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APPLYING THE AGILE APPROACH TO PROJECT MANAGEMENT: A CASE STUDY OF A TRADITIONAL FINISHED PHARMACEUTICAL PRODUCTS MANUFACTURER

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Abstract. *In the conditions of high regulatory and market uncertainty, export of medicines to the European Union (EU) requires flexible approaches to project management. This paper examines the possibility of applying Agile methodology, traditionally used in IT, to a project to enter the pharmaceutical market in Bulgaria. In this work case-oriented scenario is presented for the export preparation, where tasks divided into iterations (sprints) with the descriptions of the key roles and advantages of applying of flexible management. The article demonstrates the practical value of the Agile approach in the context of constantly changing regulatory requirements and a high degree of cross-functional cooperation.*

Keywords: *agile, project management, iterations (sprints), export, pharmaceuticals, Bulgaria, European Medicines Agency (EMA), Bulgarian Drug Agency (BDA), Scrum, hybrid approach, product backlog, case-study, Common Technical Document (CTD), waterfall project management, product labeling, regulatory requirements.*

ТАЙЁР ДОРИ ВОСИТАЛАРИНИ ИШЛАБ ЧИҚАРИШ БЎЙИЧА АНЪАНАВИЙ ТАШКИЛОТ МИСОЛИДА ЛОЙИҲАЛАРНИ БОШҚАРИШДА AGILE ЁНДАШУВИДАН ФОЙДАЛАНИШ

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Аннотация. *Юқори даражадаги тартибга солувчи ва бозордаги ноаниқликлар шароитида дори воситаларини Европа Иттифоқи (ЕИ)га экспорт қилиш лойиҳаларида бошқарувнинг мослашувчан усулларидан фойдаланиш талаб этилади. Ушбу мақолада анъанавий равишда IT соҳасида қўлланиладиган Agile методологиясини Болгария фармацевтика бозорига чиқиш лойиҳасига татбиқ этиш имкониятлари кўриб чиқилади. Экспортга тайёргарлик бўйича кейсга асосланган мисол келтирилган бўлиб, унда вазифаларнинг итерацияларга (спринтларга) бўлиниши, асосий роллар ва мослашувчан бошқарувнинг афзалликлари баён этилган. Мақола регулятор талабларининг доимий ўзгариб бориши ва бўлимлар ўртасидаги яқин ҳамкорлик шароитида Agile ёндашувининг амалий аҳамиятини намоён этади.*

Калит сўзлар: *Agile, лойиҳа бошқаруви, итератсиялар (спринтлар), экспорт, фарматсевтика, Болгария, Европа дори воситалари агентлиги (EMA), Болгария дори воситалари агентлиги (BDA), Scrum, гибрид ёндашув, маҳсулот беклоги, амалий тадқиқот, умумий техник ҳужжат (CTD), каскадли лойиҳа бошқаруви, маҳсулот маркировкаси, меъёрий талаблар.*

ИСПОЛЬЗОВАНИЕ AGILE-ПОДХОДА В УПРАВЛЕНИИ ПРОЕКТАМИ НА ПРИМЕРЕ ТРАДИЦИОННОЙ ОРГАНИЗАЦИИ ПО ПРОИЗВОДСТВУ ГОТОВЫХ ЛЕКАРСТВЕННЫХ СРЕДСТВ

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Аннотация. *В условиях высокой регуляторной и рыночной неопределенности экспорт лекарственных средств в Европейский союз (ЕС) требует гибких подходов к управлению проектами. В данной работе рассматривается возможность применения Agile-методологии, традиционно используемой в IT, к проекту по выходу на фармацевтический рынок Болгарии. Приведен кейс-ориентированный пример подготовки экспорта с разделением задач на итерации (спринты), описанием ключевых ролей и преимуществ гибкого управления. Статья демонстрирует практическую ценность Agile-подхода в условиях постоянно меняющихся требований регуляторов и высокой степени сотрудничества подразделений.*

Ключевые слова: *Agile, проектное управление, итерации (спринты), экспорт, фармацевтика, Болгария, Европейское агентство по лекарственным средствам (EMA), Болгарское агентство по лекарственным средствам (BDA), Scrum, гибридный подход, бэклог продукта, практическое исследование, Общий технический документ (CTD), каскадное управление проектами, маркировка продукта, нормативные требования.*

Introduction.

The export of pharmaceutical products to European Union countries, particularly to Bulgaria, requires strict compliance with regulatory standards set by the European Medicines Agency (EMA) as well as the national authority — the Bulgarian Drug Agency (BDA). Effective coordination between the company's departments — including regulatory, logistics, legal, and marketing — is especially critical in this process. Traditional Waterfall project management models do not always allow for timely responses to internal and external changes. In this context, increasing attention is being given to flexible approaches such as Agile.

The aim of this study is to assess the applicability of the Agile approach in managing a project for the preparation of a pharmaceutical product export to the Bulgarian market, as well as to describe its advantages and limitations.

Literature review.

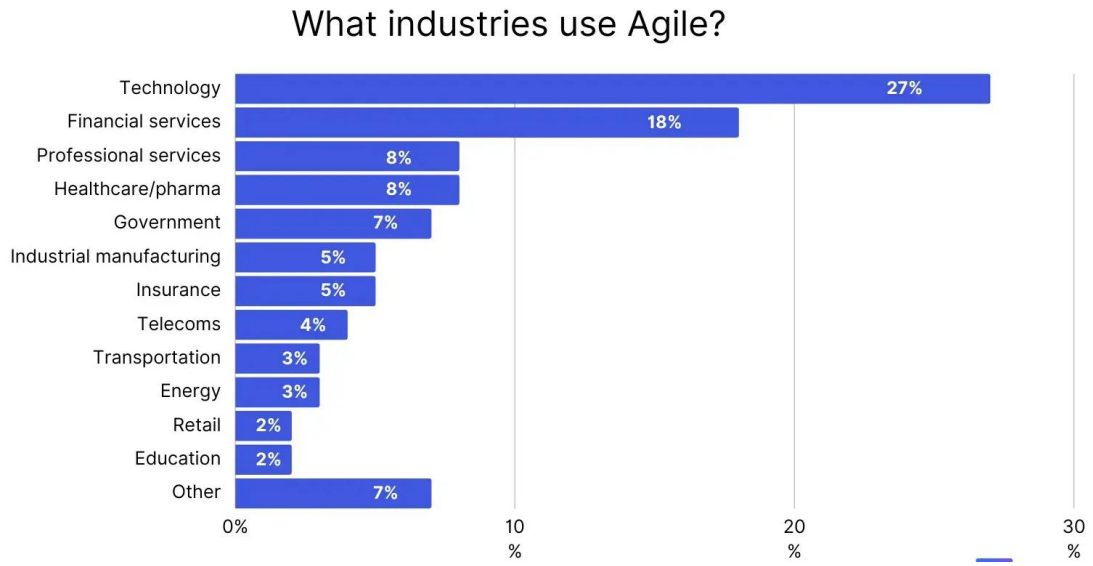
The foundation of the Agile approach was laid in the *"Manifesto for Agile Software Development"*, published by Beck K. and co-authors in (2001). This document outlines key values and principles focused on flexibility, collaboration, iterative work, and rapid delivery of results. These ideas have formed the basis for numerous Agile methodologies, including Scrum and Kanban, and are applicable not only in the IT environment but also in other industries where the ability to quickly adapt to change is essential.

The approach was further developed in the *"Agile Practice Guide"* (PMI, 2017), which provides practical recommendations for applying Agile in traditional organizations. Special attention is given to hybrid models that combine Waterfall and Agile approaches. This is particularly relevant for the pharmaceutical industry, where projects are strictly regulated but still require flexibility — for example, when interacting with regulatory authorities, preparing registration dossiers, or adapting packaging and marketing materials.

The application of Agile methodologies within the pharmaceutical industry is extensively explored by Shapiro and Safonova (2020). According to the authors, the inherently high regulatory demands and the requirement for thorough documentation often led

pharmaceutical projects to follow a predominantly Waterfall-based approach. Nevertheless, the integration of selected Agile practices is still achievable. For example, the use of sprints to streamline documentation processes and the implementation of daily stand-up meetings within cross-functional teams are highlighted as effective strategies to improve workflow transparency and accelerate communication.

Building on this perspective, Kozlov (2022) discusses how Agile frameworks such as Scrum and Kanban can be adapted to fit the constraints of highly regulated sectors. He argues that, despite stringent quality control and validation standards, it is possible to incorporate Agile tools in a targeted and efficient manner.



Research methodology.

The case-study method was used to model a project focused on launching pharmaceutical product into the Bulgarian market. The project is structured using Agile (Scrum) elements: iterations (sprints), roles (Product Owner, Scrum Master, team), results review, backlog adaptation. The project stages are divided into sprints of 2–4 weeks, each iteration includes planning, implementation, demonstration of results and retrospective.

Discussion and results.

During the study, the Agile project management methodology was applied to adapt the registration dossier to the requirements of the Bulgarian Medicines Agency (BDA). The process was divided into four main stages, each of which was accompanied by certain tasks and achievements.

Stage 1: Requirements Analysis

The first stage involves a thorough analysis of the regulatory requirements of the European Medicines Agency (EMA) and the Bulgarian Medicines Agency (BDA). The main objective is to compare the current registration dossier (Common Technical Document – CTD) with the Bulgarian national requirements. A detailed comparison of the structure, content and format of the dossier is carried out to determine which elements require revision, adaptation or translation. The result of this stage is a Gap Analysis, based on which a Product Backlog is formed – a list of all necessary tasks, broken down into priorities and prepared for implementation within the framework of Agile sprints.

Stage 2: Preparation of the dossier

This stage begins the actual preparation of the registration dossier in accordance with the BDA requirements. First of all, Module 1 of the CTD is adapted - the administrative and national module, including forms, applications, translations and legalization of the necessary

documents. The completeness and relevance of the clinical and pharmaceutical data (modules 2-5) is also checked. Particular attention is paid to the compliance of the dossier with GMP requirements, the evidence base for efficiency and safety, stability, quality of the substance and the finished product. In parallel, consultations with local regulatory experts or consultants are organized. Their participation helps to avoid errors and speed up the process due to the early detection of possible comments from the regulator.

Stage 3: Adaptation of packaging and logistics

This stage ensures that the packaging, labelling and logistics scheme comply with the requirements of Bulgarian legislation. It is necessary to organize the translation and adaptation of the text on the packaging and the instructions for use into Bulgarian in accordance with BDA regulations. The logistics chain of supplies to the country is also built: from the selection of a warehouse and logistics partners to compliance with the requirements of Good Distribution Practice (GDP). Reliable local distributors and/or logistics operators are selected, an audit of compliance with quality and licensing requirements is carried out.

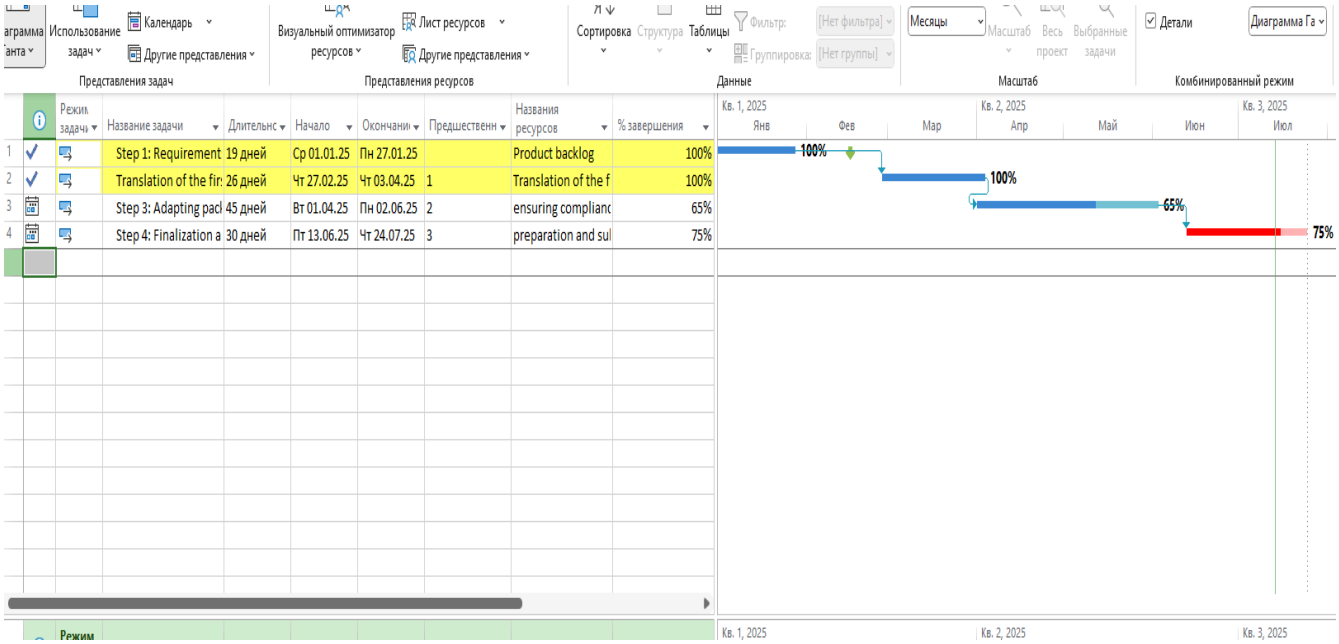
Stage 4: Finalization and Submission

The final stage involves preparing the complete registration dossier and submitting it to the Bulgarian Medicines Agency. Submission may be accompanied by administrative support, provision of additional information or responses to requests from the regulator. In parallel, marketing and educational materials are developed for the future launch of the product – for both medical professionals and end users. At the final stage, the market entry strategy is also formed: the competitive environment, pricing policy, distribution channels and PR activities are assessed. This ensures a smooth and controlled launch of the product.

Advantages of Using the Agile Approach

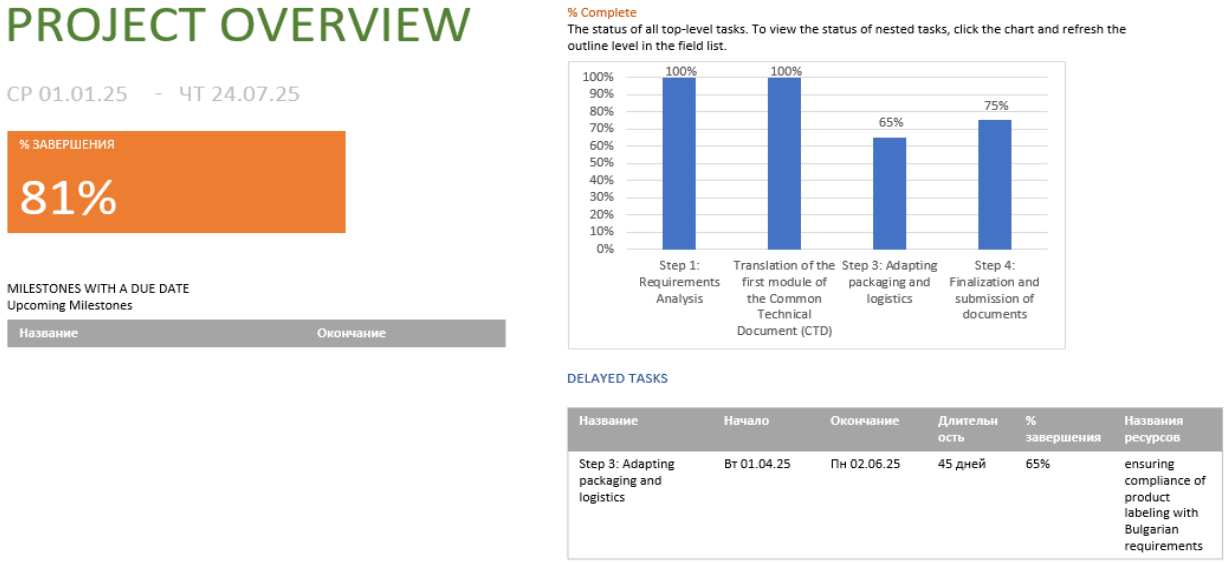
The application of the Agile methodology enabled a flexible process and allowed for quick responses to regulatory comments during document preparation. The transparency of all work stages contributed to increased team engagement and accountability, which had a positive impact on both the quality and speed of task execution. As a result, the documentation preparation timeline was significantly shortened, and the decision-making process was accelerated.

Project task visualization through a Gantt chart



Limitations of the Methodology in the Pharmaceutical Sector

However, it should be noted that the high level of formality and strict regulatory requirements in the pharmaceutical industry limit the application of classical Agile. The need to produce legally binding and final documentation reduces the degree of iteration and flexibility in project execution. Moreover, the successful implementation of Agile requires an experienced and stable team of specialists capable of working effectively in a regulated environment and quickly adapting to changing requirements.



Conclusion.

The Agile approach can be effectively adapted for managing pharmaceutical export projects to the Bulgarian market, particularly during the stages of requirements analysis, documentation preparation, and cross-functional collaboration. Flexible project management enhances team adaptability, reduces time-related costs, and increases the likelihood of successful market entry. However, it is important to take into account the limitations imposed by the regulatory environment of the pharmaceutical industry.

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