Universal Library of Engineering Technology Research Article

ISSN: 3064-996X | Volume 1, Issue 2

Open Access | PP: 69-74

DOI: https://doi.org/10.70315/uloap.ulete.2024.0102011

The Role of Business Process Automation in Enhancing the Operational Efficiency of Pharmaceutical Companies

Olha Semchenkova

Director of QUADRASOFT ETMS LLC, Chicago, USA.

Abstract

The article presents an analysis of the role of business process automation in enhancing the operational efficiency of pharmaceutical companies. The study is based on an interdisciplinary approach that combines insights from management, digital transformation, production technologies, and regulatory research. Special attention is given to the systematization of publications reflecting the implementation of robotic complexes, continuous manufacturing technologies, and digital analytical platforms. Key effects of automation are identified, including the reduction of errors, acceleration of routine operations, redistribution of specialists' functions in favor of clinical interaction, and strengthening the resilience of supply chains. A comparative analysis of managerial and regulatory factors determining the success of CM, Lean 4.0, and Industry 4.0 integration has been conducted. It has been established that the main barriers remain the high cost of implementation, the limited experience of regulators, and the shortage of competencies in PAT, statistical modeling, and process control. It is shown that the Risk Priority Number methodology makes it possible to develop automation roadmaps focused on the most vulnerable processes. Quantitative data confirm that automation provides not only short-term effects in reducing errors and accelerating operations but also strategic advantages in shortening time-to-market and increasing the competitiveness of companies. The article will be useful for researchers in pharmaceutical economics, specialists in digital transformation, production managers, and regulatory experts interested in building sustainable models of operational efficiency management in the pharmaceutical industry.

Keywords: *Pharmaceuticals, Production, Technologies, Digitalization, Management, Processes, Efficiency, Quality.*

INTRODUCTION

The modern pharmaceutical industry is in a phase of large-scale change, driven by the increasing complexity of manufacturing processes, the tightening of regulatory requirements, and the growing expectations of patients and society. Companies are forced to adapt to a highly competitive environment where the key factor for sustainability is the ability to increase operational efficiency without compromising product quality and reliability [2]. One of the central tools for achieving these goals is the automation of business processes, covering both the production sphere and management practices.

The relevance of the topic is determined by a combination of several factors. Significant investments in research and development make it critically important to reduce the time-to-market for new drugs. Regulatory bodies are imposing stricter requirements on the quality, transparency, and resilience of supply chains, which necessitates the implementation of flexible and precise control systems. The uncertainty of the external environment is intensifying. Companies face fluctuating demand, global crises, and local disruptions in logistics [6]. In these conditions, automation is seen as a strategic tool that allows for the optimization of production cycles, a reduction in the probability of errors, and an increase in the transparency of operations.

Nevertheless, the implementation of automated solutions is associated with a number of challenges. Robotic systems, continuous manufacturing systems, and digital analytical platforms have high potential, but their integration into traditional business models faces barriers—from the high cost of investment to the conservatism of corporate culture. A significant limitation is the shortage of specialists with the necessary competencies to work with new technologies. Furthermore, the effect of automation does not always manifest instantly. Strategic benefits depend on the quality of change management, the level of top-management involvement, and the alignment of actions across all company divisions.

The objective of this study is to analyze the role of business process automation in increasing the operational efficiency of pharmaceutical companies. The work will examine examples of the implementation of automated solutions, their impact on key indicators of quality, time, and resource efficiency, and the managerial and organizational factors that determine the success of technology integration.

MATERIALS AND METHODS

This study is based on the methodology of a systematic analytical review, the purpose of which is to identify the role of business process automation in increasing the

operational efficiency of pharmaceutical companies. The key method used was a thematic synthesis of concepts related to digitalization, robotization, the implementation of continuous manufacturing, and "Pharma 4.0" management models. This approach made it possible to connect strategic and applied aspects and to consider the regulatory, organizational, and technological factors of integrating automated solutions.

The study by Domokos A. [1] offers a review of integrated continuous pharmaceutical technologies, where the architectures and methodological approaches to their implementation are systematized. The regulatory aspect is presented in the work of Fisher A. [3], which conducted an audit of submissions for the registration of products manufactured using continuous manufacturing and identified the main difficulties in obtaining approval. A similar issue is addressed in the study by Wahlich J. [9], which examines the barriers to transitioning from batch processes to continuous ones.

Organizational readiness for automation was studied by Foley I. [4], who, using the example of a Lean 4.0 project, showed that the success of digital transformation largely depends on the maturity of management practices and employee involvement. The practical effectiveness of robotic systems is confirmed in the research by Takase T. [8], where a detailed assessment of the safety and reliability indicators of automated systems was conducted.

The technological context of digitalization is explored in the work of Hole G. [5], which describes the key focuses when implementing digital strategies in the pharmaceutical industry. The study by Miller J. [6] proposes a rethinking of the manufacturing paradigm, indicating the need for flexible integration of automation into the modern pharmaceutical landscape. Special attention is given to innovations by Raza M. [7], where the applications of artificial intelligence in pharmaceuticals, including robotic process automation, are systematized. Institutional and practical barriers are further reflected in the study by ElLithy M. [2], which, using an FMEA approach, shows the difficulties of implementing automation and robotics in a hospital pharmacy. These findings are important for understanding which risks and vulnerabilities should be considered when scaling technologies.

Thus, the research is based on a multi-dimensional comparison of conceptual, empirical, and normative sources. This approach provides a holistic understanding of the impact of automation on the indicators of quality, time, and resource efficiency in pharmaceutical companies.

RESULTS

The issue of increasing safety and productivity in the pharmaceutical industry is directly linked to the integration of automated solutions. Modern research confirms that the transition from traditional manual operations to robotic systems can transform key areas of activity, including dispensing, dispensing, and control processes. The work of Takase T. [8] shows that the use of robotic systems in pharmacy and clinical settings leads to a reduction in the probability of errors when dispensing medications and frees up a significant amount of pharmacists' time, which can be reallocated to clinical consultations and patient interaction.

At the same time, the implementation of robotic systems cannot be considered in isolation from risk analysis. The study by ElLithy M. [2] applied the FMEA method, which made it possible to identify areas with the highest probability of errors and to determine their priority for automation. This approach is of particular value, as it allows resources to be directed to critically vulnerable processes and thereby achieve the maximum effect from the implementation of technologies. Table 1 examines the priority areas for intervention where automation demonstrates the greatest potential for minimizing risks and reducing operational costs.

Table 1. Areas of Intervention in the Sequence of Priorities (compiled by the author based on: [2])

Priority	Potential Failure Modes	O	S	D	RPN 0
First	Multiple modifications to the patient's regimen in the same day	10	10	10	1000
	Health Information System (HIS)	10	10	10	1000
Second	Patient history and reconciliation of data at admission and discharge	8	10	10	800
Third	Medication filling and shelf placement	8	9	9	648
Fourth	Order review	7	9	10	630
Fifth	Preparation and dosing	7	7	10	490
Sixth	Order validation	6	9	9	486
Seventh	Receipt of medication at the pharmacy	9	6	7	378
	Prescription of unavailable, inaccessible, or in-house drugs	7	6	9	378

Note: O – Occurrence; S – Severity; D – Detection; RPN – Risk Priority Number.

The data presented show that the highest risk values are observed in areas related to the modification of the therapeutic regimen and the functioning of health information systems, where the RPN indicators reach a critical value of 1000. It is these processes that should be a priority for the implementation of automation, as any error here can lead

to serious clinical consequences. In contrast, stages such as the receipt of medications or the substitution of unavailable drugs, although still significant, are characterized by lower criticality and can be optimized in subsequent stages.

Considering the systemic context, it should be noted that automation is not limited exclusively to robotic systems or local information modules. The study by Domokos A. [1] emphasizes the importance of integrating continuous pharmaceutical technologies, which create the conditions for reducing variability and improving product quality throughout the entire production cycle. In turn, Wahlich J. [9] notes that continuous manufacturing, in conjunction with process analytical technologies, allows for accelerating production and ensuring control transparency, which directly affects the reduction of the probability of systemic errors.

From the perspective of management practices, Foley I. [4] demonstrated that the application of Lean 4.0 in medical and pharmaceutical companies allows for a reduction in non-value-adding operations and an increase in personnel involvement in the quality control process. Digitalization and the implementation of artificial intelligence are of particular importance. The study by Raza M. [7] indicates that AI algorithms can be integrated into automated systems to analyze large arrays of data related to dispensed medications, which enhances the effect of error reduction and increases operational accuracy. Supplementing this finding, Hole G. [5] showed that the successful digitalization of the pharmaceutical sector requires the correct selection of implementation areas, as excessive automation without process analysis can create new bottlenecks.

The modern pharmaceutical industry is increasingly turning to the concept of continuous manufacturing as a strategic direction for digitalization and automation. The study by Wahlich J. [9] emphasizes that CM allows for the acceleration of production cycles, an increase in process flexibility, and the integration of modern control tools such as Process Analytical Technology (PAT) and Real-Time Release Testing (RTRT). These advantages create the basis for reducing the time-to-market for drugs and increasing quality transparency. However, despite the appeal of CM, its implementation is associated with numerous institutional, technical, and regulatory barriers, which requires a comprehensive analysis.

The transition to CM involves a deeper integration of automation than traditional robotization or digitalization projects. Unlike partial solutions, such as the robotic dispensing of medications, CM covers the entire technological cycle—from the dosing of active substances to the quality control of the finished product. The study by Domokos A. [1] shows that it is the end-to-end automation embedded in the architecture of continuous processes that forms the basis for reducing quality variability and eliminating production bottlenecks. At the same time, the integration of CM is closely linked to the tasks of digital transformation: Hole G. [5] notes that successful implementation is impossible without the correct choice of technology application points, as excessive automation without considering the specifics of the processes can create new barriers.

Special attention is given to regulatory aspects during the implementation of CM. Fisher A. [3] showed that submitting applications for the registration of continuous manufacturing technologies is accompanied by significant difficulties related to the lack of globally unified approval procedures and the limited experience of regulators in dealing with such projects. Moreover, Miller J. [6] indicates that even with the support of the FDA and EMA, companies face problems in harmonizing control methodologies, including PAT and RTRT, which slows the widespread adoption of CM practices. Table 2 presents the challenges of implementing CM, which systematize the institutional, technical, and organizational barriers that hinder its integration into pharmaceutical companies.

Table 2. Challenges to implementing CM (compiled by the author based on: [9])

Category	Challenge
Existing equipment and facilities	Geared to batch processes; initial investment cost (though lower subsequent costs); facilities not located to achieve end-to-end processing (API and drug product sites often in different countries).
Expertise requirements	Need for specialists in statistics, process control, modelling, QbD, and PAT; requirement for deeper understanding of material attributes.
CM process	Limited possibilities for re-work; limited opportunities to halt mid-process.
Maintenance	Control algorithms and models require adjustment to raw material changes (may have regulatory implications); sophisticated PAT equipment needed.
Submission requirements	New submissions required to switch from batch to CM; no globally harmonised approval process; longer approval times for global registration.
Equipment	Lack of appropriate bench/pilot-scale equipment; not all unit operations can be included; difficulties handling dry solids and solid-laden fluids.
Experience	Lack of end-to-end process examples; limited company experience in CM submissions; limited regulator experience (especially EMA, MHRA, PMDA).

The data presented demonstrate that the main barriers to CM implementation lie at the intersection of technology and institutional mechanisms. The high cost of modernization and the lack of expertise in statistical modeling and process control hinder the large-scale adoption of CM, despite its obvious advantages. The limited number of successful case studies and the absence of globally harmonized regulatory procedures reinforce company inertia.

At the same time, the effect of implementing CM can be strategic. The study by Foley I. [4] shows that the principles of Lean 4.0, when integrated into pharmaceutical production, can significantly reduce non-value-adding operations and improve personnel interaction with digital control systems. In conjunction with the possibilities of AI, as outlined by Raza M. [7], this opens the way to forming a new paradigm of pharmaceutical manufacturing, where automation becomes a tool for increasing efficiency and a factor for sustainable development.

DISCUSSION

One of the key directions of transformation in the pharmaceutical industry is the reduction of time-to-market. In a context of high capital intensity of research and development and strict regulatory requirements, every week of delay leads to significant economic losses [2]. Therefore, the automation of business processes and the implementation of continuous manufacturing are considered strategic tools that allow for an increase in operational efficiency and an acceleration of the commercialization of innovative drugs.

The study by Wahlich J. [9] emphasizes that CM enables the integration of PAT and RTRT, which makes quality control a part of the production cycle itself, eliminating the need for lengthy and costly post-factum verification stages. In turn, Domokos A. [1] showed that continuous manufacturing architectures help to eliminate the time losses characteristic of batch technologies and thereby contribute to the optimization of end-to-end cycles. The regulatory context, however, remains one of the main factors influencing the speed of product launch. Fisher A. [3] found that the complexity of aligning new technologies with regulators leads to longer registration times, despite the internal efficiency of CM. Nevertheless, as Miller J. [6] shows, the automation of production processes is gradually reducing the dependence on traditional bottlenecks and giving companies more opportunities to maneuver in the face of supply chain uncertainty. Table 3 reflects the effects of accelerated time-to-market, presenting different levels of device complexity and the corresponding time savings.

Table 3. Advantages of faster time-to-market (compiled by the author based on: [4])

Device complexity	Average time-to-market (months)	% improvement with ECM	Adjusted time-to-market (months)	Time saving (months)
High	27	15%	22.95	4.05
Moderate	16	10%	14.40	1.60
Low	9	5%	8.55	0.45

The data presented demonstrate that automation can achieve a significant effect even with moderate device complexity. The reduction in time-to-market in the case of high-tech solutions confirms the economic feasibility of investing in CM and related digital practices. These results are consistent with the findings of Foley I. [4], which show that the integration of Lean 4.0 in the medical industry provides for the elimination of non-value-adding operations and allows for a reduction in the duration of production cycles. In conjunction with the conclusions of Hole G. [5], which emphasize the importance of correctly choosing digitalization points, it can be asserted that the reduction in time-to-market is a consequence of comprehensive automation that covers both production stages and organizational processes.

When considering the implementation of automation and continuous manufacturing, it is necessary to emphasize that technical solutions in this area are inextricably linked with managerial and regulatory conditions. Modern pharmaceutical companies are faced with the fact that even with ready-made technologies, their successful use requires a restructuring of the organizational structure, an updating of the competence system, and the establishment of constructive interaction with regulatory authorities. The study by Domokos A. [1] shows that CM places fundamentally different demands on personnel: specialists must be proficient in statistical methods, process modeling, Quality by Design (QbD) methodologies, and Process Analytical Technology (PAT).

The factor of interaction with regulators is of key importance. The study by Fisher A. [3] notes that the transition from batch production to CM requires the submission of new applications, which is associated with the lack of a globally unified approval process. This leads to longer timelines and increased uncertainty for companies seeking international registration of their drugs. Additional difficulties are created by the limited experience of some regulatory bodies, such as the EMA, MHRA, or PMDA, which reduces the predictability of review outcomes. An important element of management decisions is the phased integration of IT systems. Hole G. [5] emphasizes that digitalization in pharmaceutical manufacturing must be based on a clear choice of intervention points. Excessive automation without an analysis of real

bottlenecks can create new risks. In this context, the tool of risk analysis through a priority indicator becomes key.

A comprehensive understanding of the managerial and regulatory aspects shows that the implementation of CM and related technologies is impossible without a reorientation of the entire corporate strategy. The development of competencies, the building of a dialogue with regulators, and the prioritization of automation in critical areas create the conditions for technological solutions to truly transform the operational efficiency of pharmaceutical companies.

CONCLUSION

The study conducted has allowed for a comprehensive analysis of the role of business process automation in increasing the operational efficiency of pharmaceutical companies. It has been shown that the use of robotic dosing and dispensing systems and the implementation of digital analytical platforms lead to a reduction in the number of errors, an acceleration of routine procedures, and the freeing up of specialists' time for clinical work with patients. This effect confirms that automation is ceasing to be an auxiliary tool and is becoming an element of the strategic development of the industry.

It has been established that the transition to continuous manufacturing goes beyond local improvements and reflects a deep restructuring of the organizational logic of pharmaceutical companies. The integration of PAT and RTRT allows for the combination of quality control with production cycles, which leads to their shortening, a reduction in variability, and the formation of new standards of resilience. At the same time, key barriers have been identified related to the high cost of implementation, the lack of unified regulatory procedures, and a shortage of specialists with competencies in statistics and process modeling.

The analysis confirmed the dependence of automation success on institutional and managerial conditions. The readiness of top management to support digital transformations, the ability of companies to build a dialogue with regulators, and the use of risk prioritization tools to form automation roadmaps play a decisive role. This approach allows for focusing efforts on the most vulnerable areas, minimizing the probability of failures, and ensuring the sustainability of the implemented solutions.

The quantitative data showed that automation combines both immediate effects, expressed in a reduction of operation execution time and a decrease in the number of errors, and long-term strategic advantages. Particularly significant is the impact on accelerating time-to-market, which gives companies additional months of competitive advantage and increases their resilience in the face of global pressure.

The necessity of viewing automation not as a set of separate tools, but as a multi-level system of transformations covering operational, production, and managerial levels has been substantiated. In this system, automation acts as a means of increasing efficiency and an independent factor in the formation of the competitiveness of the pharmaceutical industry. Prospects for further research are related to the development of integrated models of digital pharmaceutics, the standardization of continuous manufacturing processes, and the analysis of management practices that ensure the success of digital transformation.

REFERENCES

1. Domokos, A., Nagy, B., Szilágyi, B., Marosi, G., & Nagy, Z. K. (2021). Integrated continuous pharmaceutical technologies—A review. Organic Process Research & Development, 25(4), 721–739. https://doi.org/10.1021/acs.oprd.0c00504
2. ElLithy, M. H., Alsamani, O., Salah, H., Opinion, F. B., & Abdelghani, L. S. (2023). Challenges experienced during pharmacy automation and robotics implementation in JCI accredited hospital in the Arabian Gulf area: FMEA analysis–qualitative approach. Saudi Pharmaceutical Journal, 31(9), 101725. https://doi.org/10.1016/j.jsps.2023.101725
3. Fisher, A. C., Liu, W., Schick, A., Ramanadham, M., Chatterjee, S., Brykman, R., Lee, S. L., Kozlowski, S., Boam, A. B., Tsinontides, S. C., & Kopcha, M. (2022). An audit of pharmaceutical continuous manufacturing regulatory submissions and outcomes in the US. International Journal of Pharmaceutics, 622, 121778. https://doi.org/10.1016/j.ijpharm.2022.121778
4. Foley, I., McDermott, O., Rosa, A., & Kharub, M. (2022). Implementation of a Lean 4.0 project to reduce non-value add waste in a medical device company. Machines, 10(12), 1119. https://doi.org/10.3390/machines10121119
5. Hole, G., Hole, A. S., & McFalone-Shaw, I. (2021). Digitalization in pharmaceutical industry: What to focus on under the digital implementation process? International Journal of Pharmaceutics: X, 3, 100095. https://doi.org/10.1016/j.ijpx.2021.100095
6. Miller, J. A., Fredrickson, M. E., Greene, J. M., Jay, M., & Oyewumi, M. O. (2022). Reimagining drug manufacturing paradigm in today's pharmacy landscape. Journal of the American Pharmacists Association, 62(6), 1761–1764. https://doi.org/10.1016/j.japh.2022.08.024
7. Raza, M. A., Aziz, S., Noreen, M., Saeed, A., Anjum, I., Ahmed, M., & Raza, S. M. (2022). Artificial intelligence (AI) in pharmacy: An overview of innovations. Innovations in Pharmacy, 13(2). https://doi.org/10.24926/iip.v13i2.4839

8. Takase, T., Masumoto, N., Shibatani, N., & others. (2022). Evaluating the safety and efficiency of robotic dispensing systems. Journal of Pharmaceutical Health Care and Sciences, 8, 24. https://doi.org/10.1186/s40780-022-00255-w

9. Wahlich, J. (2021). Review: Continuous manufacturing of small molecule solid oral dosage forms. Pharmaceutics, 13(8), 1311. https://doi.org/10.3390/pharmaceutics13081311

Citation: Olha Semchenkova, "The Role of Business Process Automation in Enhancing the Operational Efficiency of Pharmaceutical Companies", Universal Library of Engineering Technology, 2024; 1(2): 69-74. DOI: https://doi.org/10.70315/uloap.ulete.2024.0102011.