharmacies can be formulated as follows:

- lack of regular staff training;
- misunderstanding and / or rejection of current requirements;
- low level of staff awareness;
- lack of free access of employees to sources of methodical and educational information;
- difficult ("non-partner") relationships with doctors;
- failure to fully comply with some requirements;
- insufficient regulation of individual operations;
- the absence or formality of some SOPs;
- low motivation of employees.

Vectors of our "Pharmacy optimization programs":

1. Strengthening of staff management (based on the program!), include

- increasing the motivation and competence of staff, creating conditions for continuous improvement;
- ensuring the availability of professional literature;
- staff training on modern requirements (GXP, psychology, marketing, etc.);
- regular attendance of trainings, seminars, courses, internships;
- regular meetings of Quality Circles.

2. Improving the services quality (key activities):

- development of documented procedures for performing all activities;
- implementation of corporate "Client Communication Policy";
- expanding the range of services provided by pharmacies;
- unification of stylistic design of premises of all network pharmacies (standard bright attractive color solutions of interior, showcases, counters, etc.);
- introduction of a musical accompaniment in the pharmacies (similar to supermarkets: for a good mood and abstraction from diseases and doctors);
- introducing the uniform dress code for all workers (except for the robe there are other clothes);
- development of the Appearance Policies;
- provision of information to hospitals on the available assortment of medicines and medical devices (sending to hospitals "prices" and booklets listing with describe of the pharmacies services);
- organization of "Quality Circles: for the immediate initiation of work improvement activities in the workplace;
- introduction of a Database to collect customer information for the purpose of analyzing the contingent (gender, age, amount and range of purchases etc.);
- expanding the range of consultations provided to clients (except for adverse reactions, compatibility – advice on disease prevention, city hospitals, diagnostic tools, etc.).

This will improve the level of service quality, reduce the number of complaints, increased visitor loyalty and increased the number of customers.

Some of our proposals related pharmacy workflow. We propose:

- structuring the hierarchy of company documents (development of a single Register of documentation),
- organize all documents that are developed at different times by different people with different approaches;
- introduce uniform requirements for writing SOPs and provide training of staff on handling these procedures;
- create a single computer network for communication between pharmacies and the office on-line.

The development of SOPs for all important activities offers a number of advantages:

- possibility of effective training of employees;
- reducing staff errors;
- reduce the risk of implementation substandard and / or counterfeit medicines.

We have developed the Procedure for executing of Customer Engagement process (this activity is often not regulated in domestic pharmacies). The procedure establishes a conditions for effective determination of customer satisfaction and response to their complaints and suggestions.

As part of the implementation of the Customer Engagement process, a questionnaire was developed to determine customer satisfaction. The process of questioning and processing the obtained results is now being established. All willing clients of different sex and age, at different times and days of the week, are subject to questioning in all pharmacies of network. It is planned to interview about 500 people, then analyze the data and develop improvement measures. Questionnaires are scheduled each season (customer needs and questionnaires may vary).

Conclusions. Considering the above, it can be concluded that activity of domestic pharmacies needs improvement. This is due to both increased regulatory requirements and significant competition in the pharmaceutical market.

In the framework of our research we have done the following:

- The normative documentation regulating the activity of the pharmacy institution was studied.
- The successful experience of the activity of the subjects of the national pharmaceutical market is analyzed.
- The activity of some pharmacy networks is critically analyzed.
- Measures have been developed to optimize the activities of typical pharmacies, which include proposals for staffing, infrastructure improvement, use of information technology, regulation and documentation of important processes, and more.
- Implementation of the proposals will improve the quality of customer service and improve the pharmacy processes at a higher level.

ELEMENTS OF HACCP IMPLEMENTATION IN THE STUDENT FOOD COMPLEX

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Introduction. One of the factors that have the greatest impact on the human body and health is nutrition. A considerable number of students attend the NUPh Nutrition Complex, which requires the creation of appropriate conditions for the organization of their complete and safe nutrition.

In Ukraine, there is a legal framework of regulatory documents, the observance of which is obligatory and is the key to the organization of quality and safe food.

HACCP (Hazard Analyzes and Critical Control Points) is a system of identification, assessment and control of hazardous factors of food raw materials, technological processes and finished products, which is intended to ensure high quality and safety of food products. The development of the HACCP concept began in the 1960s in the US at NASA and in several US military laboratories. The main task was to create safe food for astronauts.

Thus, in 2017, 163 outbreaks of diseases were reported in Ukraine, 63 percent of which occurred in organized teams. In 2018, 163 outbreaks were also reported (54.6 percent in organized teams).

The investigation materials state the only mechanism for the development of epidemic discomfort for all: the presence of an infectious disease skid due to numerous disturbances at food establishments.

Aim. Implement the HACCP system on the example of a food complex. Consider the HACCP system, taking into account seven basic principles for the NUPh food complex.

Materials and methods. As materials of research and development used the regulatory documentation mentioned above. The HACCP system controls not the end result (food produced), but the entire product and production chain, from the supply of raw materials to the consumption of the product. Accordingly, the HACCP system harmoniously fits into a quality management system built in accordance with the requirements of ISO 9001.

Results and discussion. The introduction of HACCP is the first step towards European standards and new opportunities to enter the international market with its products. Today, many countries recognize the issue of quality and safety as a priority. Frequent outbreaks of food-related illnesses indicate a need for change in their safety approaches. One of the most reliable ways to protect consumers is through the HACCP Food Safety Management System. It guarantees the safety of products throughout the food chain "from the field to the table", because it allows to identify all the critical points that can affect the safety of the final product, eliminate them and constantly monitor. HACCP implementation is required by the laws of the European Union, the United States, Canada, Japan, New Zealand and many other countries.

It is planned to conduct an audit in the NUPh food complex, with the aim of analyzing the focus on those stages, processes and conditions of production where lack of management and control will become critical for food safety. Consider the programmatic prerequisites of the HACCP system for the proper planning of industrial, auxiliary and domestic premises.

Zoning on the degree of risk on the principle of "color coding". The main purpose of "color coding" of different power zones is to eliminate any possibility of cross contamination or contamination with the help of cleaning equipment, cloths. Develop a color coding system for production equipment. Compliance with all requirements of the legislation on export, disposal of waste. Monitor the pest control system, species identification, prevention, prevention and control measures.

A questionnaire is being developed to determine the current level of customer satisfaction of the food complex. The questions are answered in the form of a 5-point scale. The questionnaire provides fields for reporting gender, age, social status and income level of clients. Answers to these questions allow you to evaluate not only the level of satisfaction, but also the contingent of customers.

The results of the survey will be summarized in the table, where the rows contain the question numbers from the questionnaire and the number of answers in% of their total number, and in the columns the corresponding percentage of the points of each assessment.

It is planned to develop a draft Policy on Customer Service Quality, as well as to develop passports of ingredients that include the following information: the name of the ingredient. Important product characteristics (biological, chemical, physical). Prescription composition. Method of production. Method of packaging and delivery. Conditions and shelf life. Preparation and / or processing before end use. Acceptance criteria.

Conclusions. The implementation of the HACCP program is another step towards the integration of international standards in the field of food safety. The implementation of this program is obligatory according to the legislation of Ukraine. And the main thing is food safety.

ASSESSMENT OF THE EFFICIENCY OF THE USE OF THE MATERIAL RESOURCES INVOLVED IN THE IMPLEMENTATION OF THE INPUT CONTROL OF THE SUBSTANCE

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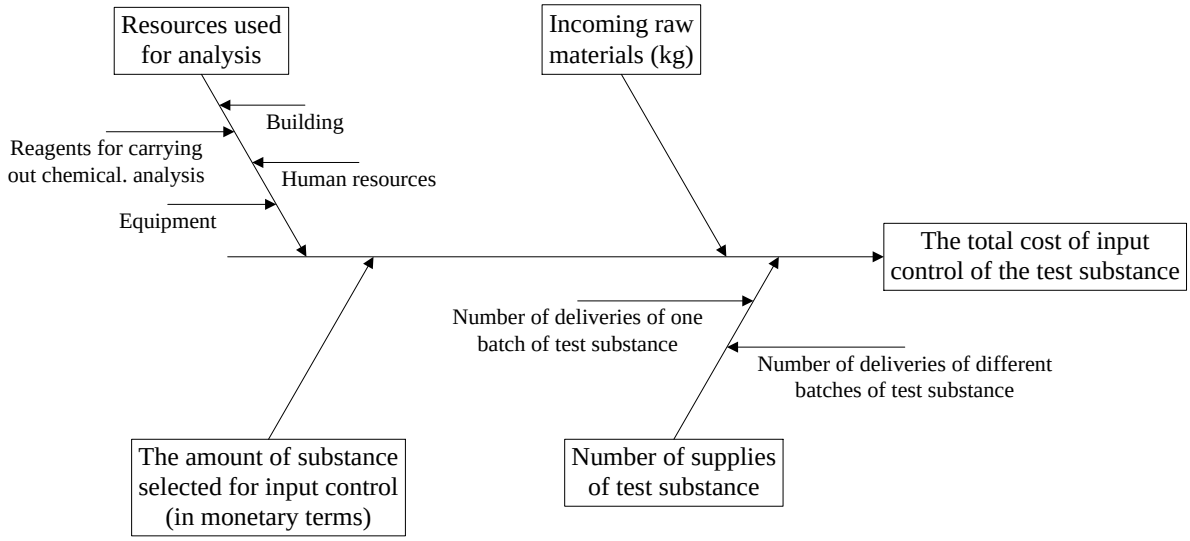
Introduction. The results of business activities are meeting the needs of consumers, economic stability in the country, job creation and many other important economic processes that contribute to improving the standard of living of the population in the country. Pharmaceutical companies are special, which must maintain the level of quality of their products and conduct business. Therefore, it is important for them to safe balance and be able to develop constantly. The principles of the concept of economical production can give them this opportunity due to a number of reasons, the main ones being: the development of management systems, the development of the most effective business management techniques; the focus of lean production principles on reducing losses that do not require additional investment; increasing the level of consumer compliance with product quality; cost minimization opens the way to modernization not only of equipment, but also of institutions (organizational business technologies), which in turn guarantees the improvement of the quality of the manufactured products.

Lean Manufacturing is a system of organizing and managing product development, production, relationships with suppliers and consumers, when the products are manufacture in exact accordance with customer requirements and with fewer losses. The goal is to eliminate time-consuming activities that consume resources but do not create value. The goal is to maximize resource efficiency through the continuous and incessant improvement of all the organization's business processes aimed at improving customer satisfaction.

Aim. Based on the urgency of the issue, the purpose of our work is to investigate the efficiency of the use of material resources in the analysis of inputs to improve the functioning of the quality control process at the pharmaceutical enterprise by reducing the cost of it.

Materials and methods. In the basis of the work used the analysis of the costs of material resources of the pharmaceutical enterprise for the input control of the substance of the active substance for the planned period.

Results and discussion. The analysis of any process requires setting its estimated parameters. Using the Ishikawa cause-and-effect diagram, we have identified and structured the basic parameters that affect the cost of an input control of a substance. The main ones include: resources used, amount of raw materials received (kg), number of supplies of test substance, amount of substance selected for input control (in monetary terms).



The analysis of the substance received to the entity was carried out by the method of statistical sampling of the substance of the active substance was received and used to create the medicinal product in 2019.

The next stage was the creation of a matrix of expenditure of cash resources used for the input control of the test substance, important that the cost of analysis, in a broader sense, should be guided not only by the cost of reagents (which can change) used for the analysis of chemical substance, but also the use of precision measuring instruments, the use of electricity, manpower, the cost of operating the premises, the permit to import products.

Table 1. Matrix of expenditure of cash resources

Number of deliveries of one series	*Number of received substance*	*Price per kg*	*The cost of the substance received by the enterprise*	*Cost of 30 g of substance*	*Cost of 16 g of substance*	*Price of analysis costs*	*Cost of microbial purity's analysis*	*Total number of series*	*The name of the substance*
1	2	3	4	5	6	7	8	9	10
The series under study 1									
The series under study 1 (1)	2,00	32403	64806	972	519	N	N_1		
The series under study 1 (2)	5,11	32403	165660	972	519	N	N_1		
The series under study 1 (3)	5,80	32403	187970	972	519	N	N_1		
The series under study 1 (4)	0,86	32403	27931,39	972	519	N	N_1	5	
The series under study 2									
The series under study 2	7.00	29710	207970	891,3	475,36	N	N_1		
The series under study 3									
The series under study 3	0,91	29380,45	26863	881,4	470,1	N	N_1		
The series under study 4									
The series under study 4	21,50	27631,69	602605	829	442	N	N_1		
The series under study 5									
The series under study 5/ 1	25,00	28521,36	713034	855,60	456,30	N	N_1	5	
The series under study 5/ 2	3,00	29803	89409	855,60	456,30	N	N_1		

For example, by examining the cost of research on the substance of the first series (investigated series 1) it was found that for one analysis of reagents worth 3200 UAH.

One hour of the laboratory employee costs 80 UAH. One hour of equipment operation costs 30 UAH, and it takes 5 hours to perform the analysis. Thus, the cost of one analysis is about 3500 UAH, and the analysis of microbiological frequency – about 1500 UAH.

The cost of substance analysis, according to the matrix, is directly proportional to the amount of deliveries of a substance of one series, which came at different intervals, and the supply of substance of different series; which leads to increased use of resources of the enterprise and in turn leads to an increase in economic costs. For example, the number 1 research series shows that the cost of raw material analysis alone is about 5%. It is worth noting that the total cost is influence by other factors that usually lead to an increase.

This can be avoid by using a one-time substance delivery method calculated according to the annual drug-production plan, since this method results in the use of only a single substance analysis in a larger sample, which will be significantly less costly.

Conclusions. Using the method of multiple delivery of a chemical substance, the enterprise spends a considerable amount of resources on control of each supply of raw materials, which is of economic costs of the enterprise. Based on the principle of lean manufacturing – cost minimization, the method of one-time supply of the required amount of raw material, pre-calculated according to the annual production plan of the medicinal product, reduces the total amount of resources used for the input control of the substance.

DEVELOPMENT OF PROPOSALS FOR IMPROVING THE QUALITY OF WORKING OF A PHARMACY

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Introduction. Changes in the external environment, the emergence of new legal and economic norms, the growing needs of the population to receive quality service services, are relevant to our research. It is important to find new approaches to improving the quality of pharmacy facilities. The competitive market requires decisive action from entities providing pharmaceutical services in Ukraine. Increasingly, pharmacy executives are deciding whether to expand their operations, comply with regulations, and, as a consequence, increase their profit margins.

Aim. The purpose of the study is to develop a program to improve the quality of service to consumers pharmacy institution. To achieve this, we must fulfill the following tasks: to analyze the regulatory framework governing pharmacies; to investigate the current state of work of pharmacy establishments and to propose a set of measures to improve the quality of the provision of pharmaceutical services in accordance with the principles of Good Pharmacy Practice.

Materials and methods. The basis of the work was the results of the analysis of the regulatory framework for the subjects of the pharmaceutical market and the experience of leading pharmacy networks.

Results and discussion. The organization of pharmacy activities and rules for the provision of pharmaceutical services are governed by a number of legal acts and regulations.

An important influence on the activity of the pharmacy institution in organizing, conducting and evaluating the work is provided by the following regulatory requirements, which are contained in: Law of Ukraine "On Amendments to the Tax Code of Ukraine and some other legislative acts of Ukraine on improving the administration and revision of the rates of individual taxes and fees"; Laws of Ukraine “On the use of registrars of settlement transactions in the sphere of trade, catering and services”; Laws of Ukraine "On Consumer Protection".

To date, our pharmacy establishments operate under the requirements of the License Terms of Ukraine and carry out business activities within the framework of legal relations "pharmacy-consumer".

According to our research, it is not enough for the average citizen to receive only quality medicines and appropriate advice on them. The consumer wants to have full confidence in the safety of the pharmaceutical services they receive and the qualified advice they have given to the standards of pharmaceutical care. Therefore, it is quite important to implement the following requirements:

- on patient well-being;
- influence decision-making on the use of medicines;
- building relationships with other healthcare professionals;

- lack of internal competition between pharmacy employees;
- responsibility for defining, evaluating and improving quality;
- possession of necessary medical and pharmaceutical information;
- knowledge of potential environmental hazards through the disposal of medicines waste;
- Responsibility for maintaining and evaluating one's competence.

Our plan to improve the pharmacy institution's activities includes a number of measures aimed at implementing the principles and provisions of Good Pharmacy Practice presented in the table:

Improvement principles	Suggested actions
Interaction with doctors	Development of information sheets for doctors on the existing product range.
	Developing proposals for friendly seminars on patient self-treatment.
Consumer interaction	Expanding the range of pharmacy services.
	Expanded counseling on disease prevention and medication management.
	Development of methodology for interaction with consumers.
Work with staff	Ensuring availability of up-to-date information on regulatory regulation of pharmaceutical activity and updating the pharmacy's assortment policy (creating a database of up-to-date information)
Staff training	Introducing the practice of regular training of staff to the modern requirements of the legislation (trainings, seminars).
	Development of internal staff training methodology.
Increasing the level of promotion	Development of intangible employee rewards procedure.
Working with internal documental	Development of procedures for specific activities of a pharmacy institution (e.g. risk assessment including environmental hazards through the disposal of medicines waste).

Conclusions. Based on the analysis, we propose a number of measures to improve the competitiveness and quality of pharmaceutical services, namely: the introduction of methods of interaction with consumers in the pharmacy; methods of internal training of pharmacy staff; non-material promotion of pharmacy staff and risk assessment. Today, the main task of the pharmacy should be compliance with the provisions of Good Pharmacy Practice, which will give benefits to the organization in the market of pharmaceutical services in Ukraine.

PHARMACEUTICAL WASTE MANAGEMENT PROBLEMS

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Introduction. The unfavorable situation in Ukraine in the field of pharmaceutical waste management can pose a real threat to public health.

Consumers are forced to throw medicines unsuitable for use together with household waste or sewage.

Medicines after entering sewage can enter the surface water through sewage treatment plants, since many of them are not biodegradable.

Drugs that enter the landfill of household waste first fall into the ground, and then, together with precipitation, into surface water. This water enters the water supply. It is used by various farmers to water vegetables and fruits, which are then consumed by the population.

Scientists confirm: after some time, antibiotics can be found in soil, water, and even food. Small concentrations of antibiotics form bacteria resistance in vitro and in vivo.

Separation of waste into medical and pharmaceutical should be carried out properly.

The processing of medical (biological) waste is largely regulated. Pharmaceutical waste requires special attention and other methods of collection and processing.

Aim. Analysis of existing methods for the disposal of pharmaceutical waste and development of a scheme to optimize waste management.

Materials and methods. As materials of research and development used the regulatory documentation mentioned above.

As above, the regulatory documentation mentioned above.

Results and discussion. In 2011, Belgian pharmacies collected approximately 572 tons of unused medicines, an average of 111 kg per pharmacy or 208 grams per family. In terms of the population of Ukraine, this can only amount to 3 thousand tons of collected pharmaceutical waste.

"Hazardous waste" means waste that falls into any of the categories listed in Annex I of the Basel Convention, the so-called "Yellow List". Waste falling into any of the categories listed in Annex II shall be considered as "other waste" for the purposes of this Convention.

Table 1. Categories of substances to be regulated under the Basel Convention and relevant to the pharmaceutical industry

Waste groups	***Annex I*** ***Categories of substances to be regulated***
1	2
Y1	Medical waste from patient care in hospitals, clinics and clinics
Y2	Wastes from the production and processing of pharmaceutical products
Y3	No pharmaceuticals, medicines and drugs needed
Y4	Wastes from the production, production and use of biocides and phytopharmaceuticals

Annex 1 to the Convention lists wastes including toxic classes of compounds as constituents.

The problem of medical and pharmaceutical waste management for Ukraine is only partially resolved. Today there is no holistic debugged system that would ensure all stages of the treatment of this waste. According to various legislative norms, only waste disposal of pharmaceutical plants and factories is established. The issue of collecting and rendering harmless the expired medicines or unused medicines in Ukraine is absolutely not resolved.

Waste removal operations, in accordance with the legislation of Ukraine, can be carried out only by specialized organizations in the presence of documents (licenses) in accordance with the Law of Ukraine "On the basic principles of state supervision (control) in the field of economic activity" and the Law of Ukraine "On licensing of types of economic activity". The Law of Ukraine “On Medicines” provides for verification of compliance with the requirements of the legislation on the rules of implementation of good practices at all stages of treatment of drugs, in particular during their disposal and destruction.

The volume of medicines to be collected and disposed of for each pharmacy is not large. It is economically unprofitable for each pharmacy to obtain a license for the collection and disposal of medicines. According to the GPP, pharmacists must provide appropriate information to patients on how to safely dispose of expired or unnecessary medicines and create conditions for their collection and disposal.

Conclusions. Despite its enormous scale, the problem of pharmaceutical waste can still be solved. But this cannot be done without legislative regulation of the collection of unused drugs in pharmacies.

Disposal of expired or unusable medications is an important step towards maintaining the safety of people and the environment by both drug companies, hospitals, and households.

REVIEW OF THE REQUIREMENTS FOR DIETARY SUPPLEMENT IN UKRAINE

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Introduction. The dietary supplements (DS) market in Ukraine is becoming one of the sectors of economy that is steadily and intensively developing. Over the last three years, the DS market has grown at a high rate and became an independent segment of the consumer market (table. 1).

Table 1. Retail sales volumes of different categories of "pharmacy basket" goods in monetary and natural terms by the results of 2017-2019.

Year	The volume of DS pharmacy sales	The share of DS in the "pharmacy basket",%
Monetary terms, million UAH		
2017	3380,7	3,7
2018	4620,9	5,2
2019	6326,2	6,1
Natural terms, million packs		
2017	62,4	3,7
2018	71,8	4,1
2019	80,9	4,8

This noticeable increase in DS sales is primarily due to the expansion of the customer base. According to the Euromonitor study, almost 48% of Ukraine's population is DS users as a result of the presence or prevention of any disease.

Due to this, the problem of legal regulation of the DS quality and safety is becoming increasingly important. The current legislation of Ukraine defines DS as a food product. They are subject to all food law regulations.

Aim. Overview of legislation regulating requirements for dietary supplements in Ukraine.

Materials and methods. Scientific professional publications, statistical information, current legislation of Ukraine. Methods of comparative and historical analysis.

Results and discussion. Today there are a number of legal acts regulating the processes of production and circulation of food products. The main legislative act of Ukraine in this field is the Law "On Basic Principles and Requirements for Food Safety and Quality". This Law was substantially amended (2014) by the Law "On Amendments to Certain Legislative Acts of Ukraine on Food Products". The Law on State Control of Compliance with Food, Feed, Animal By-Products, Animal Health and Welfare (2017, current version of 02/13/2020), the Law on Information for Consumers on Food (2019), Order of the Ministry of Health of Ukraine "On Approval of Hygienic Requirements for Dietary Supplements" (2013, entered into force 24.01.2016).

The Law "On Basic Principles and Requirements for Food Safety and Quality" regulates relations between executive authorities, food market operators and food consumers, and defines the procedure for ensuring the safety and individual quality indicators of manufactured foods, which are brought into circulation (forwarded) to the customs territory of Ukraine and / or exported (forwarded) from it.

The Law "On State Control of Compliance with Food, Feed, Animal By-Products, Animal Health and Welfare" directly defines the legal and organizational principles of state control that are carried out to verify compliance with food, feed, animal health and welfare, as well as legislation on animal by-products during the import (transfer) of such products to the customs territory of Ukraine.

This law promotes the interests of consumers of food products, as well as balancing the rights and duties of producers and state control bodies; improving the safety and quality of domestic foodstuffs, expanding their markets and strengthening their position on competition with foreign goods.

The Law on Consumer Information on Foodstuffs establishes the legal and organizational framework for providing consumers with information on foodstuffs in order to ensure a high level of protection of citizens' health and to satisfy their social and economic interests.

"Hygienic requirements for dietary supplements" is a single piece of legislation directly applicable to DS and applied exclusively to DS, and does not apply to medicines, functional foods and foods for special dietary use.

Hygienic requirements set the basic requirements for the labeling and advertising of dietary supplements, as well as the list of vitamins and minerals allowed for use in the DS production.

Conclusions. Considering the above, it can be concluded that the Ukrainian legislation mainly regulates general issues related to food safety and quality. However, specific products such as DS have not yet been addressed. This leads to abuse by manufacturers and sellers of DS, which causes both material damage to average consumers and a threat to their lives and health. Due to the lack of control by the state authorities, it is now possible to buy in the drugstore an DS whose quality is questionable. For example, the product may not have the declared components, or their number may not meet the requirements. Another important issue is compliance with the requirements for DS production processes, their quality control and transportation conditions. Our research is devoted to these issues.

ANALYSIS OF MODERN APPROACHES TO ASSESS THE CONFORMITY OF DOCUMENTATION OF THE QUALITY MANAGEMENT SYSTEM

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Introduction. The relevance of good documentation is explained by the following reasons:

- the need to formulate and communicate goals and objectives from management to all levels of the organization;
- ensuring consistency of actions among the performers of all processes;
- providing factual evidence of proper implementation of processes and conformity of products (services) to the established requirements;
- formation of information base for making reasonable management decisions.

The reasons for the need to control the quality of documents of the QMS:

- the correctness of the document affects the correctness of the actions described in these documents;
- clarity, conciseness and uniqueness are the characteristics that determine the perception of documents by their users;
- for a content and structure of the documents of many industries organizations have been established by regulatory requirements.

Aim: analysis of approaches to assessing the compliance of the organization's quality management system documentation with the model of ISO 9001 standard and development of appropriate methods.

The research objectives are:

- overview of directions of modern quality management;

- analysis of the requirements of ISO 9001:2015 for the management of documented information;
- identifying the features of circulation control and evaluating documented procedures within the quality management system;
- development of quality assessment methods and procedures for the circulation of QMS documents on the research base (distribution company "PRO.MED.CS Praha a.s.").

Materials and methods. To carry out our research, we carried out studies on the provisions of ISO 9001 and ISO 9000 as part of an overall management system based on the quality risk analysis approach needed to create, implement, operate, monitor, review, maintain and improve of QMS.

Results and discussion. Required quality management system documents according to ISO 9001:2008:

- documented Policy and Goals for quality sector;
- Quality Manual;
- documented procedures;
- documents required by the organization to ensure effective planning, operation and control of QMS processes;
- protocols (records).

The ISO 9001:2015 is required to control the documented information needed for conformity to ISO 9001, as well as the documented information that it has determined is needed for the effectiveness of its quality management system (ISO 9001:2015, 4.4.2). When ISO 9001 refers to "maintain documented information", this means ensuring that information is kept up-to-date, e.g. the information contained in documented procedures, manuals, forms and check-lists, information that could be stored in the cloud and downloaded to a smartphone or other electronic device, and other documented information (such as the quality policy and quality objectives).

When ISO 9001 refers to "retain documented information", this means ensuring that information that is used to provide evidence about whether or not a requirement has been fulfilled is protected against any deterioration or unauthorized change (that should not occur, unless an agreed correction has to be made).

In general, ISO 9001 is not prescriptive in terms of the extent of documented information needed. This will vary from organization to organization depending on the size and complexity of the operations and processes; customer, statutory and regulatory requirements; and the competence of the persons involved.

The management of documented information can be represented as a process with its inputs and outputs. It is also advisable to present each sub process as conversion of information inputs to outputs, using a process approach.

We have developed a methodology for assessing compliance of the QMS documentation with the requirements of ISO 9001.

The methodology involves evaluating the QMS documentation on the following aspects:

- Verification of documents for compliance before they are put into circulation.
- Analysis, updating and re-approval of documents.
- Ensure identification of changes and status of current document review.
- Ensure that documents are available at their point of use.
- Ensure legibility and ease of identification of documents.
- Ensure identification of external origin documents.
- Prevent unintended use of legacy document versions.

The Methods is aimed at checking not the entire documented procedures, but the entire organization's workflow system.

Document review will identify system flaws and take appropriate corrective actions to reduce the risk of inconsistencies / nonconformities.

A methodology for evaluating the quality of documented QMS procedures has also been developed (using the SOP example).

The technique allows to evaluate on a 4-point scale the quality of documented procedures developed from the user's point of view by the following parameters:

- Convenience of application of procedure (clarity, comprehensibility of text and illustrations).
- Correctness of the SOP structure (compliance of the SOP content with the established general requirements).
- Description of the procedure algorithm (completeness and correctness of instructions, requirements).
- The style of presentation of the procedure text (lexical and spelling quality of the document).

When using the technique by the expert(s), it is necessary to fill in the questionnaires.

Recommendations have been made on the preparation of reports on the verification and assessment of the quality of workflow. Reports can be prepared either during scheduled internal audits or during an unscheduled audit of the records management process.

Conclusions. The application of the proposed methods will not only improve the quality of the documented procedures at the research facility, but also improve the entire system of workflow of the organization. Based on the generalization of approaches and methods of document evaluation, an algorithm for auditing the process of document management of QMS has been developed and proposed, which can serve as a typical example for many organizations. As part of the work, an approximate list of questions that auditors should be asked when reviewing the "Document Management" process is formulated. The form of a questionnaire of the auditor is offered. The form of the report on the results of the evaluation of the "Document Management" process for compliance with the requirements of ISO 9001 is proposed. Typical nonconformities most commonly encountered by organizations in document audits are identified and summarized. The method of document flow estimation is developed. Questionnaire forms are developed to evaluate the quality of the document, which can be applied within any process of QMS. All the achievements, completed in the framework of the master's work, are proposed for implementation in the pharmaceutical company LLC "PRO.MED.CS Praha a.s.".

ANALYSIS OF THE FUNCTIONALITY OF THE QUALITY RISK MANAGEMENT PROCESS AT THE PHARMACEUTICAL DISTRIBUTION ENTERPRISES

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Introduction. One of the effective measures to increase the competitiveness of any modern organization is the implementation and continuous development and improving of the Quality Management System (QMS), for example, according to the ISO 9001 standard model, strengthening their competitive position.

The implementation of a Quality Management Systems has become a rule in many industries.

At the present stage of management development, much attention is paid to a risk-based approach. For example, all important decisions in management systems should be made taking into account the identified risks and opportunities for the organization. Risks always exist in all spheres of human activity. They appear when any uncertainty takes place. Risks are also inherent in situations where there is a multi-variance of events. In addition, you need to pay attention to the presence of both negative and positive results of the implementation of risks, i.e. emergency situations.

For example, any organization has a risk when expanding its range of products or services. However, such actions can have positive consequences for the organization.

All actions associated with risks in various fields are now called Risk Management. Risk Management is an integral and important part of modern management.

In Pharmacy Risk Management is the overall process of minimizing risks to the quality of medicines throughout the life cycle to optimize operations and balance risks / benefit for pharmaceutical company.

Risk Management is an integrated, structured, inclusive, dynamic, systematic process of risk assessment, risk impact, risk monitoring and verification, and the exchange of risk information for the quality of medicinal products.

Risk Management supports science-based and practical solutions when integrating into Quality Management Systems. Moreover, the QMS (or Pharmaceutical Quality System – PQS) include validation, quality defects - investigation, audit, verification, documentation, training of personnel and more.

Risk management for the quality of medicines is an integral and very important factor in improving the pharmaceutical quality system, because it is the systematic identification, analysis, evaluation of risks within all systematic processes, with appropriate precautions taken to eliminate the causes of potential discrepancies or reduce the risks to an acceptable level ensures proper functioning and continuous improvement.

In the current National Guideline «Medicines. Quality Risk Management», harmonized with ICH Q9, presents principles and examples of risk management tools for quality that can be applied to various aspects of quality in the operations of pharmaceutical businesses. International Standard ISO 31000: 2018 contains principles and conceptual guidelines for risk management and recommends that certain methods be applied on a case-by-case basis.

Guidelines «Medicines. Good Manufacturing Practice» (GMP) provide for mandatory risk management and do not exclude the use of the risk management model described in ISO 9000 series standards Yes, the GMP Guidelines require distributors to have risk management techniques in place. Quality risk management is a process that facilitates the adoption of scientifically sound and practical decisions when integrating them into quality systems. Effective quality risk management can help to make better and more informed decisions, which will give regulators greater assurance about the company's ability to deal with potential risks, and may affect the scale and level of direct oversight by the regulator. In addition, quality risk management can facilitate the better use of resources by all parties.

National pharmaceutical companies often manage the risk fairly formally, mainly to meet oversight requirements. As a consequence, it may adversely affect the ability of enterprises to consistently supply products that fully meet all established requirements. Scientifically sound approaches to quality risk management allow us to determine the list of undesirable situations, to assess the likelihood of their occurrence and the severity of the consequences, and to develop and take measures to eliminate or minimize the causes of the risks.

Aim. The aim of the work is to analyze the state of functioning of the process of quality risk management at national pharmaceutical enterprises distributors.

Materials and methods. The following methods of research were used: the review of literature data and generalization of the material, methods of analysis and synthesis, marketing, system, logical-structural and comparative analysis, forecasting and programming.

Results and discussion. During 2018-2019, a marketing survey was conducted among distributor pharmaceutical companies on the functioning of the quality risk management process. Questionnaires were sent to 45 enterprises, and 18 respondents received answers, accounting for 40% of their total number. The representativeness of this sample can be considered acceptable. Respondents included representatives of all major pharmaceutical companies in Ukraine's distributors, which are among the top ten in terms of sales of drugs to pharmacies. The enterprises are located in 10 regions of Ukraine; organizations were of different ownerships, sales volumes of medicines, all interviewees indicated that they had valid certificates of Good Distribution Practice.

The survey showed that 78% of participants in the risk management process at pharmaceutical companies in Ukraine's distributors are specialists in the quality department, employees of all departments of distributors conduct 17% of the process and only 5% of respondents mentioned the joint work of the quality department and employees of all departments.

More than 70% of respondents to the risk management process faced the problem of lack of information on methodology and practical aspects of risk management for quality in drug distribution, consultants. 16% of respondents find useful information on risk management in textbooks, guidelines and 11% of respondents in periodicals.

According to the respondents, the greatest difficulties in implementing and operating the risk management process at enterprises were related to the training of risk managers (55%).

Regarding the question of the relevance of risk management results to management expectations, the majority of respondents (88%) said that management is generally skeptical about risk management, perceiving risk management only as a regulatory process.

55% of respondents consider it critical to develop methodological recommendations; 28% of respondents agreed that such recommendations would be useful.

Conclusions. The main problems with the effectiveness of quality management are related to the lack of competence of risk managers, the lack of staff time required to train risk managers, the process itself, the analysis of the results obtained, and the lack of experts involved.

Many businesses most urgently need to improve elements of the risk management process, such as choosing a methodology, documenting the process, enhancing the competence of risk managers, monitoring the implementation of risk mitigation decisions, and more.

According to the data we receive, we plan to formulate a set of proposals on optimal organization of risk management at the pharmaceutical companies of distributors, to substantiate the set of competencies of risk managers, the composition of the team of risk managers, to define scientific and methodological approaches to regulation and documentation of risk management activities.

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