



AI-Driven Efficiency in Pharmaceutical Manufacturing: Enhancing Productivity, Compliance, and Decision-Making

Aditya Pradeep Sohoni^{1*}

¹Independent researcher

¹Adityapsohoni@gmail.com



*Corresponding Author

Article History:

Submitted: 27-02-2024

Accepted: 20-03-2025

Published: 24-03-2025

Keywords: AI, pharmaceutical manufacturing, ChatGPT, automation, compliance, efficiency, predictive analytics.

Brilliance: Research of

Artificial Intelligence is licensed under a Creative Commons

Attribution-Noncommercial 4.0

International (CC BY-NC 4.0).

ABSTRACT

The pharmaceutical manufacturing business exists in a strictly controlled sector needing high standards of efficiency along with precise operations and complete adherence to standards. The current manual work practices in traditional systems result in both workflow inefficiencies together with opportunities for human mistakes. Artificial Intelligence (AI) through its ChatGPT application provides modern industrial solutions that optimize workflows and automatically document processes and create decision-enhancing technology. The study investigates how AI enables pharmaceutical manufacturing operations to become more efficient as well as ensuring product quality and handling supply chains and meeting regulatory needs. Organizations achieve better productivity rates and decreased manual labor while basing decisions on data through AI-driven solutions which create enhanced compliance as well as greater manufacturing performance.

INTRODUCTION

Within pharmaceutical manufacturing operations strict regulations demand maintenance of high efficiency along with accurate performance and full compliance. Every stage of pharmaceutical operations demands exact execution of stringent guidelines that includes both production and quality control in addition to supply chain management and regulatory documentation. The processes that rely on traditional procedures involve hand activity with repetitive steps and documentation needs which produces delays and inefficient operations and human mistakes [1]. Artificial Intelligence has transformed numerous industries including pharmaceutical manufacturing into a key operational force. The AI technology including the powerful ChatGPT tool demonstrates capabilities that enhance business output and streamlines operations while enabling data-based decision support. Manufacturing operations experience substantial efficiency improvements through artificial intelligence because this technology performs regular activities and analyzes large data collections in addition to generating predictive calculations [2].

The paper demonstrates how AI systems including ChatGPT enhance pharmaceutical production by improving efficiency through workload reduction and communication enhancements and improved database evaluation. The discussion depicts functional examples of writing email content along with meeting note creation and document automation and deviation prediction capabilities for root cause analysis aid and CAPA enhancement [3]. This paper investigates AI adoption hurdles together with regulatory requirements for proper implementation of AI solutions in highly controlled business settings. The main goal of this analysis is to deliver an extensive review of AI-based performance enhancements in pharmaceutical production. Organizations that use AI tools such as ChatGPT will transform their operations into a nimble data-based system which yields higher compliance results and better production outcomes [4].

UNDERSTANDING AI IN PHARMACEUTICAL MANUFACTURING

AI serves as a highly useful instrument in pharmaceutical manufacturing operations to transform how businesses monitor data while enhancing their production processes and maintaining regulatory compliance. The chapter describes AI applications in pharmaceutical manufacturing while explaining how ChatGPT-type technologies modify standard operational frameworks. AI contains multiple categories of applications which include machine learning together with natural language processing (NLP) and robotics and deep learning technologies [5]. Manufacturing processes and predictive maintenance and quality assurance exist as part of various pharmaceutical applications that AI makes possible together with supply chain optimization and regulatory framework requirements. AI models based on NLP such as ChatGPT serve to boost both communication methods and documentation processes as well as problem-solving functions [6].

The pharmaceutical manufacturing industry adopted first AI-driven solutions during early 2000s for functions such as drug discovery and clinical trials before expanding into other manufacturing processes. The application range of AI technology progressively included industrial manufacturing as well as quality regulation assessments alongside





regulatory requirements. Sensorial technology continues advancing through AI model improvements so organizations use ChatGPT for operational efficiency and data-driven decision-making as well as automatic task execution [7]. OpenAI employs ChatGPT as its language-based AI technology to produce authentic text while processing extensive data stores. nemocare manufacturing operations benefit from ChatGPT because it provides support in the following ways:

- The platform assists with writing and summarizing documents that pertain to manufacturing regulations.
- Generating meeting minutes and reports
- Automating communication across teams
- Supporting decision-making through data analysis and pattern recognition

The system helps teams with deviation investigations through its capacity to produce CAPA documentation. Pharmaceutical manufacturing workflows gain significant improvement when they employ ChatGPT through which companies achieve operational efficiency while minimizing human error and simplifying their complex processes. The following chapter demonstrates specific operational enhancements which AI provides during pharmaceutical manufacturing processes [8].

AI FOR ENHANCING OPERATIONAL EFFICIENCY

The production of pharmaceuticals requires operational excellence because manufacturers need to maintain strict compliance elements as well as complicated workflows with stringent quality standards. Through ChatGPT and other AI-driven solutions pharmaceutical companies achieve improved efficiency through automation of regular duties and better communication systems and enhanced documentation management features. The different techniques through which AI strengthens operational excellence within pharmaceutical manufacturing receive analysis in this chapter [9]. Numerous pharmacy operations demand manual repetition through tasks that include both data entry work and report generation along with documentation updates. Through automated processes AI lowers human handling needs which enables employees to spend their time on essential activities including process development and compliance monitoring duties [10].

The system assists with writing regulatory documents as well as checking and condensing both batch records and standard operating procedures (SOPs). AI models use automation to extract valuable critical data from manufacturing records and perform accurate data entry functions. The use of AI-powered systems allows teams to perform batch record review and detect inconsistencies which results in prompt regulatory approval procedures [11]. The pharmaceutical manufacturing sector requires efficient communication methods which enable team alignment along with deviation tracking for maintaining compliance. AI technology enhances communication operations because it simplifies both documentation production and meeting summary creation and reporting processes. The AI system ChatGPT creates professional simple emails to deliver standard business updates along with mandatory compliance alerts and work follow-up communications [12].

AI enables the transcription of meeting content followed by summary generation to produce correct documentation of meeting details and action tracking records. Through structured input requirements ChatGPT produces reports for deviation analysis and CAPA summary documents as well as investigation case records. AIs can help produce training manuals along with their updates which helps staff receive information about technical procedures and regulatory requirements [13]. The pharmaceutical industry needs precise record-keeping for regulatory requirements to meet its needs for documentation precision and compliance. The documentation system of compliance maintains accuracy through AI-based assistance which delivers consistent information that stays updated at all times [14].

The AI system performs analysis to manage change control activities which help pharmaceutical industries meet their Good Manufacturing Practices (GMP) requirements through documented process modifications. The system uses AI to examine past CAPAs together with deviations and recognizes persistent problems which leads to automatic suggested improvements. Pharmaceutical companies who adopt ChatGPT and other AI solutions into operations can boost operational efficiency without the need for manual labor while improving productivity across the organization. AI's function in pharmaceutical manufacturing prediction analytics and proactive leadership activities will receive detailed discussion in the following chapter [15].

AI FOR PREDICTIVE ANALYTICS AND PROACTIVE DECISION-MAKING

Deviations and Non-Conformances Prediction AI evaluates historical data for forecasting when potential deviations will occur thus allowing proactive quality control. Predictive deviation detection through machine learning becomes possible because algorithms identify patterns in deviation activity thereby enabling teams to prevent problems from deteriorating into major issues. The intelligent detection tools of AI monitor current operational data to alert about anomalies resulting in the prevention of manufacturing defects and compliance incidents [16]. RCA analysis receives speedup through AI because it recognizes past investigation patterns for quicker implementation of corrective measures.

The system uses ChatGPT to connect data from various reports which reveals shared failure patterns. The





analysis of historical data through AI process correlation reveals potential causes that emanate from established data associations. CAPA processes receive improvements through AI which generates optimal corrective steps and tracks their accomplishment rates. Through its CAPA Recommendation System AI generates recommended solutions that stem from recorded successes of comparable CAPA actions [17]. The system maintains effective automated checks to measure CAPA success rates during post-implementation periods for regulatory compliance verification. AI technology reveals continuous insights which enable data-driven decisions that optimize operational efficiency. The optimization system uses AI to plan production operations as it forecasts expected demand while respecting machine availability [18].

AI provides supply chain risk assessment capabilities which detect possible supply chain disruptions therefore organizations can implement preventive action plans. Predictive analytics implementation with AI enables pharmaceutical manufacturers to create operational resilience together with reduced compliance risks as well as continuous improvement development [19].

AI IN QUALITY ASSURANCE AND RISK MANAGEMENT

Software-based systems utilizing AI vision capabilities inspect pharmaceutical product photos to recognize manufacturing flaws which include contamination alongside wrong labeling and packaging damage. Real-time manufacturing parameter monitoring serves as an effective method to identify quality standards violations thus minimizing defective batch production. The implementation of AI-based statistical process control (SPC) methods enables manufacturers to assess process variations as well as manage inconsistencies in advance [20]. The assessment of risk levels together with the prediction of future deviations relies on historical deviation data through AI models. Through predictive analytics the manufacturing system shows weaknesses in its processes so organizations can apply preventive actions [21].

Our production system utilizes AI technology for Failure Mode and Effects Analysis (FMEA) to locate manufacturing failures before running into complications. The system identifies these potential failures to apply necessary improvements ahead of time. AI tools for supplier risk assessment conduct data analysis of supplier performance to detect potential threats within the supply network. The implementation of AI technologies to manage quality control and risks within pharmaceutical production leads to decreased defects and superior compliance standards for products as well as superior product quality results and improved risk mitigation [22].

AI FOR SUPPLY CHAIN OPTIMIZATION IN PHARMACEUTICAL MANUFACTURING

Pharmaceutical supply chains operate at high complexity because they need exceptional levels of coordination as well as absolute adherence to quality standards to deliver medications in a prompt manner. AI-driven solutions with ChatGPT among them act as critical supply chain operation optimizers through their function of enhancing demand forecast accuracy and inventory control and logistics management and supplier relations. The chapter digs into how AI systems build up supply chain performance and defensive capabilities for pharmaceutical product production. AI uses historical sales data and seasonal trends and external market factors including changes in regulations to produce precise demand predictions [23].

Advanced analytics driven by artificial intelligence enables organizations to manage inventory optimally which results in waste reduction and prevents both running out of stock and having excessive inventory. The implementation of automated reorder systems using AI leads to just-in-time inventory replenishment which results in better efficiency together with cost savings. AI algorithms optimize transportation routes which achieves delivery time reduction together with cost minimization while keeping to regulatory standards. Real-time tracking systems employ AI to monitor shipments before they automatically detect delays then propose different logistics solutions [24].

AI predicts temperature changes in cold chain operations to maintain correct handling of pharmaceutical products that require specific temperature conditions. AI performs supplier reliability assessments through examination of historical supplier performance records together with data about pricing tendencies and record of compliance standards. Risk assessment programs powered by AI identify unstable supply chain components before creating and recommending defensive strategies to keep operations normal [25]. Supplier contracts get assistance from ChatGPT for both writing and reviewing procedures which maintains alignment between regulatory needs and business targets. The documentation and reporting tasks for supply chain audits run automatically through AI tools which guarantee compliance with both Good Distribution Practices (GDP) and additional regulatory standards [26].

The tracking system for raw materials and finished goods operates automatically which leads to transparent and traceable procedures. The AI-powered monitoring system detects regulatory risks through its compliance systems before giving recommended solutions. Corporations that implement AI solutions in pharmaceutical supply chain management make their operations more efficient and maximize decision quality while minimizing operational risks. Businesses using AI insights create strategic campaigns that build supply chain strength and optimization for pharmaceutical industries [27].





AI IN WORKFORCE PRODUCTIVITY AND COLLABORATION

Additional efficiency requirements and departmental collaboration exist within the pharmaceutical industry that covers manufacturing quality supply chain management and regulatory affairs. Workplace efficiency rises when AI technology including ChatGPT enables users to produce standardized documents alongside robotized repetition elimination and enhances decision processes and adds better information exchange features [28]. AI technology generates standard operating procedures (SOPs) together with batch records and regulatory reports which both meet accuracy standards and regulatory requirements. ChatGPT enables the creation of key documents alongside their summaries which shortens manual documentation tasks. AI transcription systems automates the process of note capturing during meetings and then automatically produces action plans [29].

Through automated chatbot functions organizations can process repetitive inquiries that allow staff members to concentrate on substantial work responsibilities. Production planning benefits from automated scheduling tools which reduce operational stoppages while improving the use of resources. Artificial Intelligence handles data handling tasks through automated processes which both decreases human mistakes and enhances workplace performance. AI-enabled learning systems use individual worker role analysis along with experience assessment to give customized training content [30]. The platform operates through chat functions as a virtual assistant which delivers employee responses regarding procedural guidelines along with regulatory and practice-oriented information. Employee decision quality rises and manual search requirements decrease because AI-driven knowledge bases provide prompt access to contemporary information. The artificial intelligence technology offers virtual assistant functionality that makes meeting summaries accessible alongside important discussion points alongside proposed action steps [31].

Multinational pharmaceutical companies can enhance their employee communication through the use of AI-driven tools for language translation. Internal and external communication gets better through the use of ChatGPT which generates well-structured emails and reports for workers. Employment of artificial intelligence technologies for collaboration and productivity among workers leads pharmaceutical companies to maximize operational performance across decision-making and flexible working structures. Through AI technologies companies enable their staff to work on essential matters by decreasing time-consuming administrative workloads [32].

AI IN QUALITY CONTROL AND COMPLIANCE

The product quality and compliance requirements stand as essential components for pharmaceutical manufacturing operations. Through its applications ChatGPT and additional AI technologies enhance QC by performing automatic deviation management while making risk predictions and managing regulatory documentation. Through artificial intelligence-based system enhancement pharmaceutical companies achieve better compliance accuracy while minimizing their operational costs and regulatory violations. By studying historical deviation patterns AI programs identify future quality issues that may occur in advance [33].

Artificial Intelligence systems use database analysis tools to find correlations between past manufacturing deviations and their corresponding corrections along with the involved production factors. ChatGPT helps deviation investigation work by creating reports with important findings summaries while developing corrective and preventive actions (CAPA). Numerical systems powered by artificial intelligence predict possible risks by analyzing combination measures of previous batch information and environmental triggers and manufacturing deviation data [34]. Through live monitoring technology AI detects irregularities in manufacturing processes which prevents the generation of non-conformances. Through risk prioritization assistance AI allows quality teams to direct their efforts towards urgent quality needs.

AI joins forces with Internet of Things sensors to keep observing quality parameters including temperature control and humidity regulation and contamination prevention aspects at all times. Machine learning algorithms evaluate in-line quality data through detection methods which find early product defects to minimize product waste. The product's consistency with specifications and the adherence to specifications become possible through the use of AI-powered vision systems which ensure enhanced inspection accuracy. AI technology helps regulatory bodies through automation of documentation submissions which lowers their manual labor requirements. ChatGPT helps create audit reports by providing assistance for complete documents that maintain clear regulatory submission standards [35].

AI systems utilize tracking capabilities to observe global regulatory pattern changes which helps pharmaceutical firms guarantee standard compliance throughout industry modifications. The implementation of AI systems throughout quality control and compliance frameworks enables pharmaceutical producers to strengthen product safety measures while decreasing operational risks together with speeding up regulatory requirements management. The ability to process data using artificial intelligence produces insights that empower companies to handle quality tasks in advance while meeting exacting industry regulations [36].

AI IN PHARMACEUTICAL SUPPLY CHAIN OPTIMIZATION

The pharmaceutical supply chain operations need exact coordination between its raw material suppliers and manufacturers and distributors and healthcare providers. The AI-driven tools such as ChatGPT boost supply chain operational effectiveness through optimization of inventory management systems and improve both demand prediction





capabilities and manage logistics functions and enhance supplier relationship performance [37]. AI algorithms utilize historical sales records and seasonal market patterns and liberal trends to generate more precise demand projections. The integration of AI devices in pharmaceutical operations enables businesses to maximize stock levels which leads to fewer missing items and negligent quantities. Through machine learning models pharmaceutical organizations obtain dynamic lead time data as well as consumption data to control their procurement process effectively [38].

The software uses AI technology to evaluate suppliers through both their quality output and their delivery efficiency and their compliance track record. The procurement team gets assistance from ChatGPT by creating supplier reports and evaluating contract terms while the tool also automates production of purchase orders. The AI-based evaluation system detects supply chain hazards while providing suggestions for different supply routes [39]. AI technologies optimize transportation routes which allows both faster deliveries and less production delays for pharmaceutical medications. Through machine learning analysis warehouse operations achieve maximum space utilization which decreases handling periods. The predictive maintenance capabilities of AI ensure equipment in logistics operations and storage facilities operate at their best to protect temperature sensitive products from spoiling [40].

AI control towers provide real-time monitoring of shipments through comprehensive supply chain tracking capabilities. Data from the supply chain undergoes analysis through AI models that trigger prompt decision-making activities for preventing operational disruptions. The combination of ChatGPT helps create logistics reports and performs essential analytical tasks that generate supplier and distributor communication via automation. The implementation of AI technology within pharmaceutical supply chains decreases operational difficulties and allows better market-demand adaptations resulting in enhanced business operational strength. The combination of artificial intelligence insights enables better corporate choices which produces both a responsive and economical supply chain system [41].

THE FUTURE OF AI IN PHARMACEUTICAL OPERATIONAL EXCELLENCE

The continuous development of AI is set to extend its pharmaceutical operational excellence capabilities beyond its present applications. AI development in the pharmaceutical industry will progress through modern trends and business impacts that lead to successful implementation strategies. The combination of robotics and machine learning with natural language processing under hyper automation will achieve complete process automation through automation techniques. AI augmentation with better predictive capabilities will benefit manufacturing teams and the quality function and supply chain staff by improving operational decision-making. ChatGPT alongside other advanced Natural Language Processing models will achieve sophisticated capabilities in dealing with complex regulatory and technical documentation to decrease compliance requirements [42].

Digital replicas enhanced by AI technology will monitor manufacturing processes in real-time to execute predictive models and test scenarios which enable efficiency optimization. The incorporation of AI into personalized medicine production enables adaptive manufacturing which results in high-quality outputs of small-scale therapeutic products. The partnership between AI and block chain technology creates a system which brings better security measures to pharmaceutical supply chain monitoring [43].

Through automation AI will optimize three key areas of pharmaceutical production by cutting labor routines for documentation processing as well as data analysis and compliance oversight. Though it also operates as a predictive analytics system to reduce deviations and promote better regulatory compliance thus cutting down recalls. The implementation of AI technology will enable organizations to add intelligence that strengthens human talent which enables strategic work rather than wasting time on administrative tasks. The application of AI-driven insights provides pharmaceutical businesses with the ability to develop innovative new business structures which include on-demand drug manufacturing alongside AI-optimized R&D programs [44].

Enterprises need to build complete AI strategies which unite operational targets with defined goals for AI systems implementation. Companies need to spend money on developing AI capabilities among their staff while providing appropriate education to be efficient with AI systems. Enterprises should build detailed AI strategies which follow their operational directions. Businesses should invest in both AI-skilled personnel and employee training to let workers effectively use AI systems. High-quality data requires companies to build robust data governance policies which secure information security standards. Organizations should run limited-scale AI model testing through pilots which enable them to improve solutions until they are prepared for enterprise-wide deployment [45]. Organizations must build an AI-friendly environment through which employees see AI as platform that enhances work output instead of replacing jobs to achieve successful implementation. All organizations need to actively collaborate with regulatory agencies to validate that AI systems stay compliant with developing rules and regulations [46]. The proper adoption of artificial intelligence systems by pharmaceutical manufacturers enables them to maintain continuous improvement while boosting efficiency which in turn leads to sustainable industry achievement.





CONCLUSIONS

The pharmaceutical industry is reinventing its production approach through ChatGPT AI technology which achieves higher efficiency and decreases both human mistakes and improves regulatory compliance standards. Through automatic documentation processing as well as communication optimization and supply chain improvements AI-based solutions help organizations reach their operational peak. Planned predictions give organizations the ability to take proactive actions while lowering potential dangers and enhancing manufacturing quality. AI technology will bring increasing significance to pharmaceutical operations because it will evolve into an essential part of developing an agile industry that runs through data analysis and complies with regulations. Successful benefits from AI will depend on adopting strategic approaches coupled with regulatory alignment to achieve ethical responsible use.

REFERENCES

- [1]. Chukwunweike JN, Praise A, Bashirat BA, 2024. Harnessing Machine Learning for Cybersecurity: How Convolutional Neural Networks are Revolutionizing Threat Detection and Data Privacy. <https://doi.org/10.55248/gengpi.5.0824.2402>.
- [2]. Schmitt M. Automated machine learning: AI-driven decision making in business analytics. *Intelligent Systems with Applications*. 2023 May 1; 18:200188.
- [3]. Debbadi RK, Boateng O. Developing intelligent automation workflows in Microsoft Power Automate by embedding deep learning algorithms for real-time process adaptation. *Int J Sci Res Arch*. 2025;14(2):802-820. doi:10.30574/ijrsra.2025.14.2.0449.
- [4]. Paramesha M, Rane NL, Rane J. Big data analytics, artificial intelligence, machine learning, internet of things, and blockchain for enhanced business intelligence. *Partners Universal Multidisciplinary Research Journal*. 2024 Jul 25;1(2):110-33.
- [5]. Ali H. AI for pandemic preparedness and infectious disease surveillance: predicting outbreaks, modeling transmission, and optimizing public health interventions. *Int J Res Publ Rev*. 2024 Aug;5(8):4605-19. Available from: <https://ijrpr.com/uploads/V5ISSUE8/IJRPR32657.pdf>.
- [6]. Emma L. Data-Driven Decision-Making and Business Intelligence in Modern Organizations
- [7]. Debbadi RK, Boateng O. Optimizing end-to-end business processes by integrating machine learning models with UiPath for predictive analytics and decision automation. *Int J Sci Res Arch*. 2025; 14(2):778-796. doi:10.30574/ijrsra.2025.14.2.0448.
- [8]. Ajayi, Olumide, Data Privacy and Regulatory Compliance Policy Manual This Policy Manual shall become effective on November 23 rd, 2022 (November 23, 2022). No , Available at SSRN: <http://dx.doi.org/10.2139/ssrn.5043087>
- [9]. Ameh B. Sustainable supply chains as strategic instruments for environmental protection, public health, and economic resilience. Graduate Research Assistant, Department of Supply Chain and Management Science, University of West Georgia, USA. doi:10.55248/gengpi.5.1224.3428.
- [10]. M. Puri, S. Manwatkar, P. Karpe and S. Kulkarni, in *Biosystems, Biomedical & Drug Delivery Systems: Characterization, Restoration and Optimization*, ed. S. Kulkarni, A. K. Haghi and S. Manwatkar, Springer Nature Singapore, Singapore, 2024, pp. 179–196
- [11]. Heinemann L, Krell K, Bertele-Harms RM, et al. (2021). "Risk-Based Inspection Planning for Pharmaceutical Manufacturing Using Machine Learning and Multivariate Data Analysis." *Pharmaceutical Research*, 38(8), 1600-1614.
- [12]. Chowdhury MA, Kumar S, and Kumar A. (2020). "Anomaly Detection in Pharmaceutical Manufacturing Processes: A Review." *Computers & Chemical Engineering*, 135, 106665.
- [13]. Hussain A, Thomas D, and Dougherty M. (2020). "Pharmaceutical Manufacturing: An AI-Inspired Future." *Applied Sciences*, 10(14), 5039
- [14]. Zhang C, Zheng H, and Ding Q. (2021). "Predictive Modeling for Quality Control in Pharmaceutical Manufacturing Using Machine Learning." *IFAC-PapersOnLine*, 54(4), 1075-1080.
- [15]. Ulrich H, Munteanu R, Heinrich M, et al. (2020). "Predictive Maintenance in Pharmaceutical Manufacturing Using Deep Learning." *Proceedings of the 2020 Winter Simulation Conference*, 1552- 1563
- [16]. Sarker A, Chong I, and Kumar A. (2019). "A Survey of Recent Developments in Machine Learning Techniques for Pharmaceutical Manufacturing Processes." *Computers & Chemical Engineering*, 124, 206-219.
- [17]. Al-Amin M, Alam F, and Miah S. (2021). "Role of Artificial Intelligence in Pharmaceutical Manufacturing for Quality Enhancement." *SN Computer Science*, 2(6), 1-17.
- [18]. Zhou L, Chen H, and Xie M. (2019). "Quality Prediction in Pharmaceutical Manufacturing Using Deep Learning." *IEEE Access*, 7, 169233-169243.
- [19]. Yingngam B, Navabhatra A, Sillapapibool P. AI-Driven Decision-Making Applications in Pharmaceutical Sciences. In *Using Traditional Design Methods to Enhance AI-Driven Decision Making 2024* (pp. 1-63). IGI Global Scientific Publishing.





- [20]. G. Calzavara, E. Oliosi and G. Ferrari, A Time-aware Data Clustering Approach to Predictive Maintenance of a Pharmaceutical Industrial Plant, Paper presented at: 2021 International Conference on Artificial Intelligence in Information and Communication (ICAIIIC); 13–16 April, 2021, 2021.
- [21]. Kavasidis, E. Lallas, V. C. Gerogiannis, T. Charitou and A. Karageorgos, *Procedia Comput. Sci.*, 2023, 220, 576–583.
- [22]. Z. Zhou, X. Li and R. N. Zare, *ACS Cent. Sci.*, 2017, 3, 1337–1344. 68 D. Q. Gbadago, J. Moon, M. Kim and S. Hwang, *Chem. Eng. J.*, 2021, 409, 128163.
- [23]. W. C. Wong, E. Chee, J. Li and X. Wang, *Mathematics*, 2018, 6, 242. 70 I. Baranilingesan, *Curr. Sci.*, 2021, 120(8), 1324–1333
- [24]. H. Salami, M. A. McDonald, A. S. Bommarius, R. W. Rousseau and M. A. Grover, *Org. Process Res. Dev.*, 2021, 25, 1670–1679.
- [25]. S. Chen, T. Liu, D. Xu, Y. Huo and Y. Yang, Image based measurement of population growth rate for l-glutamic acid crystallization, Paper presented at: 2019 Chinese Control Conference (CCC), 2019.
- [26]. Y. Roggo, M. Jelsch, P. Heger, S. Ensslin and M. Krumme, *Eur. J. Pharm. Biopharm.*, 2020, 153, 95–105. 74 B. Nagy, D. L. Galata, A. Farkas and Z. K. Nagy, *AAPS J.*, 2022, 24,
- [27]. S. Ramakrishna, L. Tian, C. Wang, S. Liao and W. E. Teo, *Medical devices: regulations, standards and practices*, Woodhead Publishing, 2015.
- [28]. US FDA, Guidance for Industry Part 11, Electronic Records; Electronic Signatures – Scope and Application, 2003, FDA-2003-D-0143.
- [29]. US FDA, Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry and Other Interested Parties, 2025, FDA-2024-D-4689.
- [30]. US FDA, Center for Drug Evaluation and Research, Artificial Intelligence in Drug Manufacturing, 2023, FDA2023-N-0487.
- [31]. S. S. Kuwahara, *Continuous Biomanufacturing–Innovative Technologies and Methods: Innovative Technologies and Methods*, 2017, 533–548.
- [32]. N. Bhatnagar, Role of Robotic Process Automation in Pharmaceutical Industries, Paper presented at: The International Conference on Advanced Machine Learning Technologies and Applications (AMTLA2019), 2020, https://link.springer.com/chapter/10.1007/978-3-030-14118-9_50.
- [33]. O. Joel, A. Oyewole, O. Odunaiya and O. Soyombo, *Int. J. Manag. Entrep. Res.*, 2024, 6, 707–721. 82 M. DeMello, Artificial Intelligence at Pfizer – 3 Use Cases, <https://emerj.com/artificial-intelligence-at-pfizer/>, (accessed 26.01.2025).
- [34]. N. Shah, *Comput. Chem. Eng.*, 2004, 28, 929–941. 84 M. Salas, J. Petracek, P. Yalamanchili, O. Aimer, D. Kasthuril, S. Dhingra, T. Junaid and T. Bostic, *Pharm. Med.*, 2022, 36, 295–306.
- [35]. L. Liang, J. Hu, G. Sun, N. Hong, G. Wu, Y. He, Y. Li, T. Hao, L. Liu and M. Gong, *Drug Saf.* 2022, 45, 511–519. 86 Y. Chen, J. D. Elenee Argentinis and G. Weber, *Clin. Ther.* 2016, 38, 688–701.
- [36]. F. H.-L. R. Ltd, *A Year in Review 2020*, Basel, Switzerland, 2021. 88 I. Singh, J. Kaur, S. Kaur, B. R. Barik and R. Pahwa, *Braz. Arch. Biol. Technol.*, 2023, 66, 1–16
- [37]. S. Singh, P. Shaktwippee and D. Shrimali, *Harnessing Artificial Intelligence in Financial Operations: Opportunities and Challenges Conference paper First Online: 31 October 2024*, pp. 547–560, https://link.springer.com/chapter/10.1007/978-981-97-6678-9_48?fromPaywallRec=false.
- [38]. Joseph Chukwunweike, Andrew Nii Anang, Adewale Abayomi Adeniran and Jude Dike. Enhancing manufacturing efficiency and quality through automation and deep learning: addressing redundancy, defects, vibration analysis, and material strength optimization Vol. 23, *World Journal of Advanced Research and Reviews*. GSC Online Press; 2024. Available from: <https://dx.doi.org/10.30574/wjarr.2024.23.3.2800>
- [39]. Schmitt M. Automated machine learning: AI-driven decision making in business analytics. *Intelligent Systems with Applications*. 2023 May 1; 18:200188.
- [40]. M. Vaghela, S. Rathi, R. Shirole, J. Verma, Shaheen, S. Panigrahi and S. Singh, *Chin. J. Appl. Physiol.*, 2024, 40, e20240005
- [41]. F. M. Talaat and E. Hassan, Artificial intelligence in 3D printing, in *Enabling Machine Learning Applications in Data Science, Algorithms for Intelligent Systems*, Singapore: Springer Nature, 2021, pp. 77–88.
- [42]. B. R. Hunde and A. D. Woldeyohannes, *Results Eng.*, 2022, 14, 100478. 61 I. Rojek, D. Mikołajewski, E. Dostatni and M. Macko, *Materials*, 2020, 13, 5437.
- [43]. M. Elbadawi, L. E. McCoubrey, F. K. Gavins, J. J. Ong, A. Goyanes, S. Gaisford and A. W. Basit, *Adv. Drug Delivery Rev.*, 2021, 175, 113805.
- [44]. Banerjee, H. K. Haridas, A. SenGupta and N. Jabalia, *Emerging Applications of 3D Printing During CoVID 19 Pandemic*, 2022, pp. 57–79.
- [45]. Z. Grof and F. Štěpánek, *Comput. Chem. Eng.*, 2021, 154, 107492. 65 G. Subramanian, *Process control, intensification, and digitalisation in continuous biomanufacturing*, John Wiley & Sons, 2021





- [46]. H. Valizadeh, M. Pourmahmood, J. S. Mojarrad, M. Nemati and P. Zakeri-Milani, Drug Dev. Ind. Pharm., 2009, 35, 396–407.

