Ф А 2.2.1-32-367

MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY
pharmaceutical faculty
department of social pharmacy

QUALIFICATION WORK

on the topic**: "**RESEARCH ON TRENDS IN THE DEVELOPMENT OF THE PHARMACEUTICAL SECTOR BASED ON MODERN INFORMATION TECHNOLOGIES"

Prepared by higher education graduate of group Фм20(4,10д) англ-03
specialty 226 Pharmacy, industrial pharmacy
educational and professional program Pharmacy
Wissal ZAKARIA
Supervisor: head of the department of social pharmacy, PhD, associate professor
Alina VOLKOVA
Reviewer: head of the department of management, marketing and quality assurance in pharmacy, D.Sc. in Pharmacy, professor Volodymyr MALYI

Kharkiv – 2025

ANNOTATION

The qualification work presents the results of a study of the introduction and application of modern information technologies in the pharmaceutical sector of the healthcare, in particular the electronic prescription system. The paper highlights the advantages, disadvantages and limitations of digitalisation in the pharmaceutical industry, from the early stages of drug discovery and development, through manufacturing and supply chain management, to the final delivery of pharmaceutical care and medication management in clinical practice.

The results of the study are presented in 56 pages. The paper contains 7 figures, 5 tables and a bibliography of 33 references.

Key words: pharmaceutical business, information technology, e-prescription, digital healthcare, medication errors, pharmaceutical informatics.

АНОТАЦІЯ

Кваліфікаційна робота представляє результати дослідження впровадження та застосування сучасних інформаційних технологій у фармацевтичному секторі сфери охорони здоров’я, зокрема системи електронних рецептів. У роботі висвітлено переваги, недоліки та обмеження у цифровізації фармацевтичної галузі, від початкових етапів відкриття та розробки ліків через виробництво та управління ланцюгами поставок до остаточного надання фармацевтичної допомоги та управління ліками в клінічній практиці.

Результати дослідження викладено на 56 сторінках. Робота містить 7 рисунків, 5 таблиць та список літератури з 33 джерел.

Ключові слова: фармацевтична діяльність, інформаційні технології, цифрова охорона здоров’я, електронний рецепт, помилки при призначенні ліків, фармацевтична інформатика.

CONTENT

ABBREVIATIONS

ADC – automated dispensing cabinet

AI – artificial intelligence

BCMA – barcode medication administration

CDS – clinical decision support

CPOE – computerized provider order entry

EHR / EMR– electronic health /medical record

eMAR – electronic medication administration record

EPCS – electronic prescribing of controlled substances

eRx – electronic prescribing (e-prescribing)

IT – information technology

IoT - Internet of things

ML – machine learning

MTM – medication therapy management

NHS – national healthcare system

INTRODUCTION

Actuality of topic. The pharmaceutical sector stands as a cornerstone of global healthcare systems, driving innovation in disease treatment, prevention, and overall public health. Its continuous evolution is critical for addressing emerging health challenges, improving patient outcomes, and enhancing the quality of life worldwide. In recent decades, this evolution has become inextricably linked with the rapid advancement and integration of modern information technologies (IT). The digital transformation sweeping across industries has profoundly impacted the pharmaceutical landscape, reshaping everything from drug discovery and development to manufacturing, supply chain management, regulatory compliance, and patient care. IT is no longer merely a supporting function but a strategic imperative, enabling unprecedented efficiency, accuracy, and innovation within the sector.

The integration of IT into the pharmaceutical industry signifies a paradigm shift, moving towards more data-driven, patient-centric, and efficient operational models. Technologies such as artificial intelligence (AI), machine learning (ML), Big Data analytics, cloud computing, blockchain, and the internet of things (IoT) are revolutionizing traditional processes. AI and ML, for instance, are accelerating the complex and costly process of drug discovery by analyzing vast datasets to identify potential drug candidates, predict their efficacy and safety, and optimize clinical trial design. McKinsey Global Institute estimates that generative AI alone could unlock $60 billion to $110 billion annually for the pharma and medical-product industries, primarily by speeding up compound identification. Big Data analytics allows for the extraction of valuable insights from diverse data sources, including clinical trials, electronic health records (EHRs), and real-world evidence (RWE), leading to advancements in personalized medicine and improved understanding of treatment effectiveness.

The purpose of the study is to conduct comprehensive research on the current and future trends in the development of the pharmaceutical sector driven by

modern information technologies.

Research objectives:

- to analyse scientific information sources on the topic;
- to study the role of information technologies in healthcare;
- to study on current trends and challenges of digitalisation in the pharmaceutical sector;
- to identify the future prospects for information technology in pharmaceutical practice;
- to develop recommendations for the successful implementation of information technology in pharmaceutical practice.

The object of study: publications and research results related to the implementation of digital technologies in the pharmaceutical sector of the healthcare; regulatory documents; analytical references. Subject of research: theoretical, methodological, applied foundations of the digitalization of the pharmaceutical sector.

Research methods. In the analysis methods of the content analysis, comparative, analytical, graphical methods were used.

Approbation of results. The main scientific results obtained during the qualification work were published in the abstracts at the XXXI International Scientifical and Practical Conference of Young Scientists and Students “Topical issues of new medicines development” (23-25 April 2025, Kharkiv, Ukraine).

Structure and scope of qualification work. The qualification work consists of the introduction, three chapters, conclusions to each chapter, general conclusion, and list of used sources. The results of the study are presented on 56 pages of text, the number of figures - 7, tables - 5, and the list of references - 33 titles.

CHAPTER 1. THE ROLE OF INFORMATION TECHNOLOGIES IN THE HEALTHCARE

1.1. The digital transformation of the healthcare: historical aspects

Information Technology (IT) has transitioned from a peripheral support function to a central, transformative force within the global healthcare ecosystem. Its influence permeates every aspect of health and medicine, from fundamental research and drug discovery to clinical practice, patient engagement, and public health management. The pharmaceutical sector, in particular, has been profoundly reshaped by the relentless march of digital innovation. Modern IT underpins the complex processes of developing new drugs, ensuring their quality and safety during manufacturing, managing intricate global supply chains, facilitating regulatory compliance, and optimizing their delivery and use by patients. Understanding the role of IT is therefore fundamental to comprehending the current state and future trajectory of the pharmaceutical industry [1, 3, 6, 9].

The integration of IT into healthcare has been a gradual yet transformative journey, spanning several decades. What began as simple automation of administrative tasks has evolved into a complex digital ecosystem that influences clinical decision-making, research, patient care, and operational efficiency. Understanding this historical trajectory is crucial for appreciating the current state of digital health and its impact on the pharmaceutical sector (fig. 1.1).

Early Days and Conceptual Seeds (Pre-1970s). Before the widespread availability of computers, healthcare operated almost entirely on paper. Patient records were handwritten charts stored in vast filing rooms, prescriptions were manually written notes, billing was a laborious manual process, and communication relied heavily on telephones and physical mail. Data analysis for research or public health was incredibly time-consuming, often involving manual tabulation of data from paper records. While rudimentary compared to today's standards, the limitations of this paper-based system implicitly highlighted the need for more

efficient methods of information management [6, 7].

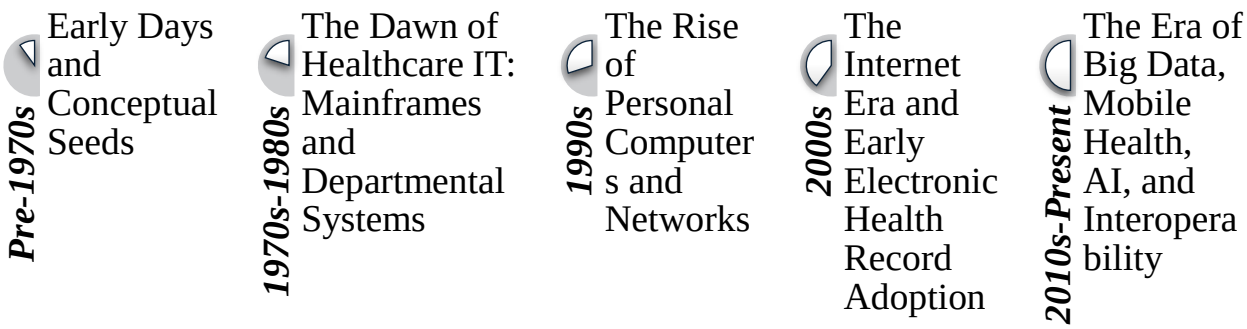

Fig. 1.1. Historical stages of development of information technologies in healthcare

The mid-20th century saw the birth of electronic computing. While these early machines were large, expensive, and primarily used by government, military, and large research institutions, visionaries began to conceptualize their potential application in medicine. Early theoretical work explored the use of computers for statistical analysis of medical data, managing hospital inventories, and potentially even aiding in diagnosis. However, the technology was far from practical for routine clinical use. The focus remained largely on automating back-office functions where the benefits of speed and calculation power were most immediately apparent. For instance, computers began to be used for processing payroll and managing basic hospital accounting functions, freeing up administrative staff from purely manual calculations but having little direct impact on patient care or pharmaceutical processes initially. The concept of storing patient medical information electronically was nascent, often limited to specialized research projects rather than integrated clinical systems [6, 29, 33].

The Dawn of Healthcare IT: Mainframes and Departmental Systems (1970s-1980s). The 1970s marked the true beginning of healthcare information technology, driven by the increasing power and slightly decreasing (though still substantial) cost of mainframe computers. Hospitals began adopting these systems more broadly, primarily for financial and administrative purposes. Patient billing,

admissions/discharge/transfer systems, and scheduling became common applications. These systems improved administrative efficiency and revenue cycle management, demonstrating the tangible benefits of computerization in a hospital setting [7, 29].

Simultaneously, specialized departmental systems started to emerge. Laboratories were among the first clinical areas to benefit, with Laboratory Information Systems developed to manage test orders, track specimens, interface with automated analyzers, and report results. Radiology Information Systems followed, managing patient scheduling, imaging procedures, and reporting. Pharmacy departments also saw early adoption, with systems designed to manage drug dispensing, inventory control, and basic drug interaction checks. These departmental systems, often running on minicomputers, were typically standalone "silos," designed to optimize workflows within a specific department but with limited or no ability to share information with other systems within the hospital [6].

This era also saw the development of pioneering academic projects exploring integrated electronic health records (EHRs). Notable examples include the COSTAR (Computer Stored Ambulatory Record) system developed at Massachusetts General Hospital and the HELP (Health Evaluation through Logical Processing) system at LDS Hospital in Utah. These systems aimed to create comprehensive, longitudinal patient records, incorporating clinical data, order entry, and even clinical decision support rules. While highly influential and demonstrating the potential of integrated EHRs, these systems were often complex, expensive to develop and maintain, and largely confined to the institutions where they were created. They faced significant challenges, including the high cost of hardware, the need for specialized programming expertise, resistance from clinicians accustomed to paper records, and the lack of standardized medical vocabularies and data exchange formats, which severely limited interoperability [6, 20, 30].

The Rise of Personal Computers and Networks (1990s). The advent of the personal computer and local area networks in the late 1980s and throughout the 1990s significantly democratized computing within healthcare organizations.

personal computers offered a more affordable and user-friendly alternative to mainframes and minicomputers, leading to wider adoption across various departments and clinical settings, including smaller clinics and physician practices.

This period saw a proliferation of specialized software applications designed for personal computers. Clinical documentation systems, practice management software, and more sophisticated departmental systems became available. The ability to connect personal computers via local area networks enabled better information sharing within departments and laid the groundwork for more integrated hospital-wide systems. However, interoperability remained a major challenge, as different systems often used proprietary data formats and communication protocols [6, 11, 17].

A significant development during this time was the emergence and growth of Picture Archiving and Communication Systems in radiology. Driven by advancements in digital imaging modalities (like CT and MRI) and improvements in network speed and storage capacity, Picture Archiving and Communication Systems allowed for the digital acquisition, storage, retrieval, and display of medical images. This eliminated the need for physical film, improving efficiency, enabling remote consultations (teleradiology), and facilitating integration with Radiology Information Systems and, eventually, EHRs [2, 3].

The 1990s also witnessed the growing influence of the internet. While initially used primarily for email and accessing static information resources (like medical literature databases), its potential for broader healthcare applications began to be recognized. Early online health information portals emerged, providing resources for both professionals and patients.

Crucially, the challenges of integrating disparate systems highlighted the urgent need for standardization. Health Level Seven (HL7), founded in 1987, emerged as a key organization developing standards for the exchange, integration, sharing, and retrieval of electronic health information. Early versions of HL7 standards focused on messaging formats for transmitting administrative and clinical data between different healthcare applications (e.g., sending

admissions/discharge/transfer systems information from a hospital registration system to a departmental system). Similarly, the digital imaging and communications in medicine standard became essential for ensuring interoperability between imaging equipment, picture archiving and communication systems, and other systems. These standardization efforts, though complex and ongoing, were critical steps towards achieving seamless data flow in healthcare. For the pharmaceutical industry, this era meant improved access to medical literature online and the beginnings of more sophisticated software for managing clinical trial data, although integration with hospital systems was still minimal [3, 6, 9].

The Internet Era and Early EHR Adoption (2000s). The 2000s were characterized by the explosion of the World Wide Web and the development of web-based applications, profoundly impacting healthcare IT. The internet facilitated easier communication, information dissemination, and the development of more accessible and potentially interoperable systems.

This decade saw a significant push towards the adoption of Electronic Health Records (EHRs). Recognizing the potential of EHRs to improve quality of care, patient safety, and efficiency, governments in several countries launched initiatives to incentivize their adoption. A landmark example was the Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the American Recovery and Reinvestment Act of 2009 in the United States. HITECH allocated billions of dollars in incentive payments for healthcare providers demonstrating "Meaningful Use" of certified EHR technology. This legislation dramatically accelerated EHR adoption rates in the US, although challenges remained [11, 17].

Despite increased adoption, interoperability continued to be a major hurdle. While HL7 standards existed, their implementation varied, and sharing data seamlessly between different EHR systems (e.g., between a hospital and a primary care physician using different vendors) remained difficult. Concerns about data privacy and security also grew, leading to the strengthening and enforcement of regulations like the Health Insurance Portability and Accountability Act in the US, which established national standards to protect sensitive patient health information

[11, 25, 27].

The internet also enabled the rise of patient portals, secure websites allowing patients to access parts of their medical record, view test results, schedule appointments, request prescription refills, and communicate securely with their providers. This marked a shift towards greater patient engagement and empowerment. Early forms of telemedicine and remote monitoring also began to gain traction, although adoption was often limited by technology constraints, reimbursement issues, and regulatory hurdles.

Within the pharmaceutical sector, the 2000s saw the maturation of Clinical Trial Management Systems and the increasing use of Electronic Data Capture systems to streamline clinical research. Web-based platforms facilitated multi-site trials and improved data quality and collection speed compared to traditional paper-based methods. The growing availability of digitized health data, albeit fragmented, also sparked interest in using real-world data for pharmacovigilance and outcomes research [6, 27].

The Era of Big Data, Mobile Health, AI, and Interoperability (2010s-Present). The period from 2010 onwards has witnessed an acceleration of digital transformation, driven by several converging trends:

- Explosion of Health Data (Big Data): The widespread adoption of EHRs, combined with advances in genomic sequencing, digital imaging, wearable sensors, and patient-generated health data, has led to an unprecedented volume, velocity, and variety of health-related data. Harnessing this "Big Data" offers immense potential for improving diagnostics, treatment personalization, drug discovery, population health management, and operational efficiency, but also presents significant challenges in terms of storage, processing, analysis, and interpretation.
- Mobile Health (mHealth): The ubiquity of smartphones and tablets has fueled the growth of mHealth. Mobile apps now exist for numerous health purposes, including fitness tracking, chronic disease management, medication reminders, telehealth consultations, and accessing patient portals. Wearable devices

(smartwatches, fitness trackers, continuous glucose monitors) continuously collect physiological data, providing valuable insights for patients and clinicians.

- Cloud Computing: Cloud platforms (like AWS, Google Cloud, Microsoft Azure) provide scalable, flexible, and often more cost-effective infrastructure for storing vast amounts of health data, running complex analytical workloads, hosting EHRs, and delivering telehealth services. Cloud computing facilitates collaboration and data sharing, although security and compliance remain critical considerations.
- Advanced Analytics, AI, and Machine Learning (ML): Sophisticated analytical techniques are being applied to large health datasets to uncover patterns, predict outcomes, and support clinical decision-making. AI and ML are finding applications across healthcare, including medical image analysis (radiology, pathology), predictive diagnostics, identifying patients at risk for certain conditions, optimizing hospital operations, and, significantly for the pharmaceutical sector, accelerating drug discovery and development by analyzing biological data, predicting molecular interactions, and optimizing clinical trial design.
- Focus on Interoperability: Recognizing that the full potential of digital health cannot be realized with siloed systems, there has been a renewed and intensified focus on achieving true interoperability. Newer standards like Fast Healthcare Interoperability Resources, developed by HL7, use modern web technologies (APIs) to enable more flexible and efficient data exchange between different systems. Initiatives promoting standardized data elements and APIs aim to create a more connected healthcare ecosystem.
- Cybersecurity: As healthcare becomes more digitized and interconnected, it also becomes a more attractive target for cyberattacks. Protecting sensitive patient data and ensuring the resilience of critical healthcare IT infrastructure against ransomware and other threats has become a major priority.
- Impact of the COVID-19 Pandemic: The pandemic acted as a massive catalyst

for digital health adoption. Lockdowns and infection control measures led to an explosive growth in telehealth utilization for routine consultations, mental health services, and chronic disease management. Remote monitoring technologies were deployed to manage patients at home. The need for rapid data sharing for public health surveillance and vaccine development further highlighted the importance of robust digital infrastructure and interoperability [1, 3, 29, 31, 32].

This latest era has seen IT become deeply embedded in pharmaceutical processes. AI is revolutionizing drug discovery, clinical trial data is managed electronically globally, manufacturing relies on sophisticated automation and data analytics (PAT, MES), supply chains leverage track-and-trace and IoT, and regulatory submissions are increasingly electronic. The historical journey from paper records and basic administrative computing to today's AI-driven, data-intensive digital health landscape has laid the essential foundation for the modern, technology-enabled pharmaceutical sector.

1.2. Key information technologies used in drug development and distribution

The development and distribution of drugs is an immensely complex, lengthy, and costly process, subject to stringent regulatory oversight. IT has become indispensable across this entire value chain, enhancing efficiency, improving accuracy, enabling innovation, and ensuring safety and compliance. We have collated data from scientific articles, journals and specialist agency websites, and grouped specific IT tools and platforms used in the modern pharmaceutical sector by stage of the drug lifecycle. (fig. 1.2).

Drug Discovery and Development is initial phase focuses on identifying potential drug candidates and evaluating their safety and efficacy through preclinical and clinical research. IT plays a critical role in managing the vast amounts of data generated and accelerating the discovery process.

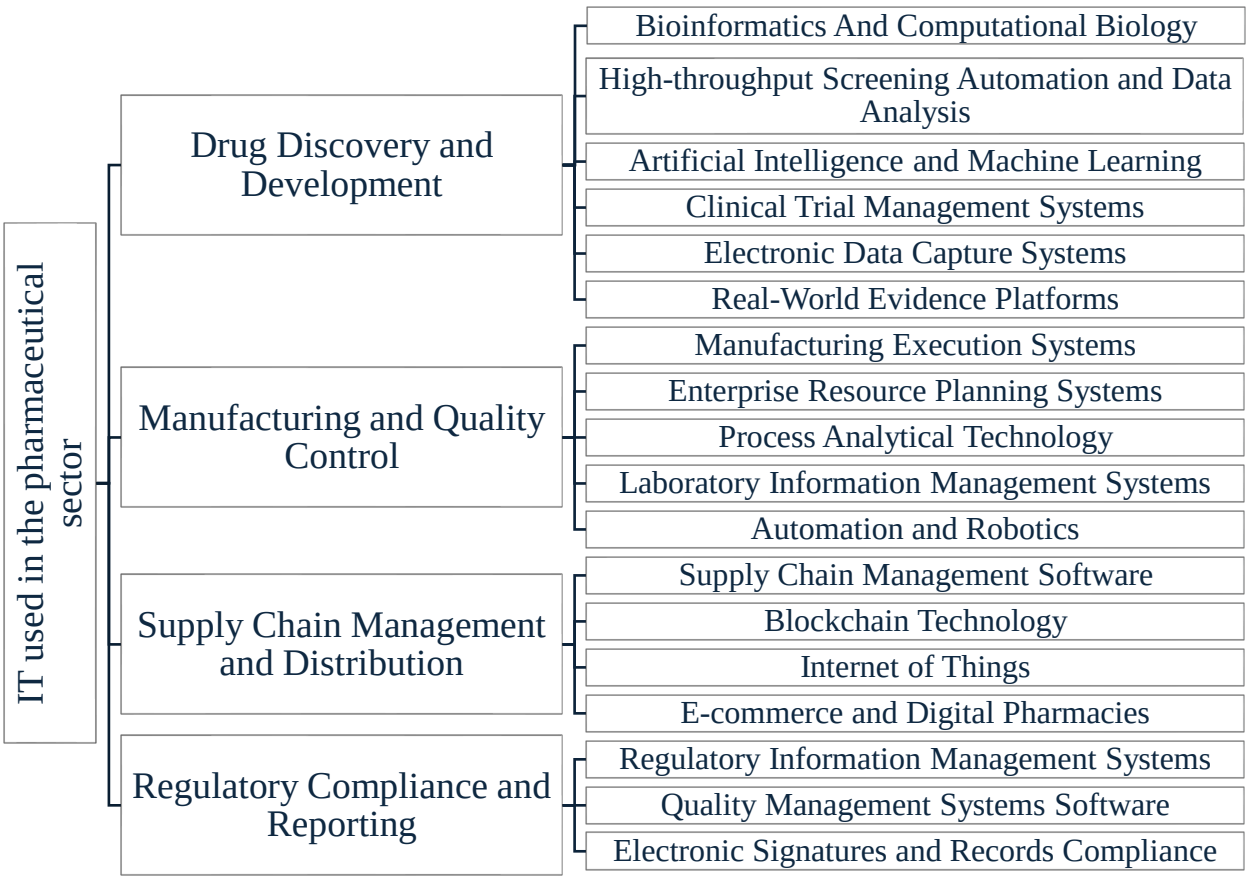

Fig. 1.2. Modern IT used in the pharmaceutical sector

Bioinformatics and Computational Biology leverages computer science, statistics, and mathematics to analyze complex biological data. Key IT tools include biological databases (vast repositories like GenBank (genetic sequences), protein data bank (PDB - protein structures), and specialized databases (e.g., ChEMBL for drug-like molecules) store and organize biological information, making it accessible for researchers worldwide), sequence analysis tools (software for analyzing DNA, RNA, and protein sequences is essential for understanding genetic variations, identifying potential drug targets, and designing experiments), molecular modeling and simulation (software allows researchers to create 3D models of molecules (proteins, potential drugs) and simulate their interactions (in silico). This helps predict how a drug might bind to its target, assess its potential efficacy, and optimize its chemical structure before expensive laboratory synthesis and testing. Computational fluid dynamics can model drug delivery mechanisms, such as inhalation [5, 29, 32].

High-Throughput Screening automation and data analysis involve rapidly testing hundreds of thousands, or even millions, of chemical compounds for activity against a specific biological target. IT is crucial for robotics and automation (automated liquid handling systems, plate readers, and robotic arms manage the physical screening process, enabling massive scale and reducing manual error.), data capture and analysis (integrated software automatically captures the large volumes of data generated by High-Throughput Screening assays, performs quality control checks, identifies potential "hits" (active compounds), and facilitates visualization and interpretation of results. Statistical analysis tools help distinguish true hits from false positives) [29, 32].

Artificial Intelligence (AI) and Machine Learning (ML) algorithms are increasingly used to analyze complex datasets and make predictions, significantly accelerating drug discovery: target identification and validation (AI can analyze genomic, proteomic, and clinical data to identify novel biological targets implicated in disease and predict their "druggability"), lead optimization (models can predict the absorption, distribution, metabolism, excretion, and toxicity properties of potential drug candidates based on their chemical structure, helping researchers prioritize compounds with favorable profiles and reducing late-stage failures), predictive modelling (AI can predict the efficacy and potential side effects of drug candidates before clinical trials begin, potentially reducing the need for extensive animal testing and improving trial success rates), in silico trials (computer simulations, sometimes powered by AI, model how drugs might behave in virtual patient populations, complementing or potentially reducing the scope of traditional clinical trials), generative AI (emerging generative AI models can design novel molecular structures with desired properties from scratch, opening new avenues for drug discovery), literature analysis (AI tools can rapidly scan and synthesize information from vast amounts of scientific literature and patents to identify trends, potential drug targets, or existing compounds that could be repurposed) [4, 5, 10].

Managing complex, global clinical trials requires sophisticated software like Clinical Trial Management Systems. It helps planning and setup (tools for protocol

design, budget management, site selection, and feasibility assessment), operational management (tracking patient enrolment, managing study milestones, scheduling visits and procedures, managing investigational product supply, and facilitating communication between sponsors, and study sites), monitoring and reporting: tools for monitoring site performance, tracking data entry progress, managing deviations, and generating reports for regulatory submissions and internal review [5, 29, 32].

Electronic Data Capture Systems have largely replaced paper-based Case Report Forms for collecting patient data during clinical trials: electronic case report forms (web-based forms for direct data entry by site staff), Data Validation (built-in edit checks identify errors or inconsistencies at the point of entry, improving data quality), real-time access (sponsors and CROs can access and review data in near real-time, enabling faster decision-making and identification of potential issues), audit trails (secure, time-stamped audit trails track all data entries and modifications, ensuring regulatory compliance) [17, 18].

Real-World Evidence Platforms collect and analyze data generated outside of traditional clinical trials, such as from EHRs, insurance claims databases, patient registries, and wearable devices. Real-World Evidence is increasingly used for: post-market surveillance (monitoring the safety and effectiveness of drugs in larger, more diverse populations after approval), comparative effectiveness research (comparing the outcomes of different treatments in real-world settings), supporting regulatory decisions (providing supplementary evidence for label expansions or new indications), informing clinical trial design (understanding disease progression and treatment patterns in the real world can help optimize future trial protocols [9, 14-16].

Manufacturing Execution Systems provide real-time control and visibility over the manufacturing process on the shop floor: process monitoring and control (interfacing with production equipment to monitor critical process parameters (temperature, pressure, etc.) and ensure they remain within specified limits), electronic batch records (digitally guiding operators through manufacturing steps, capturing data electronically, enforcing procedural compliance, and creating a

comprehensive, error-checked record of each batch, replacing paper batch records), resource management (tracking equipment usage, operator qualifications, and material consumption), Integration (connecting shop floor activities with higher-level planning systems like enterprise resource planning) [5, 13, 20].

Enterprise Resource Planning Systems integrate various business functions across the pharmaceutical company, including manufacturing, finance, supply chain, human resources, and sales. In manufacturing, Enterprise Resource Planning helps with production planning and scheduling (aligning production schedules with demand forecasts and material availability), inventory management (tracking raw materials, work-in-progress, and finished goods across the supply chain), cost accounting (tracking the costs associated with manufacturing processes) [5, 20].

Process Analytical Technology involves using online or inline sensors and analytical tools to monitor critical quality attributes of materials during the manufacturing process in real-time. This data is analyzed using IT systems to real-time quality assurance (understand and control the process to ensure the final product meets quality specifications, potentially reducing the need for extensive end-product testing) and process optimization (identify opportunities to improve process efficiency and consistency based on real-time data) [5, 24].

Laboratory Information Management Systems are used in quality control laboratories to manage workflows, data, and samples: sample tracking (managing the lifecycle of qc samples from receipt to testing and disposal), workflow automation (managing test schedules, instrument integration, data capture from analytical instruments), data analysis and reporting (performing calculations, comparing results against specifications, generating certificates of analysis, and managing stability study data), compliance (maintaining audit trails and ensuring compliance with regulations like good laboratory practice) [5, 24].

Usage of Automation and Robotics, similar to HTS, helps manufacturing and QC labs with utilize automation for repetitive tasks like filling, packaging, inspection (e.g., using machine vision), and sample preparation/analysis, to improve consistency and reduce human error.

Ensuring that drugs reach patients safely, securely, and efficiently requires robust *supply chain management*, increasingly reliant on IT. Based on the analysis of publications, the following modern technologies were identified as the main ones:

- Supply Chain Management Software helps manage the complex pharmaceutical supply chain: Demand Forecasting (using historical data and predictive analytics to forecast demand for different products in various markets), Inventory Optimization (balancing inventory levels across the network to minimize holding costs and prevent stockouts, considering factors like shelf life), Logistics Planning (Optimizing transportation routes and modes, managing warehouse operations), Track-and-Trace/Serialization (systems mandated by regulations in many countries (e.g., DSCSA in the US, FMD in the EU) require unique serial numbers on drug packages, which are tracked throughout the supply chain to prevent counterfeiting and facilitate recalls. IT systems manage serial number generation, aggregation (linking unit-level serial numbers to cases/pallets), and reporting to regulatory bodies) [3, 20].
- Blockchain Technology. Blockchain offers a decentralized, immutable ledger with potential applications in: Drug Provenance and Anti-Counterfeiting (creating a secure and transparent record of a drug's journey through the supply chain, making it harder for counterfeit products to enter), Clinical Trial Data Integrity (Securely recording and sharing clinical trial data), Supply Chain Transparency (Providing stakeholders, including potentially patients, with verifiable information about a drug's origin and handling) [1, 3].
- Internet of Things. Sensors connected to the internet provide real-time data for supply chain visibility: Cold Chain Monitoring (temperature sensors in shipping containers and storage facilities continuously monitor conditions for temperature-sensitive drugs (e.g., vaccines, biologics), alerting stakeholders to deviations), Real-time Shipment Tracking (GPS and other sensors provide real-time location and condition monitoring of shipments), Smart Warehousing (IoT sensors can monitor environmental conditions, optimize storage space, and track assets within warehouses) [1, 6].

- E-commerce and Digital Pharmacies. Online platforms allow patients to order prescriptions and over-the-counter medications for delivery, increasing convenience and access. These platforms require sophisticated IT infrastructure for order processing, payment, fulfilment, and compliance with pharmacy regulations [3, 24].

The pharmaceutical industry is subject to strict regulation. IT systems are essential for managing compliance activities and documentation, ensuring regulatory compliance and reporting. The following IT tools are currently used for this purpose:

- Regulatory Information Management Systems centralize and manage regulatory information and processes (Submission Management: compiling, publishing (e.g., eCTD format), and tracking regulatory submissions to health authorities worldwide), Health Authority Interaction Tracking (recording communications and commitments with regulatory agencies), Product Registration Tracking (managing product licenses and registrations across different countries), Labeling Management (controlling the creation, approval, and distribution of product labeling information)).
- Quality Management Systems (QMS) Software. Electronic Quality Management Systems platforms manage quality processes and documentation (Document Control (managing the creation, review, approval, distribution, and archiving of standard operating procedures (SOPs), policies, and other GxP documents), Audit Management (planning, conducting, and tracking internal and external audits), Corrective and Preventive Action Management (tracking deviations, investigating root causes, and managing corrective and preventive actions), Training Management (tracking employee training records and qualifications).
- Electronic Signatures and Records Compliance**.** Systems handling critical GxP data must comply with regulations like the US FDA's 21 CFR Part 11, which defines requirements for electronic records and electronic signatures to be considered trustworthy and equivalent to paper records and handwritten signatures. This involves features like secure access controls, audit trails,

signature manifestations, and system validation [2, 20, 26, 32, 33].

The results of summarising the information on the possibilities of using modern information technologies in pharmacy are presented in table 1.1.

Table 1.1

Overview of key IT systems in pharmaceutical R&D

Technology	Function	Contribution
Artificial Intelligence and Machine Learning	Analyzing complex biological/chemical data, predicting molecular properties/interactions, pattern recognition.	Accelerates target identification, predicts drug efficacy/safety (absorption, distribution, metabolism, excretion, and toxicity), optimizes lead compounds, potentially designs novel molecules.
Clinical Trial Management Systems	Managing operational aspects of clinical trials (planning, site selection, enrollment, milestones, budget).	Streamlines trial management, improves oversight, facilitates communication across sites/sponsors, manages resources and documentation.
Electronic Data Capture Systems	Electronically capturing patient data during clinical trials via e case report forms, including data validation checks.	Replaces paper case report forms, improves data quality/accuracy at point of entry, enables faster data access/review, supports regulatory compliance.
Bioinformatics Tools	Storing, retrieving, analyzing, and interpreting large biological datasets (genomics, proteomics, etc.).	Enables analysis of genetic sequences/protein structures, identifies potential drug targets, supports molecular modeling and simulation (*in silico*).

In summary, a diverse array of sophisticated information technologies underpins virtually every stage of the pharmaceutical lifecycle. From accelerating the discovery of novel therapies using AI and bioinformatics to ensuring manufacturing quality with Manufacturing Execution Systems and Process Analytical Technology, managing global supply chains with Supply Chain Management and Internet of Things, and maintaining rigorous regulatory compliance with Regulatory Information Management and Quality Management

Systems, IT is no longer optional but a fundamental enabler of the modern pharmaceutical industry.

1.3. Analytical review of key components of e-prescription systems

Electronic prescribing, or e-prescribing (eRx), represents a significant advancement in medication management, replacing traditional handwritten or paper-based prescriptions with electronically generated and transmitted ones. Its primary goals are to enhance patient safety by reducing medication errors, improve workflow efficiency for both prescribers and pharmacists, increase convenience for patients, and support better adherence to treatment regimens and formulary guidelines. As digital transformation accelerates in healthcare, e-prescribing systems have become a cornerstone technology, integrating medication management into the broader electronic health ecosystem. Understanding the key components and functionalities of these systems is crucial for appreciating their impact and potential [1, 2, 18, 22].

An e-prescribing system is not a single piece of software but rather an interconnected ecosystem involving multiple components that must work together securely and reliably.

Today, the core components of the electronic prescription system include the following (fig. 1.3).

Prescriber Software is the application used by authorized healthcare professionals (doctors, nurse practitioners, physician assistants, etc.) to create and transmit electronic prescriptions. It is often integrated directly within a larger Electronic Health Record (EHR) or Electronic Medical Record (EMR) system, allowing seamless access to patient demographic information, allergies, medication history, and problem lists. Standalone e-prescribing applications also exist, particularly for settings without full EHRs.

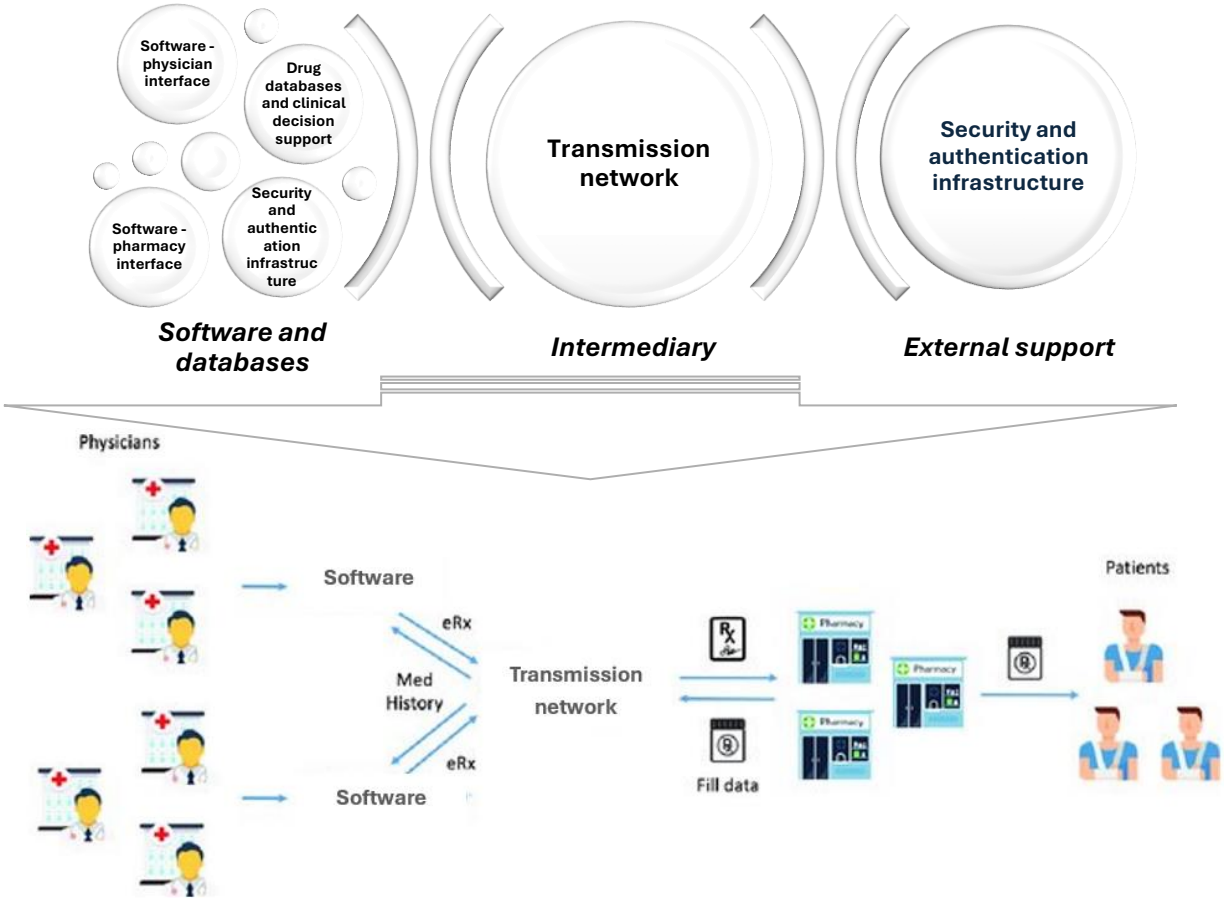

Fig. 1.3. Structure of electronic prescription system

Key features of prescriber software include patient selection (securely identifying and selecting the correct patient record), drug selection (accessing a comprehensive, up-to-date drug database to search for medications by name (brand or generic), indication, or class), order entry (structured fields for entering dosage, route, frequency, duration, quantity, and refills, minimizing ambiguity compared to handwriting. sig (directions for use) builders often help standardize instructions), clinical decision support (integration with drug databases provides real-time alerts for potential drug-drug interactions, drug-allergy interactions, duplicate therapies, contraindications based on patient conditions (e.g., age, renal function), and dose range checking. (it is also discussed as a separate component below due to its critical importance)), formulary information (displaying information about whether a selected drug is covered by the patient's insurance plan (formulary status), preferred alternatives, and potential co-pay information), signature (secure electronic or digital

signature capability (often requiring credentials like a password, token, or biometric) to authorize the prescription legally. specific, more stringent requirements exist for electronic prescribing of controlled substances), transmission (securely routing the finalized prescription to the patient's chosen pharmacy via a transmission network).

Pharmacy Software is the application used by the pharmacy to receive, process, and dispense electronic prescriptions. It must integrate seamlessly with the pharmacy's main Pharmacy Management System, which handles dispensing workflows, inventory management, billing, and patient profiles.

The main functional modules of such software for pharmacies are receiving prescriptions (securely receiving incoming electronic prescriptions from the transmission network), workflow integration (populating key prescription information (patient, drug, sig, prescriber) into the dispensing workflow, reducing manual data entry and transcription errors), status updates (ability to send electronic messages back to the prescriber system via the network, such as confirmation of receipt, dispensing status (e.g., filled, partially filled, not filled), or requests for clarification or refill authorization), inventory check (linking with pharmacy management system inventory data), verification (tools to help pharmacists verify the prescription details against the patient profile).

This acts as the secure electronic "postal service" connecting prescriber systems to pharmacy systems is a *Transmission Network.* These networks (often called switches or hubs, like Surescripts in the US or the NHS Electronic Prescription Service via the Spine in the UK) provide the infrastructure for routing e-prescriptions and related messages (refill requests, medication history, formulary information). They enforce technical and data standards (e.g., NCPDP SCRIPT standard in the US) to ensure that messages sent from various certified prescriber systems can be correctly received and interpreted by various certified pharmacy systems, regardless of the software vendor. In addition, their functions are to employ robust security measures, including encryption and authentication, to protect patient data during transmission and ensure compliance with privacy regulations; maintain directories of participating prescribers and pharmacies to ensure prescriptions are

routed correctly [23, 25, 30].

*Drug Databases and Clinical Decision Support***.** While often accessed through the prescriber software, these databases and the associated clinical decision support logic are critical components in their own right. This component provides comprehensive, regularly updated information on medications, including indications, dosages, side effects, contraindications, warnings (e.g., black box warnings), drug interactions (drug-drug, drug-allergy, drug-food, drug-lab, drug-disease), and formulary/benefit information. Content is typically licensed from third-party vendors (e.g., First Databank, Medispan, Micromedex) [3, 8-9].

The e-prescribing software uses rules engines to analyze the prescription order in the context of the patient's known clinical information (allergies, other medications, diagnoses, age, weight, renal function) and the drug database content. It then generates real-time alerts for potential safety issues or optimization opportunities. Effective drug databases are crucial for realizing the patient safety benefits of e-prescribing, although poorly implemented it can lead to "alert fatigue" if it generates too many non-critical warnings.

Patient Identification and Matching - accurately linking prescriptions to the correct patient is paramount for safety. Systems rely on robust patient demographic information (name, date of birth, address, gender) and often unique patient identifiers (e.g., medical record number, NHS number in the UK) to ensure the prescription created by the prescriber is correctly matched to the patient's record within the pharmacy system. Challenges can arise with common names or incomplete data, requiring careful matching algorithms and sometimes manual verification [8, 11, 12].

Security and Authentication Infrastructure is essential given the sensitivity of prescription data and the legal status of a prescription. This way ensuring only authorized individuals can access the system and perform specific functions (e.g., only licensed prescribers can sign prescriptions); multi-factor authentication is increasingly common, especially for electronic prescribing of controlled substances. Encrypting data both while it is being transmitted over the network and while it is

stored ("at rest") within databases.

In addition, the modern data security structure allows keeping audit logs (Audit Trails) and using digital signatures, which additionally ensures data confidentiality and security. Maintaining detailed, immutable logs of all actions performed within the system (who accessed what data, what changes were made, when), which are crucial for security monitoring and regulatory compliance. Using cryptographic techniques to ensure the authenticity (proof of who signed it) and integrity (proof it hasn't been altered) of the electronic prescription, providing non-repudiation.

Modern e-prescribing systems offer functionalities beyond simply sending a new prescription – fig. 1.4.

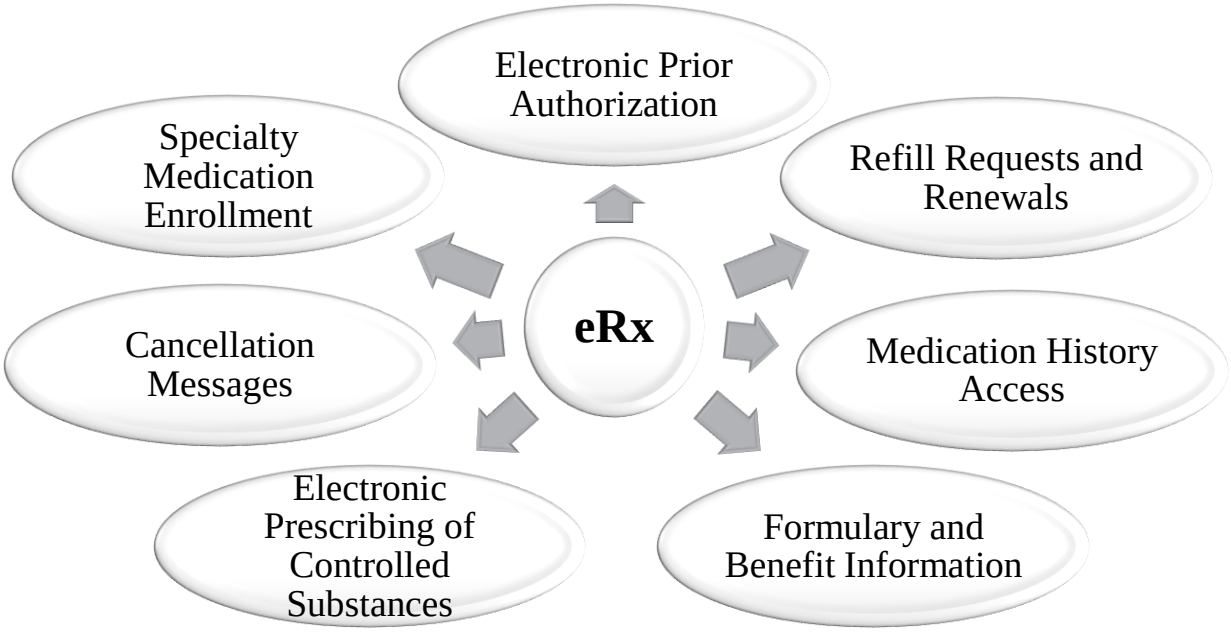

Fig. 1.4. Key functionalities of eRx beyond basic prescribing

The benefits of a well-implemented e-prescribing system are substantial: improved patient safety (reduced errors from illegibility, CDS alerts), increased efficiency for prescribers and pharmacists (less time on phone/fax, streamlined workflows), enhanced medication adherence (through clearer instructions and refill management), better formulary compliance leading to potential cost savings, improved convenience for patients, and better tracking and security, especially for controlled substances.

However, challenges remain. The initial cost of implementing certified software and integrating it into workflows can be significant. Achieving seamless interoperability between all prescriber and pharmacy systems is an ongoing effort. Workflow changes require training and adaptation by staff. Alert fatigue from poorly tuned CDS can lead to clinicians ignoring important warnings. Ensuring robust security against cyber threats is a constant necessity. The specific requirements for EPCS can add complexity and cost. Despite these challenges, e-prescribing is firmly established as a critical component of modern, digitized healthcare, essential for safe and efficient medication management in the pharmaceutical ecosystem.

CONCLUSION TO CHAPTER 1

The historical overview traced the evolution from rudimentary administrative computing to the current era of interconnected, data-driven digital health, a progressive integration of technology, overcoming significant barriers related to cost, complexity, standardization, and user acceptance, ultimately paving the way for today's sophisticated systems. The COVID-19 pandemic further accelerated this digital transformation, particularly in areas like telehealth and remote data access.

Modern IT enhances efficiency, improves data quality, enables innovation, and support rigorous regulatory compliance. The analytical review of e-prescription systems underscored their vital role in modern medication management. By dissecting the core components and key functionalities illustrated how e-prescribing enhances patient safety, improves workflow efficiency, and supports regulatory adherence. While challenges exist, e-prescribing exemplifies the successful integration of IT into clinical practice, directly impacting how pharmaceutical products are utilized.

CHAPTER 2. STUDY ON CURRENT TRENDS AND CHALLENGES OF DIGITALISATION IN THE PHARMACEUTICAL SECTOR

2.1. Investigating the impact of drug manufacturing automation and supply chain management on the quality of pharmaceutical care

The journey of a medicine from its initial conception to the patient involves intricate manufacturing processes and complex global supply chains. Traditionally, these areas operated with significant manual intervention and fragmented information systems. However, the infusion of automation and digital technologies is rapidly transforming both manufacturing and supply chain management, aiming for greater efficiency, control, and transparency. Crucially, these advancements are not merely operational improvements; they have a direct and significant impact on the quality of pharmaceutical care received by patients, influencing product quality, availability, safety, and affordability.

Modern pharmaceutical manufacturing increasingly relies on automation technologies, integrated with sophisticated IT systems like Manufacturing Execution Systems (MES), Process Analytical Technology (PAT), and Laboratory Information Management Systems (LIMS), as introduced in Chapter 1. The impact on quality of care stems primarily from enhanced product quality and consistency.

The results of studying the data of periodicals and reports of analytical companies on the introduction of information technology and automation in the production process of pharmaceutical companies and their supply chain allowed us to identify the main areas and their benefits impact on care (Fig. 2.1)

Automation minimizes human variability, a significant source of error in manual processes. Automated systems precisely control critical process parameters like temperature, pressure, mixing speed, and reaction time, ensuring they remain within validated limits. PAT allows for real-time monitoring of critical quality attributes during the process, rather than relying solely on end-product testing. This leads to greater batch-to-batch consistency and a higher assurance that each dose of

medication meets its predefined quality specifications (e.g., potency, purity, dissolution profile). Consistent quality directly translates to predictable therapeutic effects and reduces the risk of patients receiving sub-potent, super-potent, or contaminated medication, thereby enhancing treatment efficacy and safety. Electronic Batch Records within Manufacturing Execution Systems enforce procedural adherence, reducing deviations and ensuring every step is documented accurately, further contributing to quality assurance.

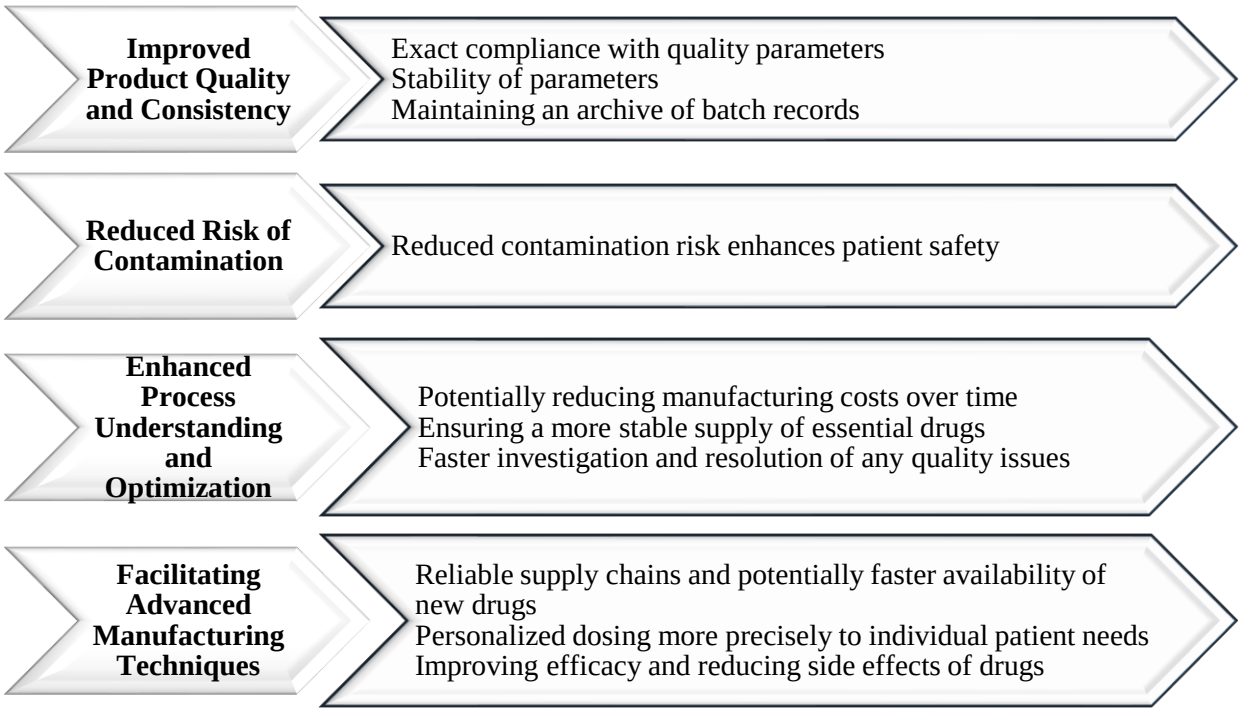

Fig. 2.1. Automation in medicine manufacturing and its impact on quality of medical and pharmaceutical care

Automated, closed systems reduce the need for human intervention in sensitive manufacturing steps, minimizing the risk of microbial or particulate contamination. Robotics can handle materials in sterile environments more consistently than humans. This is particularly critical for sterile products like injectables and ophthalmic solutions, where contamination can have severe health consequences for patients. Reduced contamination risk enhances patient safety.

Data generated by automated systems and PAT provides a wealth of information about the manufacturing process. Analyzing this data allows

manufacturers to gain deeper process understanding, identify potential areas for improvement, and optimize processes for greater robustness and efficiency. While seemingly an internal benefit, optimized processes can lead to more reliable production, potentially reducing manufacturing costs over time (which may influence drug pricing) and ensuring a more stable supply of essential drugs. Furthermore, better process understanding can facilitate faster investigation and resolution of any quality issues that might arise, minimizing potential impact on patient supply.

Automation is essential for implementing newer manufacturing paradigms like continuous manufacturing and personalized medicine production (e.g., 3D printing of dosages). Continuous manufacturing offers potential advantages in terms of consistent quality, smaller footprint, and faster production cycles compared to traditional batch manufacturing. Continuous manufacturing can lead to more reliable supply chains and potentially faster availability of new drugs. Automation enabling personalized dosing (e.g., via 3D printing) directly impacts care quality by tailoring treatment more precisely to individual patient needs, potentially improving efficacy and reducing side effects.

The next stage in the supply chain for drugs is the distribution stage, which can be considered to begin immediately after a batch of drugs has been produced and placed in the warehouse. The pharmaceutical supply chain is long, complex, and vulnerable to disruptions, inefficiencies, and security threats like counterfeiting. Digitalization, through technologies like advanced SCM software, IoT, track-and-trace systems, and potentially blockchain, aims to create more resilient, transparent, and secure supply chains.

The priority of pharmaceutical supply chain control is to improve product safety and anti-counterfeiting. Counterfeit drugs pose a significant threat to patient safety globally, containing incorrect ingredients, no active ingredients, or harmful substances. Digital track-and-trace systems, mandated by regulations like the US Drug Supply Chain Security Act (DSCSA) and the EU Falsified Medicines Directive (FMD), are primary tools to combat this.

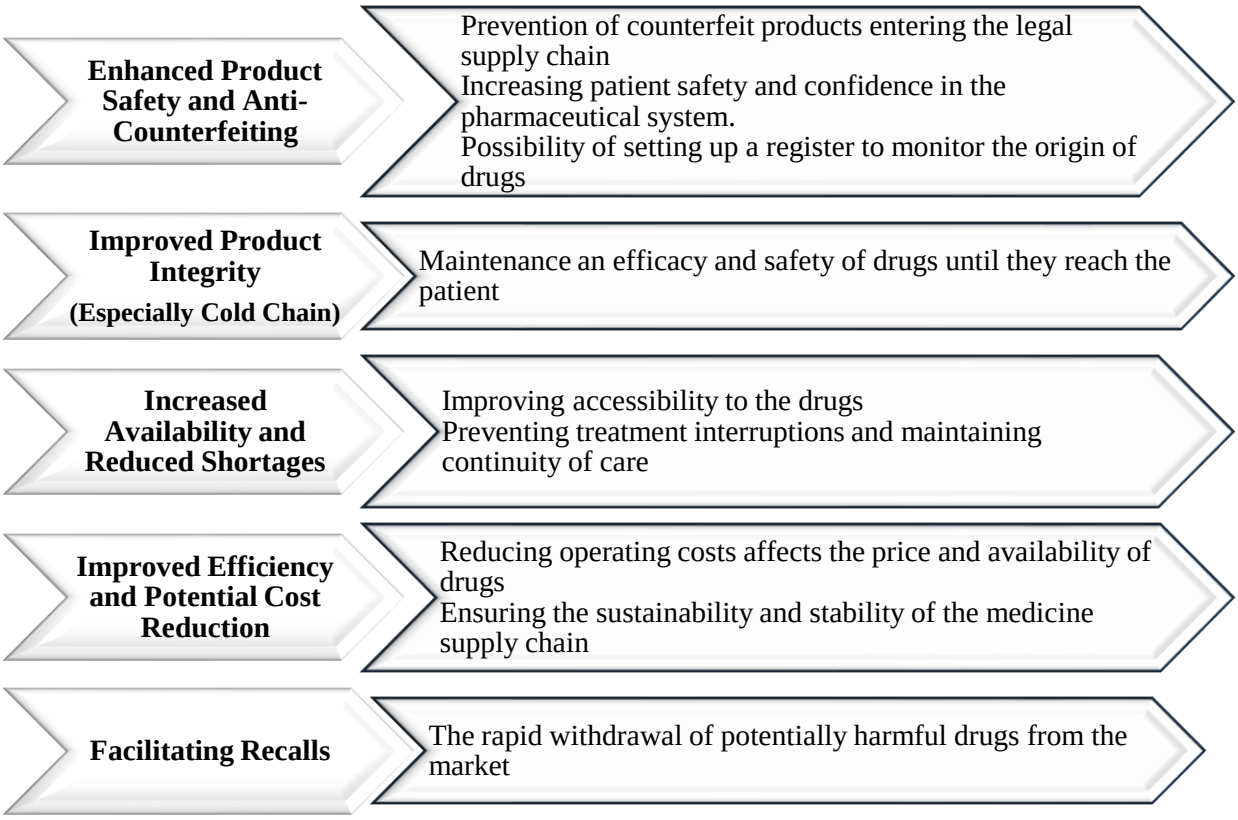

Fig. 2.2. Digital supply chain management and its impact on quality of medical and pharmaceutical care

Serialization and verification tools are used at this stage. The first tool involves assigning unique serial numbers to individual drug packages that allows each unit to be tracked through the supply chain. The second one involves pharmacists and other stakeholders can verify the authenticity of a product by scanning its unique identifier against secure databases before dispensing it. This significantly increases the difficulty for counterfeit products to enter the legitimate supply chain, providing greater assurance to patients and healthcare providers that the medication they receive is genuine and safe. This directly enhances patient safety and trust in the pharmaceutical system. Blockchain is explored as a potential future enhancement, offering a decentralized and potentially more secure ledger for tracking drug provenance.

Many modern drugs, particularly biologics and vaccines, are temperature-sensitive and require strict cold chain management. Digital technologies, especially IoT sensors, play a crucial role here. IoT sensors placed in shipping containers,

warehouses, and even pharmacy refrigerators continuously monitor temperature, humidity, and other relevant conditions. These systems can automatically alert supply chain partners if conditions deviate from the required range, allowing for timely intervention to prevent product spoilage.

Ensuring the integrity of the cold chain guarantees that temperature-sensitive medications retain their efficacy and safety until they reach the patient. Receiving a vaccine that has been exposed to improper temperatures, for example, could render it ineffective, directly impacting the quality of preventative care. Digital monitoring provides auditable proof that product integrity has been maintained.

Drug shortages are a persistent problem that can severely impact patient care, forcing treatment delays, use of less effective alternatives, or increased risk of medication errors during transitions. Digital SCM tools help mitigate shortages through:

- better demand forecasting - advanced analytics and AI applied to historical sales data, epidemiological trends, and other factors improve the accuracy of demand forecasting.
- inventory optimization - SCM software helps maintain optimal inventory levels across the supply chain network, reducing the risk of localized stockouts while minimizing waste from expired products.
- enhanced visibility - real-time visibility into inventory levels and shipment locations allows manufacturers and distributors to respond more quickly to potential disruptions (e.g., manufacturing delays, transportation issues, sudden demand spikes) and reallocate stock proactively.

Improved availability ensures that patients can access the medications they need when they need them, preventing treatment interruptions and maintaining continuity of care. This is a fundamental aspect of pharmaceutical care quality.

Digitalization streamlines many supply chain processes, reducing manual paperwork, optimizing logistics, and improving coordination between partners. While efficiency gains primarily benefit manufacturers and distributors, they can indirectly impact care quality. Reduced operational costs may eventually exert

downward pressure on drug prices, improving affordability and access for patients. Furthermore, a more efficient supply chain is inherently more resilient and less prone to the disruptions that cause shortages.

In the event a product needs to be recalled due to safety or quality concerns, digital track-and-trace systems allow for much faster and more precise identification of affected batches and their locations within the supply chain and at the pharmacy level. This enables rapid removal of potentially harmful products from circulation, minimizing patient exposure and enhancing overall safety.

Despite the clear benefits, realizing the full impact of manufacturing automation and digital supply chains on care quality faces challenges. The initial investment in these technologies can be substantial, potentially limiting adoption by smaller players. Integrating disparate IT systems (MES, ERP, LIMS, SCM, track-and-trace) remains complex, requiring significant technical expertise and adherence to interoperability standards. Ensuring the security of vast amounts of sensitive manufacturing and supply chain data against cyber threats is critical. Furthermore, the global nature of the pharmaceutical supply chain means that regulations and standards vary across jurisdictions, adding complexity to implementing universally effective digital solutions. Finally, translating operational improvements into direct, measurable improvements in patient-reported outcomes or overall pharmaceutical care quality requires robust data collection and analysis linking upstream activities to downstream effects.

2.2. Analysing the practice of implementing e-prescriptions and electronic medical records in pharmaceutical practice

The implementation of Electronic Health Records (EHRs)/Electronic Medical Records (EMRs) and eRx systems has fundamentally altered the landscape of healthcare delivery, including pharmaceutical practice. As discussed in Chapter 1, these systems aim to improve efficiency, enhance patient safety, and provide better access to clinical information. This section analyzes the practical realities of how

these technologies are integrated into the daily workflows of pharmacists and other pharmaceutical care providers, examining the tangible benefits realized, the persistent challenges encountered, and the evolving role of the pharmacist in this digital environment.

E-prescriptions arrive electronically at the pharmacy, typically via a secure transmission network (like Surescripts or the NHS EPS), and are received directly into the pharmacy's Pharmacy Management System (PMS). This integration is the cornerstone of the system's practical utility [2, 14, 23, 25].

Reduced Transcription Errors. Perhaps the most immediate and significant benefit in pharmacy practice is the elimination of manual transcription from handwritten or faxed prescriptions. Illegible handwriting, ambiguous abbreviations (like 'U' for units or trailing zeros), and simple typing mistakes during manual entry are major sources of medication errors. E-prescriptions populate key fields (patient name, drug, strength, dosage form, sig, quantity, refills, prescriber details) directly into the PMS, drastically reducing these risks [2].

Streamlined Intake Process. Receiving prescriptions electronically eliminates the need for pharmacy staff to manually handle paper scripts, decipher handwriting, or manage fax queues. This frees up significant staff time, allowing pharmacists and technicians to focus on clinical verification, patient counseling, and other value-added services rather than clerical tasks [2, 14].

Improved Clarity and Completeness. E-prescriptions generally enforce structured data entry on the prescriber's end, leading to more complete and unambiguous orders compared to handwritten scripts. Standardized sig codes and required fields for dose, route, and frequency reduce the need for pharmacies to call prescribers for clarification, further improving efficiency and reducing potential delays in dispensing [2, 16].

While e-prescribing focuses on the prescription itself, the broader integration with HER (EMR) systems offers pharmacists access to a richer clinical context, although the extent and ease of this access vary significantly depending on the healthcare system structure, interoperability standards, and data-sharing agreements.

*Enhanced Clinical Verification***.** Access to relevant parts of the patient's EHR (often through integrated platforms or health information exchanges - HIEs) allows pharmacists to perform more robust clinical checks before dispensing. This may include:

- allergy information (verifying against a more comprehensive allergy list than might be available in the pharmacy's standalone profile);
- problem lists / diagnoses (confirming the appropriateness of the prescribed medication for the patient's documented conditions (indication checking));
- laboratory results (assessing the need for dose adjustments based on recent renal or hepatic function tests (e.g., creatinine clearance for certain antibiotics);
- medication history (comparing the new prescription against a more complete list of current and past medications documented in the EHR (medication reconciliation), potentially identifying therapeutic duplications or omissions not captured by pharmacy fill history alone).

Improved Medication Reconciliation. Having access to both prescriber-documented medication lists (from the EHR) and pharmacy dispensing history (often available via the eRx network or integrated systems) provides a more complete picture for medication reconciliation, a critical safety process during transitions of care (e.g., hospital discharge).

Support for Clinical Services. Access to EHR data empowers pharmacists to engage more effectively in clinical services, such as Medication Therapy Management. Pharmacists can identify potential drug therapy problems, develop care plans, and communicate recommendations back to the prescriber, supported by comprehensive patient data.

Despite the benefits, the implementation and routine use of eRx and EHR integration in pharmaceutical practice face several hurdles:

Interoperability Issues: seamless data exchange between diverse EHR systems used by prescribers and the various PMS systems used by pharmacies remains a significant challenge. While standards like HL7 and FHIR exist, their

implementation and adoption are inconsistent. This can lead to:

- data gaps: pharmacists may not have access to the complete EHR data needed for optimal clinical verification.
- workflow disruptions: difficulty in electronically sending clarification requests or receiving timely responses from prescribers if systems aren't fully interoperable.
- inconsistent data formatting*:* differences in how data (e.g., allergies, medication lists) is structured and coded across systems can hinder automated processing and require manual interpretation.

*Workflow Integration and Adaptation***:** integrating eRx and EHR functionalities smoothly into established pharmacy workflows requires careful planning, software configuration, and staff training. Initial implementation can be disruptive, and optimizing workflows to leverage the technology effectively takes time and effort. Poor integration can lead to workarounds that negate some of the system's benefits.

*Alert Fatigue***:** Clinical Decision Support (CDS) integrated within eRx and PMS systems is crucial for safety, flagging potential interactions, allergies, or incorrect doses. However, poorly configured or overly sensitive CDS can generate excessive, often clinically insignificant, alerts ("alert fatigue"). This can lead to pharmacists becoming desensitized and potentially overriding critical warnings, undermining the safety potential. Fine-tuning CDS to be relevant and specific to the pharmacy context is an ongoing challenge.

*Data Accuracy and Completeness***:** the utility of EHR data relies heavily on its accuracy and completeness. If prescribers do not diligently update medication lists, allergy information, or problem lists in the EHR, the data accessed by the pharmacist may be misleading or incomplete, potentially compromising clinical verification. Similarly, medication history derived from dispensing data may not capture samples, over-the-counter medications, or medications filled at non-participating pharmacies.

Cost and Resource Constraints: implementing and maintaining certified eRx/PMS software, ensuring robust security, and providing adequate staff training

requires significant financial and personnel resources. This can be particularly challenging for smaller independent pharmacies compared to large chains or health systems.

Electronic Prescribing of Controlled Substances Implementation Complexity: while EPCS enhances security, the stringent requirements (identity proofing, two-factor authentication, specific software certification) add complexity and cost for both prescribers and pharmacies, sometimes hindering adoption rates despite mandates in some regions.

System Downtime and Reliability: reliance on electronic systems means that system downtime (planned or unplanned) can significantly disrupt pharmacy operations, potentially delaying patient access to medications. Robust contingency plans are necessary but may involve reverting to less efficient manual processes.

Thus, the results of the analysis provide grounds to assert that the implementation of eRx and EHR integration is reshaping the role of the pharmacist. By automating routine dispensing tasks and providing better access to clinical information, these technologies free up pharmacists' time and empower them to focus more on patient-centered clinical activities (tab. 2.1).

Table 2.1

Challenges and mitigation strategies for eRx/EHR in pharmacy

Challenge	Description	Potential Mitigation Strategies
Interoperability Issues	Difficulty in seamless data exchange between different prescriber EHRs and pharmacy PMS systems, leading to data gaps or workflow disruptions.	Adoption of modern standards (e.g., HL7 FHIR APIs), use of health information exchanges (HIEs), standardized data coding (e.g., RxNorm, SNOMED CT), vendor collaboration.
Alert Fatigue	Excessive or irrelevant CDS alerts leading to clinicians overriding warnings, potentially missing critical safety issues.	Fine-tuning CDS rules based on clinical significance, tiering alerts by severity, incorporating patient-specific context, regular review and optimization of alert settings, user feedback mechanisms.

Data Accuracy and Completeness	Reliance on data (allergies, medication lists, diagnoses) that may be inaccurate or incomplete in the source EHR or pharmacy profile.	Improved medication reconciliation processes at all care points, tools for integrating multiple data sources (EHR, pharmacy fill, patient report), promoting diligent documentation by all clinicians, patient engagement in verifying records.
Cost and Resource Constraints	Significant financial investment required for certified software, hardware, implementation, maintenance, and staff training.	Exploring cloud-based solutions (potentially lower upfront cost), seeking available grants or incentives, phased implementation approaches, shared services models (for smaller organizations), demonstrating ROI through efficiency/safety gains.
Workflow Adaptation	Need to redesign existing pharmacy workflows to effectively integrate eRx/EHR functionalities and leverage the technology efficiently.	Careful workflow analysis prior to implementation, involving staff in design/testing, comprehensive staff training, providing ongoing support, iterative optimization based on user experience.
System Downtime and Reliability	Dependence on electronic systems makes pharmacies vulnerable to disruptions during planned or unplanned downtime.	Robust backup systems, well-defined and practiced downtime procedures (including safe reversion to manual processes), redundant network connections, reliable vendor support.

Pharmacists are increasingly leveraging the available data and freed-up time to provide medication therapy management, immunizations, chronic disease state management, adherence counseling, and collaborative drug therapy management with prescribers. With better tools for clinical verification and medication reconciliation, pharmacists play an even more critical role as a safety net in the medication use process. Also pharmacists require proficiency in using these complex IT systems, interpreting clinical data effectively, and managing information overload

(including CDS alerts). Digital literacy and health informatics skills are becoming increasingly important.

2.3. Analysing successful global practices to reduce medication errors

Medication errors represent a major global public health concern, leading to significant patient harm, increased healthcare costs, and erosion of trust in healthcare systems. These errors can occur at any stage of the medication use process: prescribing, transcribing, dispensing, administration, and monitoring. Recognizing the scale of the problem, healthcare systems worldwide have implemented various strategies to mitigate these risks, with information technology playing an increasingly central and often indispensable role. We analyzed successful global practices, highlighting how different countries and healthcare organizations have leveraged IT to enhance medication safety (tab. 2.2).

Table 2.2

Global IT-Based Medication Safety Initiatives

Strategy	Primary Function in Error Reduction	Examples of Regions/Systems with Significant Adoption
Computerized Provider Order Entry (CPOE) with Clinical Decision Support	Reduces prescribing errors (dose, drug selection, interactions, allergies) via electronic entry & real-time alerts	Hospitals in US (Meaningful Use/PI), UK (NHS Trusts), Canada, Australia, EU nations
eRx (Ambulatory)	Eliminates illegibility/transcription errors; Enables CDS at prescribing; Streamlines communication	US (widespread), UK (NHS EPS), Nordic countries (Sweden, Denmark - near universal)
Barcode Medication Administration (BCMA)	Verifies "five rights" (patient, drug, dose, route, time) at bedside using barcodes before administration	US (esp. VA system), Canada, Australia, parts of Europe; growing hospital adoption
Smart Infusion Pumps (w/DERS)	Prevents IV infusion errors (over/under-dose) via pre-set	Increasingly standard in hospitals in US, UK,

	drug library limits and alerts	Canada, Australia
Automated Dispensing Cabinets	Improves medication security & inventory control; Can link dispensing to CPOE order (reduces wrong drug access)	Commonplace in hospitals across North America, Europe, other developed regions.
Electronic Medication Administration Records (eMAR)	Provides clear electronic record of meds due/given; Reduces documentation errors, especially when linked with BCMA	Core component of most modern hospital EHR systems globally
National Reporting Systems	Collects / analyzes error reports nationally to identify trends, share lessons, and drive system improvements	UK (NRLS/LFPSE), US (FDA MedWatch), Canada (CMIRPS)

Computerized Provider Order Entry (CPOE) systems allow prescribers to enter medication orders directly into a computer system, replacing handwritten orders. When integrated with robust CDS, these systems can provide real-time alerts for potential errors at the point of prescribing – the stage where many serious errors originate. CDS checks include drug-allergy interactions, drug-drug interactions, dose range checking (based on age, weight, renal function), duplicate therapy alerts, and formulary reminders.

CPOE with CDS is widely adopted in hospitals across developed nations, including the US (driven by Meaningful Use/Promoting Interoperability programs), the UK (within NHS trusts), Canada, Australia, and many European countries. Studies from institutions like Brigham and Women's Hospital (US) demonstrated significant reductions in serious medication errors after CPOE implementation. The key to success lies not just in implementing CPOE, but in optimizing the integrated CDS to be effective without causing excessive alert fatigue. Continuous refinement of alert rules based on local data and user feedback is crucial [21, 23].

Electronic Prescribing in Ambulatory Care, as detailed in sections 1.3 and 2.2, eliminates illegibility and transcription errors associated with handwritten prescriptions in the outpatient setting. It also enables CDS checks at the point of

prescribing and facilitates clearer communication between prescriber and pharmacy.

The US has seen widespread adoption driven by incentives and mandates (including EPCS). The NHS Electronic Prescription Service (EPS) in England has become the default method for prescribing and dispensing in primary care, significantly improving efficiency and reducing paper handling. Nordic countries like Sweden and Denmark have near-universal eRx adoption. Success factors include strong government initiatives, development of national infrastructure (like the NHS Spine or Surescripts), clear standards (NCPDP SCRIPT, HL7), and integration with both prescriber EHRs and pharmacy systems [17, 21].

Barcode Medication Administration systems use barcodes to electronically verify medications at the patient's bedside before administration. Nurses scan a barcode on their ID badge, the patient's wristband, and the medication package. The system cross-references this information with the electronic medication administration record (eMAR), confirming the "five rights": right patient, right drug, right dose, right route, and right time. Alerts are generated if there is a mismatch.

Widely implemented in hospitals in the US, particularly within the Department of Veterans Affairs health system, which pioneered BCMA and demonstrated significant reductions in administration errors. Adoption is also growing in Canada, Australia, and parts of Europe. Successful implementation requires reliable barcode scanning hardware, comprehensive barcoding on medication packaging (often requiring collaboration with manufacturers or pharmacy repackaging), robust wireless network infrastructure, and integration with the hospital's EHR/eMAR system. User training and workflow adaptation are critical [14, 15, 21].

Automated Dispensing Cabinets (ADCs) are decentralized, computerized drug storage devices typically located on hospital wards. They allow nurses to access medications securely near the point of care. Integration with the EHR/CPOE system means that nurses can often only access medications specifically ordered for a patient. ADCs enhance inventory control, improve security for controlled substances, and can reduce retrieval time. Some ADCs incorporate barcode scanning

or weight checks for verification during stocking or removal.

ADCs (from vendors like Omnicell, Pyxis/BD) are commonplace in hospitals across North America, Europe, and other developed regions. Their primary benefit is often seen as inventory control and efficiency, but when integrated effectively with CPOE and requiring patient identification for access, they contribute to medication safety by ensuring only ordered medications are readily available for a specific patient. However, risks exist if overrides are used frequently or if medications for multiple patients are removed simultaneously [17, 20].

Intravenous infusion pumps are used to deliver fluids and medications at precise rates. "Smart" pumps incorporate dose error reduction software (DERS). Institutions build drug libraries into the pumps, defining concentration standards and setting minimum and maximum dose and rate limits for specific medications (often tailored to different patient care areas). If a nurse programs a rate or dose outside these limits, the pump generates an alert, potentially preventing serious over- or under-infusion errors. Many smart pumps can now integrate bidirectionally with the EHR, receiving infusion orders electronically and documenting administration back into the eMAR.

Increasingly the standard of care in hospitals in the US, UK, Canada, and Australia. Success relies heavily on the development and maintenance of comprehensive, accurate drug libraries – a resource-intensive task. Achieving high compliance rates (ensuring nurses use the DERS safety features consistently) and successful EHR integration are key implementation goals. Organizations like the Institute for Safe Medication Practices (ISMP) provide guidelines for safe smart pump use [9, 11, 18].

eMARs replace paper-based charts for documenting medication administration. They provide nurses with a clear, legible list of medications due for each patient, often linked directly to CPOE orders. Integration with BCMA automates documentation, reducing omissions and errors associated with manual charting.

eMARs are a core component of most modern hospital EHR systems globally.

Their effectiveness is significantly enhanced when used in conjunction with CPOE and BCMA, creating a "closed-loop" medication management system where orders flow electronically from prescriber to pharmacy to the patient's bedside, with barcode verification at administration.

Many countries have established national systems for reporting medication errors and adverse drug events (often anonymously). IT platforms facilitate the collection, aggregation, and analysis of this data, allowing identification of national trends, emerging risks, and system vulnerabilities. This information is then used to develop targeted safety recommendations and share lessons learned across the healthcare system [2, 3, 17].

The UK's National Reporting and Learning System (NRLS), now part of the Learn from Patient Safety Events (LFPSE) service, is a well-established example. The US FDA's MedWatch program collects reports on adverse events. Canada has the Canadian Medication Incident Reporting and Prevention System (CMIRPS). These systems rely on healthcare professionals (and increasingly patients) actively reporting incidents. The value lies in the analysis and dissemination of findings to drive system-level improvements.

In conclusion, numerous successful global practices demonstrate the power of information technology to significantly reduce medication errors across the medication use process. Strategies like CPOE with CDS, eRx, BCMA, smart pumps, and integrated eMARs, supported by national reporting systems and driven by government initiatives and standardization efforts, have demonstrably improved patient safety in many parts of the world. The key lies in integrated, well-designed systems implemented within a supportive organizational culture focused on continuous improvement and addressing the associated human factors and workflow challenges.

2.4. Evaluation of regulatory barriers and legal aspects of digital pharmaceutical solutions

The rapid digitalization of the pharmaceutical sector, while offering immense potential for innovation and efficiency, operates within a highly complex and stringent regulatory and legal framework. Ensuring patient safety, data privacy, product quality, and ethical conduct necessitates robust oversight. However, the pace of technological change often outstrips the ability of regulatory bodies to adapt, creating barriers, uncertainties, and legal complexities for companies developing and implementing digital pharmaceutical solutions. We summarized key regulatory barriers and legal aspects impacting technologies across the pharmaceutical value chain (tab. 2.3).

Table 2.3

Overview of Key Regulations Governing Digital Pharma Solutions

Regulation Category	Core Focus	Key Aspects for Digital Pharma	Examples
Software as a Medical Device (SaMD) Rules	Ensuring the safety and effectiveness of software intended for medical purposes (diagnosis, treatment, monitoring)	Classification based on risk, requirements for clinical validation, quality management systems, post-market surveillance, cybersecurity for devices	• FDA guidance • EU MDR/IVDR
Data Privacy and Security	Protecting the confidentiality, integrity, and availability of sensitive personal health information	Rules for consent, data minimization, security safeguards (technical, physical, administrative), breach notification, patient rights over their data	• General Data Protection Regulation in EU • Health Insurance Portability and Accountability Act in US
Electronic Records and Signatures	Ensuring electronic records and signatures are trustworthy,	System validation, audit trails, access controls, data integrity (ALCOA+), secure	• US FDA 21 CFR Part 11 • EU EudraLex Vol 4 Annex 11

	reliable, and equivalent to paper records and handwritten signatures in GxP environments	electronic signatures, record retention	
Supply Chain Security	Protecting the pharmaceutical supply chain from counterfeit, diverted, or adulterated drugs	Product tracing (track-and-trace), serialization of drug packages, verification requirements, interoperable data exchange between supply chain partners	• US Drug Supply Chain Security Act • EU Falsified Medicines Directive

It has been determined that the regulatory and legal landscape for digital pharmaceutical solutions is intricate, dynamic, and presents significant challenges alongside opportunities. Barriers related to software as medical device classification, data privacy compliance, GxP validation, supply chain mandates, and telehealth licensure require careful navigation. Emerging legal and ethical questions surrounding AI liability, intellectual property, bias, and transparency add further complexity. A proactive, informed, and ethically grounded approach to regulatory compliance and legal risk management is essential for any organization seeking to leverage digital technologies responsibly and successfully within the pharmaceutical sector.

Successfully navigating this complex environment requires pharmaceutical companies and technology developers to engage proactively with regulatory agencies during development; invest heavily in compliance expertise and robust quality management systems; prioritize data privacy and cybersecurity by design ("privacy by design," "security by design"); conduct thorough validation of all regulated software and IT systems; stay abreast of evolving regulations and legal precedents globally; address ethical considerations, particularly regarding AI bias and transparency.

CONCLUSION TO CHAPTER 2

The investigation into manufacturing automation and digital supply chain management revealed a clear positive impact on the quality of pharmaceutical care. Enhanced product quality and consistency, improved safety through anti-counterfeiting measures like track-and-trace, better integrity maintenance for sensitive products via IoT monitoring, and increased medication availability due to optimized inventory and forecasting all contribute directly to safer and more reliable patient treatment.

The analysis of e-prescriptions and EHR implementation in pharmaceutical practice highlighted both substantial benefits and persistent hurdles. While reduced errors, streamlined workflows, and improved access to clinical data empower pharmacists, challenges related to interoperability, workflow integration, alert fatigue, and data quality continue to impede the full realization of these systems' potential. Nonetheless, these technologies are undeniably reshaping the pharmacist's role towards more clinical engagement.

Examining successful global practices for reducing medication errors underscored the pivotal role of IT. Integrated systems encompassing CPOE with CDS, eRx, BCMA, smart pumps, and eMARs, often supported by national initiatives and reporting systems, have demonstrably improved medication safety worldwide. Success hinges on integration, standardization, and a focus on human factors alongside technology.

The evaluation of regulatory barriers and legal aspects illuminated the complex governance framework surrounding digital pharmaceutical solutions. Furthermore, emerging legal and ethical considerations related to AI liability, bias, and transparency require careful attention.

CHAPTER 3: FUTURE PROSPECTS FOR INFORMATION TECHNOLOGY IN PHARMACEUTICAL PRACTICE

3.1. Analysing the possibilities of telemedicine, AI-based medicine discovery and personalised pharmacy

The trajectory of information technology suggests that its future impact on pharmaceutical practice will be even more transformative than what has been witnessed to date. Three key areas stand out for their potential to reshape the landscape profoundly: the evolution of telemedicine and telepharmacy into more integrated care models, the application of increasingly sophisticated Artificial Intelligence (AI) to accelerate and refine medicine discovery, and the realization of personalised pharmacy delivering treatments tailored to the individual.

While telehealth adoption surged during the COVID-19 pandemic, its future potential extends far beyond simple video consultations. The next phase involves deeper integration into routine care, leveraging technology for more proactive and continuous patient management, particularly relevant for pharmaceutical care [19].

Current telepharmacy often focuses on remote dispensing verification, basic consultations, and refill authorizations. Future possibilities include:

- *Comprehensive MTM*: conducting in-depth MTM sessions virtually, utilizing shared screens to review medication lists, access EHR data (with improved interoperability), and use digital tools for patient education;
- *Chronic Disease Management Programs*: pharmacist-led virtual programs for conditions like diabetes, hypertension, or asthma, incorporating remote monitoring data, adherence tracking, and proactive interventions;
- *Specialty Pharmacy Support*: providing specialized counselling, adherence support, and side-effect management for patients on complex specialty medications via secure virtual platforms;
- *Remote Patient Monitoring Integration*: pharmacists receiving and interpreting data from patient wearables (e.g., glucose monitors, blood

pressure cuffs, smart inhalers) to optimize drug therapy in near real-time, potentially adjusting doses or flagging issues for the prescriber.

The future is likely hybrid, not purely virtual. Telepharmacy will complement, not entirely replace, in-person interactions. Seamless integration requires:

- *Unified Platforms*: platforms allowing easy transitions between virtual and in-person appointments, with consistent access to patient records and care plans across settings;
- *Data Interoperability*: robust data sharing (leveraging standards like Fast Healthcare Interoperability Resources Application Programming Interfaces) between telehealth platforms, EHRs, pharmacy systems, and patient-facing apps/devices [1, 3, 19].

Telepharmacy will continue to break down geographical barriers, improving access for patients in rural or underserved areas, those with mobility limitations, or those simply seeking convenience. Integration with e-commerce pharmacy models offering home delivery will further enhance this.

AI chatbots or virtual assistants could handle initial patient triage for medication queries, provide standardized drug information, manage appointment scheduling, and send automated adherence reminders, freeing up pharmacists for more complex clinical tasks. Natural Language Processing will enable more intuitive interactions.

AI is already impacting drug discovery, but its future potential is vast, promising to drastically shorten timelines, reduce costs, and increase the success rate of bringing novel therapies to market. While current AI often predicts properties of existing or modified molecules, generative AI models (like Generative Adversarial Networks - GANs or Transformers) can design entirely new molecular structures de novo with specific desired properties (e.g., binding affinity for a target, favourable ADMET profile). This could unlock new chemical space and lead to truly novel drug candidates [13].

AI will become more adept at integrating multi-omics data (genomics, proteomics, transcriptomics, metabolomics) with clinical data and scientific

literature to identify novel disease pathways and druggable targets with higher confidence. AI can model complex biological systems to predict the downstream effects of modulating a specific target [10, 13].

Computational modelling and simulation, powered by AI analysing vast datasets (including Real-World Evidence and virtual patient cohorts), will play a greater role in predicting drug efficacy and safety before human trials. This could optimize trial design (e.g., patient selection, dosing), potentially reduce the size and duration of human trials, and even replace some preclinical animal testing, accelerating development and reducing costs. Regulatory acceptance of in silico evidence is a key evolving area. Beyond design, AI will increasingly optimize trial execution by:

- Predictive Recruitment: identifying eligible patients more efficiently from EHR data or other sources.
- Remote Monitoring and Data Capture: analyzing data from wearables and sensors for real-time monitoring of patient responses and adverse events in decentralized trials.
- Predicting Dropouts: identifying patients at risk of dropping out of trials, allowing for proactive intervention.
- Automated Data Analysis: accelerating the analysis of complex trial data to derive insights faster.

AI tools could potentially assist regulatory agencies by automating parts of the submission review process, identifying inconsistencies, cross-referencing data, and summarizing large volumes of information, potentially speeding up approval timelines. This requires trust, transparency, and validation of the AI tools themselves [10, 13, 20].

The increasing sophistication of AI raises challenges. Ensuring the ethical use of patient data for training, mitigating algorithmic bias to avoid exacerbating health disparities, ensuring the transparency and explainability of AI decisions ("black box" problem), and developing robust methods for validating the predictions of complex AI models (especially generative and in silico approaches) are critical areas

requiring ongoing research and regulatory guidance.

The future prospects for IT in pharmaceutical practice are centred on greater connectivity, intelligence, and individualisation. Telemedicine promises more integrated and accessible virtual care models. AI is poised to revolutionize the speed and precision of medicine discovery. Personalised pharmacy aims to leverage multi-modal data, including genomics, to tailor treatments like never before. While significant technical, regulatory, ethical, and practical challenges must be overcome, these possibilities paint a picture of a future where IT enables more proactive, predictive, personalised, and participatory pharmaceutical care.

3.2. Analyzing approaches to improve patient safety and regulatory compliance in a digital pharmacy environment

As pharmaceutical practice becomes increasingly reliant on digital technologies, ensuring patient safety and maintaining rigorous regulatory compliance remain paramount. While digitalization offers powerful tools to enhance both areas, it also introduces new complexities and potential vulnerabilities. Building on the current practices and challenges discussed in Chapter 2, we analyzed future-oriented approaches and emerging strategies aimed at further strengthening safety and compliance in the evolving digital pharmacy environment.

Leveraging advanced IT capabilities can move medication safety efforts from reactive error detection towards proactive risk mitigation and system resilienc:

- *Next-Generation CDS.* Moving beyond basic alerts for interactions and allergies towards more intelligent and context-aware CDS: (personalized alerts, predictive risk stratification, therapeutic guidance, improved user interface/workflow integration).
- *AI-Powered Pharmacovigilance.* Enhancing the detection and analysis of adverse drug events beyond traditional reporting systems: real-world evidence analysis, social media and forum monitoring, automated case processing.

- *Enhanced Medication Reconciliation.* Improving the accuracy and completeness of medication lists, especially during transitions of care (AI/NLP for data extraction, integrated data sources, smart algorithms for discrepancy detection).
- *Advanced Closed-Loop Medication Management*. Refining the integration between prescribing, pharmacy verification, dispensing, administration (BCMA), and monitoring systems (Bi-directional smart pump integration, ADC enhancements, home setting adaptation).
- *Patient-Centric Safety Tools.* Empowering patients to actively participate in their medication safety (smart packaging and devices, personalised mobile health Apps, improved patient portals).

Maintaining compliance in a digital environment requires robust systems, proactive monitoring, and adapting to evolving regulations governing data, software, and electronic processes. We have analyzed the capabilities of modern technologies for enhanced safety and compliance (tab. 3.1).

Table 3.1

Emerging technologies for enhanced safety and compliance

Approach/Technology	Potential benefits
Next-Generation CDS	• reduces alert fatigue via personalized/context-aware warnings; • proactively identifies high-risk patients (predictive analytics); • guides optimal therapy; Improves safety.
AI Pharmacovigilance	• enables earlier detection of safety signals from real-world evidence /social media; • improves efficiency of adverse event report processing; • enhances post-market surveillance.
Regulatory Technology (RegTech) Solutions	• automates compliance monitoring (GxP, privacy); • streamlines regulatory submissions; Improves change control management; • enhances audit trail analysis efficiency.
Blockchain for Integrity	• creates immutable, traceable records for critical GxP data (e.g., batch records, audit trails);

	• enhances data integrity; • potentially prevents tampering/fraud.
AI Threat Detection	• identifies novel and sophisticated cybersecurity threats faster than traditional methods; • enables quicker incident response; • enhances overall data security posture.

Therefore, enhancing patient safety and regulatory compliance in the future digital pharmacy environment requires a multi-pronged approach. It involves leveraging advanced technologies like AI, blockchain, and RegTech for proactive risk management, data integrity assurance, and streamlined compliance processes. It also necessitates a strong focus on cybersecurity resilience, agile validation methods, and continuous improvement, all underpinned by robust data governance and a culture that prioritizes safety and compliance by design. These approaches are essential for building trust and realizing the full benefits of digitalization responsibly.

3.3. Development of recommendations for the successful implementation of information technology in pharmaceutical practice

Based on the comprehensive analysis of the historical context, key technologies, current trends, practical impacts, challenges, future prospects, and approaches for safety and compliance, we developed a set of strategic recommendations for stakeholders aiming to successfully implement and leverage information technology within pharmaceutical practice. Successful implementation requires more than just adopting new software; it demands a holistic approach encompassing strategy, technology, data, people, regulation, and collaboration (fig. 3.1).

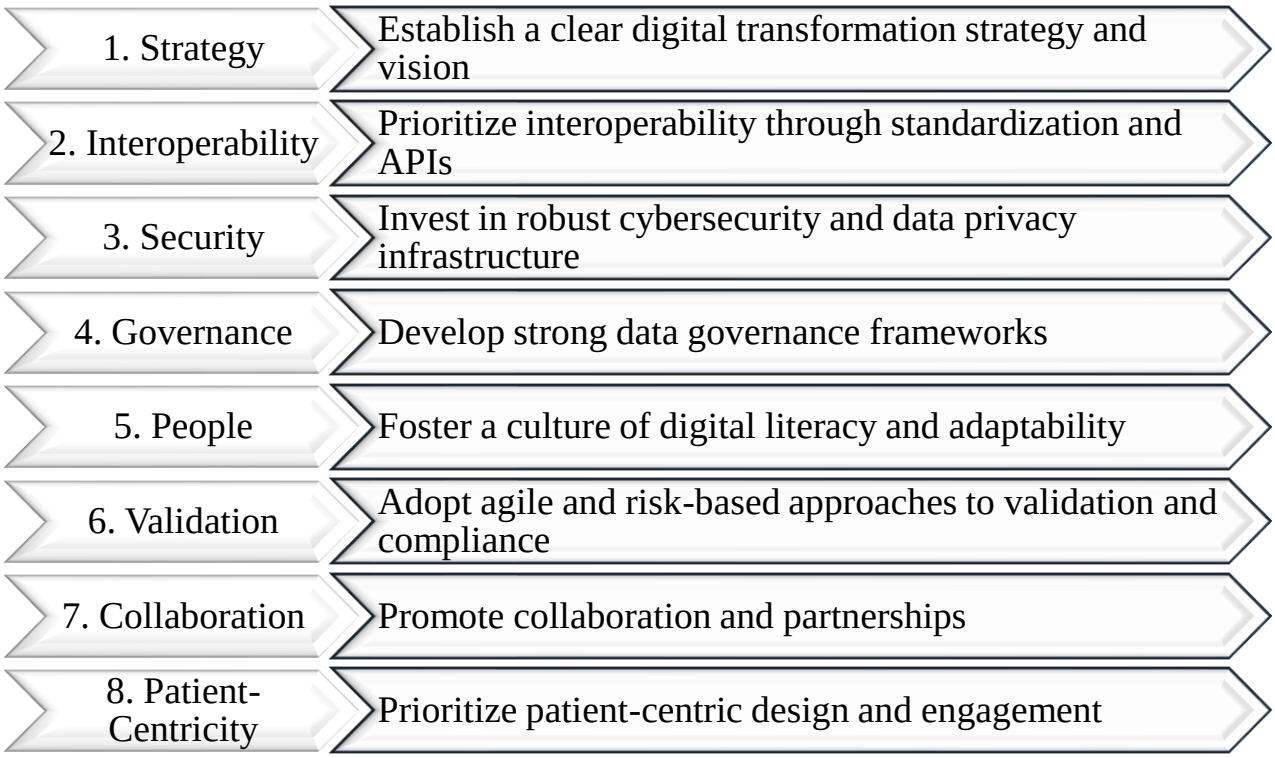

Fig. 3.1. Recommendations for the successful implementation of information technology in pharmaceutical practice

Establish a clear digital transformation strategy and vision. Pharmaceutical organizations (manufacturers, distributors, pharmacies, health systems) should develop a clear, long-term digital transformation strategy aligned with their overall business and clinical goals. This vision should articulate how IT will be used to improve patient outcomes, enhance operational efficiency, drive innovation, and ensure compliance. A lack of strategic direction leads to fragmented IT adoption, wasted resources, and failure to realize synergistic benefits. A clear vision provides direction for investment and prioritisation. Actionable steps include conducting a thorough assessment of current digital maturity, identifying key strategic priorities (e.g. improving supply chain resilience, enhancing patient engagement, accelerating R&D), securing executive sponsorship and communicating the vision across the organisation.

Prioritize interoperability through standardization and APIs. Actively adopt and advocate for modern interoperability standards, particularly HL7 Fast Healthcare Interoperability Resources, across all relevant systems (EHRs, PMS,

LIMS, MES, CTMS, patient-facing apps). Invest in developing and utilizing Application Programming Interfaces (APIs) to facilitate seamless data exchange. Lack of interoperability remains a primary barrier to leveraging data effectively for clinical verification, medication reconciliation, RWE generation, and integrated care models. FHIR offers a more flexible, web-based approach compared to older standards. Actionable steps include requiring compliance with specific interoperability standards in IT procurement contracts, investing in middleware or integration engines, participating in industry initiatives that promote interoperability (e.g. FHIR accelerators), and exposing data via secure APIs where appropriate.

Invest in robust cybersecurity and data privacy infrastructure – making cybersecurity and data privacy foundational pillars of the digital strategy. Implement multi-layered security controls (including zero trust principles), leverage AI for threat detection, ensure compliance with relevant regulations (HIPAA, GDPR), and prioritize privacy-preserving techniques ("privacy by design"). The increasing value and volume of pharmaceutical and health data make the sector a prime target for cyberattacks. Breaches have severe consequences for patient safety, regulatory compliance, and organizational reputation. Actionable steps include conducting regular security risk assessments and penetration tests, implementing robust access controls and encryption, developing comprehensive incident response plans, providing ongoing security awareness training for employees, and ensuring that third-party vendors meet stringent security requirements.

Develop strong data governance frameworks - establishment clear organizational policies and procedures for data governance, addressing data ownership, quality standards, integrity controls (ALCOA+ principles), access rights, usage policies (especially for secondary use like AI training), retention schedules, and ethical considerations (e.g., mitigating bias). Effective use of Big Data, AI, and RWE depends on access to high-quality, reliable, and ethically sourced data. Poor data governance undermines analytics, compromises compliance (data integrity), and erodes trust. Actionable steps include creating a dedicated data governance committee, defining clear roles and responsibilities, implementing data quality

monitoring tools, establishing master data management practices, and ensuring transparency in data use policies.

Foster a Culture of Digital Literacy and Adaptability. Recommendation is to invest significantly in training and workforce development to enhance digital literacy across all roles, from researchers and manufacturing operators to pharmacists and clinicians. Foster an organizational culture that embraces change, encourages experimentation with new technologies, and values data-driven decision-making. Technology implementation fails without user adoption and proficiency. Resistance to change and lack of digital skills are significant barriers. New roles (e.g., clinical informaticists, data scientists) are needed, and existing roles require upskilling. Actionable steps include developing tailored training programmes for different IT systems and user groups, integrating health informatics into professional education curricula (pharmacy, medicine), creating internal champions for digital initiatives, and implementing effective change management strategies during technology rollouts.

Adopt agile and risk-based approaches to validation and compliance – to move towards more agile, risk-based validation methodologies for IT systems, particularly in GxP environments. Leverage automated testing tools where possible and engage proactively with regulators on validating novel technologies like adaptive AI/ML and SaMD. Utilize RegTech solutions to streamline compliance processes. Traditional, rigid validation approaches can be slow and costly, hindering the adoption of innovative digital tools. Regulators are increasingly open to risk-based approaches, and technology can automate many compliance tasks. Actionable steps are implementing risk assessment frameworks to guide the scope of validation, exploring automated validation tools, developing strategies for validating cloud-based systems and AI, staying abreast of evolving regulatory guidance (e.g., FDA's Digital Health Center of Excellence), and evaluating RegTech vendors.

Promote collaboration and partnerships. The recommendation encourages collaboration between pharmaceutical companies, technology providers, healthcare providers, academic institutions, patient advocacy groups and regulators. Engage in

pre-competitive consortia and public-private partnerships to address shared challenges like interoperability, data standards, and ethical AI development. Solving complex challenges like interoperability, developing validated AI models, or establishing robust RWE platforms requires collective effort and diverse expertise that often extends beyond a single organization. Actionable steps include participating in industry working groups and standards bodies, exploring research collaborations with universities, partnering with technology companies on pilot projects, and maintaining an open dialogue with regulators and patient groups.

Prioritize patient-centric design and engagement. The recommendation is to design digital solutions (patient portals, apps, telehealth platforms, adherence tools) with a strong focus on user experience, accessibility and meeting real patient needs. Actively involve patients in the design and testing process and empower them with access to their data and tools for managing their health. Ultimately, the goal of digitalization in healthcare is to improve patient outcomes and experiences. Technology adoption hinges on usability and perceived value by patients. Patient engagement is crucial for personalised medicine and adherence. Actionable steps include applying user-centred design principles, conducting usability testing with diverse patient groups, ensuring that solutions meet accessibility standards (e.g. WCAG), providing clear patient education on the use of digital tools, and implementing secure mechanisms for patient data access and control.

By adopting these recommendations, stakeholders in the pharmaceutical sector can navigate the complexities of digital transformation more effectively, mitigate risks, and harness the full potential of information technology to innovate, improve safety and compliance, and ultimately deliver better pharmaceutical care.

CONCLUSION TO CHAPTER 3

Therefore, the future of pharmaceutical practice is inextricably linked with the continued evolution and intelligent implementation of information technology. The potential to create a more efficient, effective, safer, and personalised pharmaceutical

ecosystem is immense. However, realizing this potential requires not only technological prowess but also strategic foresight, ethical consideration, collaborative spirit, and a commitment to navigating the associated challenges responsibly. The successful integration of IT, guided by principles outlined, will be crucial in shaping a future where pharmaceutical practice can better meet the evolving health needs of the global population.

GENERAL CONCLUSION

1. The research demonstrates that modern information technology is not merely an incremental addition but a fundamental catalyst reshaping the entire pharmaceutical sector. The trends observed point towards an industry progressively transitioning from traditional, often siloed and paper-based processes, towards a highly interconnected, data-driven, automated, and increasingly intelligent ecosystem. IT is driving significant improvements in the efficiency and speed of drug discovery and development, enhancing the quality, consistency, and security of manufacturing and supply chains, and enabling safer, more personalized, and more accessible pharmaceutical care.

2. Across every facet of the pharmaceutical lifecycle, from molecule to patient, IT has become indispensable for operational efficiency, quality assurance, regulatory compliance, and innovation.

3. The ability to generate, capture, manage, integrate, analyze, and interpret vast amounts of diverse data (biological, clinical, manufacturing, supply chain, real-world) is central to the digital transformation and future competitiveness of the sector. Effective data governance and analytics capabilities are paramount.

4. AI is a major transformative force, in its various forms, is emerging as arguably the most disruptive technology, with the potential to revolutionize drug discovery timelines, optimize manufacturing, personalize treatments, enhance pharmacovigilance, and streamline regulatory processes.

5. Integration and interoperability remain key challenges. Despite significant

progress, achieving seamless data flow and process integration between disparate IT systems across different organizations (pharma companies, CROs, hospitals, pharmacies, regulators) remains a major technical and logistical hurdle limiting the realization of full potential.

6. Safety and compliance must evolve with technology. While IT offers powerful tools to enhance patient safety (e.g., CDS, BCMA) and compliance (e.g., eBRs, track-and-trace), digitalization also introduces new risks (cybersecurity, data privacy breaches, algorithmic bias) and necessitates evolving regulatory frameworks and validation approaches.

7. Successful implementation is not solely about technology but also about people and processes. User adoption, digital literacy, workflow integration, change management, and fostering a supportive organizational culture are crucial determinants of success.

8. The future is personalized and patient-centric. Technological trends are converging towards a future of more personalised medicine, tailored to individual genetic and phenotypic characteristics, and a greater emphasis on patient engagement, empowerment, and convenience through digital tools and virtual care models.

9. Successfully harnessing the power of IT requires a strategic, collaborative, patient-centric, and ethically grounded approach from all stakeholders. By embracing innovation responsibly and addressing the inherent complexities proactively, the pharmaceutical sector can leverage information technology to significantly advance its mission of improving human health and well-being worldwide.

LIST OF SOURCES USED

1. 5 digital trends transforming pharma and healthcare in 2025. URL: https://www.graphitedigital.com/insights/5-digital-trends-transforming-pharma-and-healthcare-in-2025. (Date of access: 15.04.2025).

2. Aljabari S., Kadhim Z. Common Barriers to Reporting Medical Errors. *The Scientific World Journal*. 2021. Vol. 2021. P. 6494889. DOI: 10.1155/2021/6494889.

3. Almeman A. The digital transformation in pharmacy: embracing online platforms and the cosmeceutical paradigm shift. *Journal of health, population, and nutrition*. 2024. Vol. 43(1). P. 60. DOI: 10.1186/s41043-024-00550-2.

4. Artificial intelligence in the field of pharmacy practice: A literature review / S. H. Chalasani et al. *Exploratory research in clinical and social pharmacy*. 2023. Vol. 12. P. 100346. DOI: 10.1016/j.rcsop.2023.100346.

5. Breaking Down the Barriers to Digitalization in Pharma Manufacturing. URL: https://www.aizon.ai/blog/breaking-down-the-barriers-to-digitalization-in-pharma-manufacturing (Date of access: 20.04.2025).

6. Digital transformation in healthcare — Architectures of present and future information technologies / G. Gopal et al. *Clin. Chem. Lab. Med. CCLM*. 2019. Vol. 57. P. 328–335. DOI: 10.1515/cclm-2018-0658.

7. Digital transformation in healthcare: Analyzing the current state-of-research / S. Kraus et al. *J. Bus. Res*. 2021. Vol. 123. P. 557–567. DOI: 10.1016/j.jbusres.2020.10.030.

8. Effects of eHealth on hospital practice: Synthesis of the current literature / R. Eden et al. *Aust. Health Rev*. 2018. Vol. 42. P. 568–578. DOI: 10.1071/AH17255.

9. Gauthier P., Cardot J.-M. Health care digitalization, the straightest pathway to personalization. *Farmacia.* 2021. Vol. 69. P. 238–245. DOI: 10.31925/farmacia.2021.2.7.

10. Generative AI in the pharmaceutical industry: Moving from hype to reality. *McKinsey & Company Insights*. URL:

https://www.mckinsey.com/industries/life-sciences/our-insights/generative-ai-in-the-pharmaceutical-industry-moving-from-hype-to-reality (Date of access: 20.04.2025).

11. Global and national overview of the digital health ecosystem / S. Z. Attila et al. *Inf. Tarsad*. 2021. Vol. 21. P. 47–66. DOI: 10.22503/inftars.XXI.2021.3.3.

12. Global medicine spending set to reach $US1.6 trillion by 2025. *PharmacoEconomics & outcomes news*. 2021. Vol. 878(1). P 12. DOI: 10.1007/s40274-021-7698-8.

13. Inzaugarat M. E. AI in Pharmaceuticals: Benefits, Challenges, and Insights. *DataCamp Blog*. URL: https://www.datacamp.com/blog/ai-in-pharmaceuticals (Date of access: 20.04.2025).

14. Karande S., Marraro G. A., Spada C. Minimizing medical errors to improve patient safety: An essential mission ahead. *Journal of postgraduate medicine*. 2021. Vol. 67(1). P. 1–3. DOI: 10.4103/jpgm.JPGM_1376_20.

15. Kesavadev J., Krishnan G., Mohan V. Digital health and diabetes: Experience from India. *Ther. Adv. Endocrinol. Metab*. 2021. Vol. 12. P. 20420188211054676. DOI: 10.1177/20420188211054676.

16. Luetsch K., Rowett D., Twigg M. J. A realist synthesis of pharmacist-conducted medication reviews in primary care after leaving hospital: what works for whom and why? *BMJ quality & safety*. 2020. Vol. 30(5). P. 418–430. DOI: 10.1136/bmjqs-2020-011418.

17. Management challenges for future digitalization of healthcare services / C. Gjellebæk et al. *Futures*. 2020. Vol. 124. P. 102636. DOI: 10.1016/j.futures.2020.102636.

18. Miller A. What are the latest trends in digital pharmacy management? URL: https://www.quora.com/unanswered/What-are-the-latest-trends-in-digital-pharmacy-management (Date of access: 20.04.2025).

19. Mues S., Surges R. Telemedicine and mobile Healthcare Technologies Digitalization in Epilepsy Care—Needs and Challenges. *Z. Epileptol*. 2021. Vol. 34. P. 251–252. DOI: 10.1007/s10309-021-00431-2.

20. Olmstead L. Digital Transformation in Pharma (+Examples, Challenges). URL: https://whatfix.com/blog/pharma-digital-transformation/ (Date of access: 20.04.2025).

21. Outcomes of Medication Misadventure Among People With Cognitive Impairment or Dementia: A Systematic Review and Meta-analysis / A. S. Zaidi et al. *The Annals of pharmacotherapy*. 2021. Vol. 55(4). P. 530–542. DOI: 10.1177/1060028020949125.

22. Pharmacists' perceived responsibility for patient care when there is a risk of misadventure: a qualitative study / G. Bennett et al. *The International journal of pharmacy practice*. 2020. Vol. 28(6). P. 599–607. DOI: 10.1111/ijpp.12580.

23. Role and Services of a Pharmacist in the Prevention of Medication Errors: A Systematic Review / S. W. Gillani et al. *Current drug safety*. 2021. Vol. 16(3). P. 322–328. DOI: 10.2174/1574886315666201002124713.

24. Sinapov I. The Future of Pharmaceutical Information Technology. *BGO Software*. URL: https://www.bgosoftware.com/blog/the-future-of-pharmaceutical-information-technology/ (Date of access: 20.04.2025).

25. Smart & Safe – Digitalisation strategy from a patient safety perspective / V. Zoltan et al. *Orv. Hetil*. 2021. Vol. 162. P. 1876–1884. DOI: 10.1556/650.2021.32289.

26. Sokolova V. Top Trends in the Pharmaceutical Industry 2025: What to Expect? URL: https://www.epicflow.com/blog/top-trends-in-the-pharmaceutical-industry-what-to-expect/ (Date of access: 20.04.2025).

27. Stoumpos A. I., Kitsios F., Talias M. A. Digital Transformation in Healthcare: Technology Acceptance and Its Applications. *International journal of environmental research and public health*. 2023. Vol. 20(4). P. 3407. DOI: 10.3390/ijerph20043407.

28. Talebreza S., McPherson M. L. Recognizing and Managing Polypharmacy in Advanced Illness. *The Medical clinics of North America*. 2020. Vol. 104(3). P. 405–413. DOI: 10.1016/j.mcna.2019.12.003.

29. The Role of Information Technology in the Pharmaceutical Industry.

URL: https://www.healthcaretalentlink.com/blog/role-of-information-technology-in-the-pharmaceutical-industry/ (Date of access: 20.04.2025).

30. The Role of Physicians in Digitalizing Health Care Provision: Web-Based Survey Study / A. Burmann et al. *JMIR Med. Inform*. 2021. Vol. 9. P. e31527. DOI: 10.2196/31527.

31. Top 9 Digital Transformation Trends in Pharmaceutical Industry (Update 2023). URL: https://msbdocs.com/pharmaceutical/trends-in-pharmaceutical-industry-2021/ (Date of access: 20.04.2025).

32. Ullagaddi P. Digital Transformation in the Pharmaceutical Industry: Ensuring Data Integrity and Regulatory Compliance. *The International Journal of Business & Management*. 2024. Vol. 12(3). DOI: 10.24940/theijbm/2024/v12/i3/BM2403-013.

33. Ziadlou D. Strategies during digital transformation to make progress in achievement of sustainable development by 2030. *Leadersh. Health Serv*. 2021. Vol. 34. P. 375–391. DOI: 10.1108/LHS-08-2020-0056.

ANNEXES

ANNEX A

МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ
НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

АКТУАЛЬНІ ПИТАННЯ СТВОРЕННЯ НОВИХ ЛІКАРСЬКИХ ЗАСОБІВ

МАТЕРІАЛИ
XXXI МІЖНАРОДНОЇ НАУКОВО-ПРАКТИЧНОЇ
КОНФЕРЕНЦІЇ МОЛОДИХ ВЧЕНИХ ТА СТУДЕНТІВ

23–25 квітня 2025 року
м. Харків

Харків
НФаУ
2025

УДК 615.1

Редакційна колегія: проф. Котвіцька А. А., проф. Владимирова І. М.
Укладачі: Сурікова І. О., Боднар Л. А., Комісаренко М. А., Комісарова Є. Є.

Актуальні питання створення нових лікарських засобів: матеріали XXXI міжнародної науково-практичної конференції молодих вчених та студентів (23-25 квітня 2025 р., м. Харків). – Харків: НФаУ, 2024. – 515 с.

Збірка містить матеріали міжнародної науково-практичної конференції молодих вчених та студентів «Актуальні питання створення нових лікарських засобів, які представлені за пріоритетними напрямами науково-дослідної 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; суспільствознавства; фундаментальних та мовних наук.

УДК 615.1

and insurance coverage. Data from WHO Mental Health Atlas (2020) and national health statistics were utilized to support the analysis.

Results. The analysis showed significant disparities in the availability and affordability of medications across countries with different income levels. In high-income countries such as Canada, the existence of national formularies and government-subsidized pharmaceutical programs ensures the wide availability of psychotropic medications with minimal out-of-pocket expenses. For example, over 80% of patients diagnosed with mental health conditions receive medication support through public insurance schemes. Pharmacists in these systems actively contribute to medication management, adherence monitoring, and patient education.

In contrast, middle-income countries like Morocco demonstrate partial availability of essential psychotropic medicines, with significant gaps in public sector supply. Approximately 60% of psychiatric medications are available in public healthcare institutions, while many patients rely on private pharmacies, often facing high out-of-pocket costs. Mental health coverage under national health insurance remains limited, and pharmacists are only partially integrated into mental health service delivery.

In low-income countries such as Kenya, medication availability is critically low, with essential medicines for mental health being available in less than 30% of public health facilities. The high cost of medications in the private sector further restricts access, with psychotropic drug prices exceeding monthly minimum wages in some cases. Community pharmacists, although potentially important actors in expanding access, are underutilized due to systemic limitations and lack of targeted mental health training.

Overall, the study highlights that the broader the integration of pharmaceutical support and pharmacist-led interventions into national mental health policies, the higher the treatment coverage and patient satisfaction rates observed. Countries with strong pharmaceutical frameworks demonstrate reduced treatment gaps and better health outcomes among mental health patients.

Conclusions. Availability and affordability of medications are crucial indicators for evaluating the success of national mental health policies. Countries that prioritize pharmaceutical support within mental health programs demonstrate better treatment outcomes and reduced disease burden. Strengthening medication supply systems, expanding insurance coverage for psychotropic drugs, and involving pharmacists in mental health service delivery are key strategies for improving policy effectiveness globally.

STUDY ON CURRENT DIGITALIZATION TRENDS IN THE PHARMACEUTICAL SECTOR OF HEALTHCARE

Zakaria Wissal
Scientific supervisor: Volkova A.V.
National University of Pharmacy, Kharkiv, Ukraine
socpharm@nuph.edu.ua

Introduction. The pharmaceutical sector is undergoing a profound transformation driven by digitalisation, reshaping operations, research, and patient care. Digital technologies are streamlining medicines discovery, supply chain management, regulatory compliance, and communication between healthcare providers and patients. However, this digital shift comes with challenges, including data security concerns, regulatory constraints, and integration complexities.

The purpose of the study was the current trends of digitalisation in the pharmaceutical sector.

Materials and methods of research. The research materials included scientific articles from periodicals, specialized publications, and analytical data. The following methods were used in the study: content analysis, systems analysis, synthesis, generalization.

Research results. Based on the analysis of publications in periodicals, journals and analytical information, we identified the main current trends of digitalisation in the pharmaceutical healthcare sector. It finds that pharmaceutical companies are using big data analytics to optimise operations, improve outcomes and personalise the treatment of patients with their own medicines. The ability to process vast amounts of medical and pharmaceutical data enables predictive modeling for disease management, effectiveness assessment of medicines, and demand forecasting.

Other current trends include the digitalisation of healthcare, the development of telemedicine and telepharmacy. Digital healthcare solutions offer remote patient consultations, virtual diagnostics, e-referrals and e-prescriptions. In addition, mobile applications and wearable devices track patient health data, enabling continuous monitoring and more personalised pharmacotherapy plans.

With the introduction of digitisation of personal data of patients and healthcare professionals, blockchain technology is gaining ground for data protection. Blockchain technology is being used to improve the security, transparency and traceability of data in pharmaceutical supply chains, help prevent counterfeiting of medicines, ensure compliance with regulatory requirements and protect the personal data of pharmacotherapy participants by keeping unaltered records of transactions.

Another modern digitalisation tool in pharma is the use of artificial intelligence in drug development, based on predictive analytics, machine learning and automated modelling. AI-based algorithms enable more efficient identification of promising drug candidates, reducing the cost and time required for clinical trials, for example.

The main obstacles to the active implementation of electronic tools in pharmaceutical activities are identified as: the complexity of ensuring confidentiality and security of data, the need to update the regulatory framework in line with market needs and taking into account safety and ethical issues, the complexity of integration and interoperability, and the high cost of implementation.

The conclusions. In summary, digitalisation is transforming the healthcare pharmaceutical sector, driving innovation, efficiency and patient-centred care. While the industry is benefiting from artificial intelligence, blockchain and big data, overcoming regulatory barriers, security risks and integration challenges is crucial. Future advances are likely to focus on improving digital solutions while ensuring ethical and safe implementation in pharmaceutical operations.

CURRENT TREATMENT AND PREVENTING STRATEGIES FOR MEASLES IN ACCORDANCE WITH INTERNATIONAL GUIDELINES

Zhad Meryem
Scientific supervisor: Surikova I.O.
National University of Pharmacy, Kharkiv, Ukraine
socpharm@nuph.edu.ua

Intriduction. Measles remains one of the most contagious infectious diseases, with the potential to cause severe health complications and death, particularly among young children and immunocompromised individuals. Despite the availability of an effective vaccine, recent years have seen a significant resurgence of measles outbreaks worldwide, largely due to declining immunization

ANNEX B

МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ
НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

СЕРТИФІКАТ УЧАСНИКА

Цим засвідчується, що

Zakaria Wissal

Scientific supervisor: Volkova A.V.

брав(ла) участь у роботі

XXXI Міжнародної науково-практичної конференції молодих вчених та студентів

«АКТУАЛЬНІ ПИТАННЯ СТВОРЕННЯ НОВИХ ЛІКАРСЬКИХ ЗАСОБІВ»

В.о. ректора
Національного фармацевтичного
університету

Алла КОТВІЦЬКА

23-25 квітня 2025 р, м. Харків

Ф А 2.2.1–32-366

National University of Pharmacy

Faculty ~~pharmaceutical~~
Department ~~of social pharmacy~~

Level of higher education ~~master~~

Specialty ~~226 Pharmacy, industrial pharmacy~~
Educational and professional program ~~Pharmacy~~

APPROVED
The Head of Department
of Social Pharmacy

_____
Alina VOLKOVA
"11" of September 2024

ASSIGNMENT
FOR QUALIFICATION WORK
OF AN APPLICANT FOR HIGHER EDUCATION

Wissal ZAKARIA

1. Topic of qualification work: "Research on trends in the development of the pharmaceutical sector based on modern information technologies",
supervisor of qualification work: Alina VOLKOVA, PhD, associated professor,
approved by order of NUPh from "27th" of September 2024 № 237

2. Deadline for submission of qualification work by the applicant for higher education: May 2025.

3. Outgoing data for qualification work: data from scientific and periodical literature in accordance with research objectives; reports of international organizations, statistical data.

4. Contents of the settlement and explanatory note (list of questions that need to be developed):
- to study the role of information technologies in the healthcare;
- to study on current trends and challenges of digitalisation in the pharmaceutical sector;
- to analyze prospects for information technology in pharmaceutical practice;
- to develop recommendations for the successful implementation of information technology in pharmaceutical practice.

5. List of graphic material (with exact indication of the required drawings):
tables – 5, figures – 7

6. Consultants of chapters of qualification work

Chapters	Name, SURNAME, position of consultant	Signature, date	
		assignment was issued	assignment was received
1	Alina VOLKOVA, head of the department of social pharmacy	11.09.2024	11.09.2024
2	Alina VOLKOVA, head of the department of social pharmacy	21.11.2024	21.11.2024
3	Alina VOLKOVA, head of the department of social pharmacy	24.12.2024	24.12.2024

7. Date of issue of the assignment: "11" of September 2024.

CALENDAR PLAN

№	Name of stages of qualification work	Deadline for the stages of qualification work	Notes
1	Analysis of scientific, periodic literature on the topic of qualification work	September 2024	**done**
2	Study the role of information technologies in the healthcare	October-November 2024	**done**
3	Study on current trends and challenges of digitalisation in the pharmaceutical sector	December-January 2024-2025	**done**
4	Analysis of the prospects for the use of information technology in pharmaceutical practice	February 2025	**done**
5	Development of recommendations for successful implementation of information technology in pharmaceutical practice	March 2025	
6	Summary of the results of the study	April 2025	**done**
7	Finalizing the work, preparing the report	May 2025	**done**

An applicant of higher education Wissal ZAKARIA

Supervisor of qualification work Alina VOLKOVA

ВИТЯГ З НАКАЗУ № 237

По Національному фармацевтичному університету

від 27 вересня 2024 року

Затвердити теми кваліфікаційних робіт здобувачам вищої освіти 5-го курсу Фм20(4,10д) 2024-2025 навчального року, освітньо-професійної програми – Фармація, другого (магістерського) рівня вищої освіти, спеціальності 226 – Фармація, промислова фармація, галузь знань 22 Охорона здоров'я, денна форма здобуття освіти (термін навчання 4 роки 10 місяців), які навчаються за контрактом (мова навчання англійська та українська) згідно з додатком № 1.

Прізвище, ім'я здобувача вищої освіти	Тема кваліфікаційної роботи		Посада, прізвище та ініціали керівника	Рецензент кваліфікаційної роботи
по кафедрі соціальної фармації				
Закарія Віссал	Дослідження тенденцій розвитку фармацевтичного сектору на основі сучасних інформаційних технологій	Research on trends in the development of the pharmaceutical sector based on modern information technologies	Доцент Волкова А.В.	Професор Малий В.В.

Ректор Секретар

Вірно

ФА2.8-03-317

ВИСНОВОК

експертної комісії про проведену експертизу
щодо академічного плагіату у кваліфікаційній роботі

здобувача вищої освіти

«13» травня 2025 р. № 331186853

Проаналізувавши кваліфікаційну роботу здобувача вищої освіти Закарія Віссал, групи Фм20(4,10д) англ-03, спеціальності 226 Фармація, промислова фармація, освітньої програми «Фармація» навчання на тему: «Дослідження тенденцій розвитку фармацевтичного сектору на основі сучасних інформаційних технологій / Research on trends in the development of the pharmaceutical sector based on modern information technologies», експертна комісія дійшла висновку, що робота, представлена до Екзаменаційної комісії для захисту, виконана самостійно і не містить елементів академічного плагіату (компіляції).

Голова комісії,
проректор ЗВО з НПР,
професор **Інна ВЛАДИМИРОВА**

Ф А 2.2.1-32-353

REVIEW

of scientific supervisor for the qualification work of the master's level of higher education of the specialty 226 Pharmacy, industrial pharmacy

Wissal ZAKARIA

on the topic: " RESEARCH ON TRENDS IN THE DEVELOPMENT OF THE PHARMACEUTICAL SECTOR BASED ON MODERN INFORMATION TECHNOLOGIES"

Relevance of the topic. The pharmaceutical industry serves as a fundamental pillar of global healthcare, driving advancements in disease treatment, prevention, and overall public health. Its ongoing evolution is essential for tackling emerging health challenges, enhancing patient outcomes, and improving quality of life on a global scale. In recent decades, this transformation has become closely intertwined with the rapid progress and integration of modern information technologies. The digital revolution reshaping industries has profoundly influenced pharmaceuticals, revolutionizing processes from drug discovery and development to manufacturing, supply chain management, regulatory compliance, and patient care. No longer just a supportive tool, IT has become a strategic necessity, unlocking unprecedented levels of efficiency, precision, and innovation across the sector.

Practical value of conclusions, recommendations and their validity. The results of the study can be used to evaluate and select modern information technologies for implementation within particular pharmaceutical companies, and to inform management decisions regarding the outcomes of these implementations.

Assessment of work. During the research Wissal ZAKARIA showed the ability to practically use modern scientific methods of research, to draw conclusions based on the analysis. The work is of a sufficient scientific standard.

General conclusion and recommendations on admission to defend. In general, the qualification work of Wissal ZAKARIA on the topic: "Research on trends in the development of the pharmaceutical sector based on modern information technologies" is carried out at the appropriate level, meets the requirements for qualification works "Regulations on the procedure for the preparation and defense of qualification works at the National University of Pharmacy" POL A2.2-32-025 and can be recommended for defense at the Examination Commissions of the National University of Pharmacy.

Scientific supervisor Alina VOLKOVA

"14th" of May 2025

Ф А 2.2.1-32-356

REVIEW

for qualification work of the master's level of higher education, specialty 226 Pharmacy, industrial pharmacy

Wissal ZAKARIA

on the topic: "Research on trends in the development of the pharmaceutical sector based on modern information technologies"

Relevance of the topic. The integration of information technology into the pharmaceutical industry marks a fundamental transformation, steering operations toward greater efficiency, data-driven insights, and patient-centered care. Cutting-edge technologies are reshaping conventional processes. Artificial intelligence and machine learning, for example, are revolutionizing drug discovery by rapidly analyzing extensive datasets to identify promising drug candidates, assess their potential efficacy and safety, and refine clinical trial methodologies. Furthermore, Big Data analytics enables the extraction of critical insights from sources such as clinical trials, electronic health records, paving the way for advancements in personalized medicine and pharmacy and a deeper understanding of treatment effectiveness.

Theoretical level of work. The qualification work follows a conventional format, drawing upon scientific literature to examine the subject in depth. The analyses are logically arranged and clearly presented within the text.

Author's suggestions on the research topic. The results of the author's research and her proposals provide important information for managers of pharmaceutical companies, helping them to make informed decisions when implementing and using modern information technologies

Practical value of conclusions, recommendations and their validity. The review of the qualification work provides grounds for asserting the practical value of the proposed recommendations, which are based on applied results and can be used to provide a foundation for evaluating and choosing suitable modern information technologies for deployment in pharmaceutical companies

Disadvantages of work. There are numerous stylistic errors and typos in the text, which does not affect the overall grade.

General conclusion and evaluation of the work. According to the relevance and the results of the research, qualification thesis meets the requirements for a qualification thesis and can be recommended for official defence before the Examination Commission Board of the National University of Pharmacy.

Reviewer _____ D.Sc. in Pharmacy, Professor Volodymyr MALYI

"15th" of May 2025

Ф А2.5-32-231

ВИТЯГ
з протоколу засідання кафедри соціальної фармації
№ 21 від «16» травня 2025 року

ПРИСУТНІ: зав. каф. доц. Аліна ВОЛКОВА, проф. Ганна ПАНФІЛОВА, проф. Вікторія НАЗАРКІНА, доц. Галина БОЛДАРЬ, доц. Наталія ГАВРИШ, доц. Тетяна ДЯДЮН, доц. Юлія КОРЖ, асист. Альміра НОЗДРІНА, доц. Вікторія МІЩЕНКО, доц. Ірина ПОПОВА, доц. Олександр СЕВРЮКОВ, доц. Ірина СУРІКОВА, доц. Любов ТЕРЕЩЕНКО, доц. Наталія ТЕТЕРИЧ.

ПОРЯДОК ДЕННИЙ:

Про представлення до захисту в Екзаменаційній комісії кваліфікаційних робіт.

СЛУХАЛИ: завідувачку кафедри доц. Аліну ВОЛКОВУ з рекомендацією представити до захисту в Екзаменаційній комісії кваліфікаційну роботу здобувачки вищої освіти спеціальності 226 Фармація, промислова фармація Віссал ЗАКАРІЯ на тему: «Дослідження тенденцій розвитку фармацевтичного сектору на основі сучасних інформаційних технологій».

Науковий керівник: завідувачка кафедри СФ, к.фарм.н., доц. Аліна ВОЛКОВА.
Рецензент: завідувач кафедри ММЗЯФ д. фарм. н., проф. Володимир МАЛИЙ.

УХВАЛИЛИ: Рекомендувати до захисту в Екзаменаційній комісії кваліфікаційну роботу здобувачки вищої освіти Віссал ЗАКАРІЯ на тему: «Дослідження тенденцій розвитку фармацевтичного сектору на основі сучасних інформаційних технологій».

Завідувачка каф. СФ, доцент Аліна ВОЛКОВА

Секретар, доцент Наталія ТЕТЕРИЧ

Ф А2.2.1-32-042

НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

ПОДАННЯ
ГОЛОВІ ЕКЗАМЕНАЦІЙНОЇ КОМІСІЇ
ЩОДО ЗАХИСТУ КВАЛІФІКАЦІЙНОЇ РОБОТИ

Направляється здобувачка вищої освіти ~~Віссал ЗАКАРІЯ~~ до захисту кваліфікаційної роботи
за галуззю знань ~~22 Охорона здоров'я~~
спеціальністю 226~~ Фармація, промислова фармація~~
освітньою-професійною програмою ~~Фармація~~
на тему: ~~«Дослідження тенденцій розвитку фармацевтичного сектору на основі сучасних інформаційних технологій».~~

Кваліфікаційна робота і рецензія додаються.

Декан факультету _____ / Микола ГОЛІК/

Висновок керівника кваліфікаційної роботи

Здобувачка вищої освіти Віссал ЗАКАРІЯ під час виконання кваліфікаційної роботи опрацювала достатню кількість літературних джерел, звітів, а також проаналізував аналітичну інформацію з досліджуваних питань. Здобувачка показала уміння працювати з даними, проводити їх аналіз, узагальнювати результати дослідження. Усі поставлені завдання відповідно до мети роботи було виконано у повному обсязі. Результати дослідження належним чином оброблені і представлені у вигляді рисунків та таблиць.

Таким чином, кваліфікаційна робота може бути рекомендована до офіційного захисту в Екзаменаційній комісії Національного фармацевтичного університету

Керівник кваліфікаційної роботи

_____ Аліна ВОЛКОВА

«14» травня 2025 р.

Висновок кафедри про кваліфікаційну роботу

Кваліфікаційну роботу розглянуто. Здобувач вищої освіти Віссал ЗАКАРІЯ допускається до захисту даної кваліфікаційної роботи в Екзаменаційній комісії.

Завідувачка кафедри
соціальної фармації Аліна ВОЛКОВА

«16» травня 2025 р.

Qualification work was defended

of Examination commission on

“ “ June 2025

with the grade _____

Head of the State Examination commission,

DPharmSc, Professor

_____ / Volodymyr YAKOVENKO/