WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.453
Volume 14, Issue 22, 58-72. Review Article ISSN 2277–7105

DIGITAL DOCUMENTATION IN MODERN PHARMACEUTICAL QUALITY ASSURANCE: A STRATEGIC REVIEW

Sanket N. Aher[1*], Ganesh B. Sonawane[2], Vijayraj N. Sonawane[2], Pooja A. Gunjal[1], Jayshri B. Bacchav[1]

[1]Department of Pharmaceutical Quality Assurance, Divine College of Pharmacy, Satana, Nashik, Maharashtra, India.

[2]Assistant Professor, Department of Pharmaceutical Chemistry, Divine College of Pharmacy, Satana, Nashik, Maharashtra, India.

Article Received on 17 Oct. 2025,
Article Revised on 07 Nov. 2025,
Article Published on 15 Nov. 2025,
https://doi.org/10.5281/zenodo.17614902

***Corresponding Author**
Sanket N. Aher
Department of Pharmaceutical Quality Assurance, Divine College of Pharmacy, Satana, Nashik, Maharashtra, India.

How to cite this Article: Sanket N. Aher*, Ganesh B. Sonawane, Vijayraj N. Sonawane, Pooja A. Gunjal, Jayshri B. Bacchav. (2025). Digital Documentation In Modern Pharmaceutical Quality Assurance: A Strategic Review. World Journal of Pharmaceutical Research, 14(22), 58–72.

ABSTRACT

The shift to digital solutions in quality assurance (QA) in the pharmaceutical industry is marked by the replacement of paper based methods with more advanced technological systems. The use of electronic Batch Manufacturing Records (e-BMR) and electronic Batch Packaging Records (e-BPR) enhances compliance and operational efficiency by capturing data in real time and automating workflows. Remote quality assurance and monitoring is possible, which significantly reduces manual oversight. These systems also aid in minimizing human error, automating manual procedures, and expediting batch release in a unified, standardized manner across all sites. AI, IoT, and blockchain technologies are deeply integrated within the documentation systems, allowing for advanced predictive quality control and early detection of deviations, guarantees and tamper-proof audit trails that ensure system integrity. Tools, like Werum PAS-X Manufacturing Execution System (MES) and Honeywell Forge, have shown a quantifiable enhancement in batch monitoring, deviation tracking, and regulatory reporting accuracy. These systems and processes also guarantee utmost compliance with global regulations like FDA 21 CFR Part 11, EU Annex 11, and India's Schedule M. The primary concern of shift to digital systems in the pharmaceutical industry

would stem from expensive initial investments, the cost of integrating with legacy systems, and the exhaustive need for validation processes. Regardless, the advantages of digital documentation.

KEYWORDS: Electronic Batch Records, Digital Documentation, Pharma 4.0, Data Integrity, Regulatory Compliance, Pharmaceutical Quality Assurance.

INTRODUCTION

The foundation of compliance, traceability, and product quality in pharmaceutical quality assurance (QA) is documentation. From the purchase of raw materials to the release of the final product, every stage of the manufacturing process needs to be carefully documented to make sure that operations are carried out in accordance with legal and regulatory standards. The integrity and reproducibility of pharmaceutical products are supported by documentation, which includes standard operating procedures, deviation reports, batch manufacturing records (BMR), and batch packaging records (BPR).[1]

In order to prove adherence to current Good Manufacturing Practices (cGMP), which are required by regulatory bodies like the FDA, WHO, and EMA, batch manufacturing records (BMR) and batch packaging records (BPR) are essential. In addition to ensuring process uniformity and traceability, these records also act as proof in regulatory audits and inspections.[2-3] In order to maintain product quality, allow recalls when needed, and prevent fines or product recalls brought on by non-compliance, accurate and comprehensive BMR/BPR documentation is crucial.

By exposing the shortcomings of paper based systems and underlining the necessity of remote access, real time data monitoring, and optimized procedures, the COVID-19 pandemic dramatically accelerated the digital transformation in pharmaceutical quality assurance. In order to increase operational agility and compliance, numerous businesses started using electronic BMRs (e-BMRs), electronic BPRs (e-BPRs), and other digital quality systems.[4-6] The advent of Pharma 4.0—a paradigm change that incorporates automation, artificial intelligence (AI), the Industrial Internet of Things (IoT), and sophisticated data analytics into pharmaceutical manufacturing—further accelerated this shift. In addition to facilitating predictive quality assurance and continuous process verification, Pharma 4.0 cultivates a data driven quality culture and is important in redefining regulatory readiness and process efficiency.[7]

Limitations of Paper Based Systems: Paper based documentation systems in pharmaceutical quality assurance come with several limitations that hinder both operational efficiency and regulatory compliance. One major drawback is their susceptibility to human error, as manual data entry can lead to transcription mistakes, omissions, and illegible handwriting compromising data accuracy. These systems are also time consuming, with batch release schedules often delayed due to the labor intensive processes of preparing, reviewing, and archiving records. Additionally, physical documents are vulnerable to loss, unauthorized alterations, mishandling, and environmental damage, all of which pose significant risks to data integrity. Accessibility is another concern, as retrieving paper records during audits or investigations can be cumbersome and slow, adversely affecting timely decision making. Furthermore, maintaining consistent audit trails and ensuring compliance with regulatory standards such as FDA 21 CFR Part 11 is challenging with paper based systems, thereby increasing the risk of noncompliance.[8]

What is Digital Documentation (e-BMR/e-BPR) and Why It's the Future: In pharmaceutical manufacturing, digital documentation refers to the replacement of conventional paper based systems with electronic Batch Manufacturing Records (e-BMR) and electronic Batch Packaging Records (e-BPR). Real time production and packaging data is captured directly from equipment and operators by these systems, which are integrated into platforms such as Manufacturing Execution Systems (MES) and Quality Management Systems (QMS). Compliance with international regulatory standards, such as FDA 21 CFR Part 11 and ALCOA+ principles, is ensured by features like electronic signatures, automated workflows, version control, and audit trails. Digital documentation drastically lowers transcription errors, data loss, and batch review and approval delays when compared to manual processes.[9–10]

The move to e-BMR/e-BPR is a key part of the Pharma 4.0 movement because it makes things more efficient, easier to track, and more secure. Review by exception enables QA teams only look at deviations instead of whole batch records, which speeds up the release of batches. Seamless integration with ERP, LIMS, and other systems makes it possible to trace everything from start to finish and be ready for an audit. Digital documentation is becoming more and more recognized as a strategic tool for driving compliance, operational excellence, and scalability in pharmaceutical manufacturing.[11] This is because it supports real time decision making and allows for standardization across multiple sites.

Advantages of digital documentation: Digital documentation in pharmaceutical quality assurance has many important benefits that make up for the problems with old fashioned paper based systems. Automated data entry and system guided inputs help reduce mistakes made by people, which makes the system more accurate and reliable. Access to data in real time supports faster reviews, decisions, and product releases, which greatly increases operational efficiency. Also, features like audit trails, electronic approvals, and secure storage make it easier to follow the rules and keep data safe while lowering the chance of loss or manipulation.[12–13]

BACKGROUND

Pharmaceutical Documentation and Quality Assurance: Throughout the drug development and manufacturing lifecycle, pharmaceutical documentation is essential to maintaining product quality, regulatory compliance, and traceability. Important document types consist of Standard Operating Procedures (SOPs), Master Formula Record (MFR), Batch production Record (BMR), Drug Master File (DMF) Common Technical Document (CTD).[14]

e-BMR and e-BPR: Electronic Batch Manufacturing Records (e-BMR) and Electronic Batch Packaging Records (e-BPR) are digital versions of traditional documentation used in pharmaceutical production. While e-BMR tracks the manufacturing process, e-BPR records packaging activities. Both systems improve data accuracy, enable real time access, and strengthen compliance by reducing manual errors and maintaining secure audit trails.[15]

Features of e-BMR/e-BPR Systems: The features of e-BMR and e-BPR systems are meant to make pharmaceutical manufacturing processes more accurate, easier to track, and more compliant. With real time data entry, operators and supervisors can enter information directly into the system as it happens. This reduces transcription errors and makes sure that records are always up to date. These systems also use a "review by exception" method, which means that only results that are different from what was expected or out of specification are flagged for QA reviewers. This speeds up the approval process.[16-17]

Audit trails are automatically maintained, capturing every modification, addition, or deletion along with the user's identity, timestamp, and reason, ensuring full traceability and compliance with regulatory standards. Additionally, electronic signatures replace handwritten approvals, offering secure, legally valid authentication in line with regulations such as FDA

21 CFR Part 11. Together, these features make e-BMR/e-BPR systems robust tools for ensuring data integrity and regulatory readiness.[18-19]

APPLICATIONS OF DIGITAL DOCUMENTATION IN PHARMACEUTICAL QA

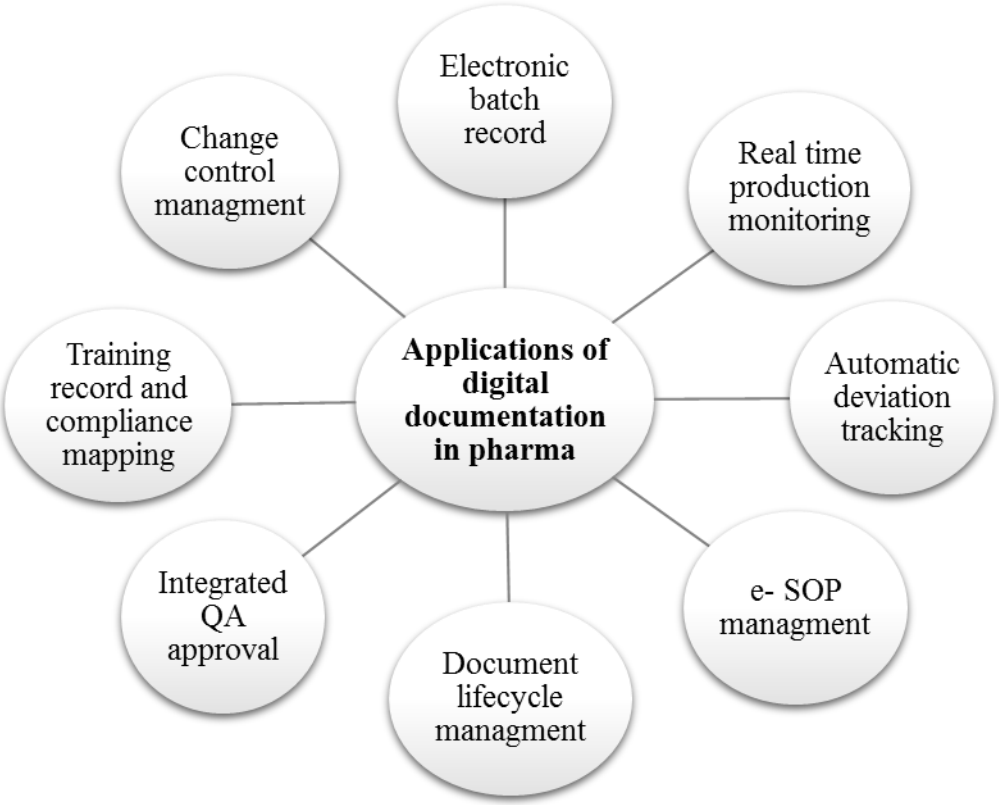

Figure 1: Applications of Digital Documentation in Pharma.

Real Time Production Monitoring: e-BMR and e-BPR systems allow continuous tracking of production activities, from material dispensing to final packaging. They integrate with process equipment to automatically record key parameters like temperature, humidity, and pressure. This real time visibility enables supervisors and quality teams to monitor batch status live and respond quickly to any deviations.[20]

Automatic Deviation Tracking: e-BMR/e-BPR systems automatically flag any out of specification values, triggering instant alerts. Each deviation is time stamped and linked to user credentials, ensuring full traceability. This supports effective investigation, corrective actions, and compliance with regulatory standards.[21]

Integrated QA Approvals: e-BMR/e-BPR systems enable real time, remote QA reviews through secure digital workflows. Electronic signatures and audit trails ensure traceable,

compliant approvals. Features like “review by exception” highlight only critical issues, making the review process faster and more efficient.[22]

BENEFITS OF DIGITAL DOCUMENTATION IN PHARMACEUTICAL QA

Regulatory Compliance

- 21 CFR Part 11 (FDA): Ensures the validity, dependability, and conformity of electronic documents and signatures to those of paper documents.[23-24]
- EU Annex 11: Includes computerized systems in GMP settings, emphasizing system validation, data integrity, and security.[25]
- ALCOA+: Digital systems uphold the values of Attributable, Legible, Contemporaneous, Original, Accurate data, together with the extra "+" components of Complete, Consistent, Enduring, and Available.[26]

Improved Data Integrity and Traceability: One of the best things about e-BMR and e-BPR systems is that they make data more secure and easier to find. These platforms automatically keep audit trails that record every change, addition, or deletion, along with information like the user's name, the time, and the reason for the change [27]. Real time data capture makes sure that records are current and original, which lowers the chance of losing, changing, or backdating data. Also, the digital format makes it easy and quick to find records during audits or investigations, which increases transparency, accountability, and overall compliance with regulatory requirements.[28]

Faster Batch Release and Real Time QA: Digital records are available instantly, so QA teams can review and approve batches in real time, which cuts down on delays caused by passing around physical documents. Automated notifications and simpler workflows speed up the review process even more, which means that batches are released much faster. Also, quickly finding and fixing problems helps get things back on track quickly, which keeps production running smoothly and minimizes disruption.[29]

Sustainability (Paperless Systems): An organization's environmental impact is greatly decreased when paper records are replaced with digital documentation. Businesses can better align with sustainability goals and corporate social responsibility initiatives if they rely less on physical storage and paper waste. Digital systems also make it easier to collaborate and work remotely, which further reduces resource usage and encourages greener operational procedures.[30]

DIGITAL DOCUMENTATION TOOLS IN PHARMA INDUSTRIES

Werum PAS-X MES: Werum PAS-X is a Manufacturing Execution System developed specifically for the pharmaceutical and biotech sectors. It facilitates end to end digitization of production processes, including electronic Batch Manufacturing Records (e-BMR) and electronic Batch Packaging Records (e-BPR). The system is widely adopted by global pharmaceutical companies and is designed to meet the stringent requirements of regulated manufacturing environments.

The system enables real time data collection and monitoring during batch production, reducing the reliance on paper based records. It provides review by exception functionality, which allows for faster batch release by highlighting only the deviations or critical checkpoints that need quality assurance attention. PAS-X also comes with preconfigured templates and workflows, reducing the burden of custom software validation during implementation.

By enabling comprehensive digital documentation, Werum PAS-X enhances operational efficiency, reduces batch documentation errors, supports real time decision making, and helps achieve faster product release. It stands out as a robust solution in Pharma 4.0 digital transformation initiatives.[31]

Honeywell Forge: Honeywell Forge is recognized as a Leader in the Magic Quadrant for manufacturing execution systems, with a primary focus on continuous process and batch manufacturing. It used for process automation and electronic records in pharmaceutical manufacturing. The Pharma Suite is specifically tailored for cGMP environments. It also serves key industries like oil and gas, chemicals, and pulp and paper. The platform has been rebranded and realigned to unify Honeywell's manufacturing software, supported by strategic partnerships and acquisitions, including Sparta Systems and Aizon, to expand into life sciences.

Honeywell Forge stands out for its industry expertise, particularly in the oil and chemical sectors. It offers a flexible architecture, intuitive user interface, and strong analytics capabilities. However, some customers have reported performance issues with the legacy Honeywell Connected Plant MES and noted that the transition to the Forge suite is still ongoing. Support concerns and rising service costs have also been reported in the pulp and

paper segment. Despite these challenges, Honeywell's continued investment and modernization efforts strengthen its market position.[32]

Moderna's AI Integrated e-BMR for mRNA manufacturing: To facilitate its worldwide mRNA vaccine production, Moderna launched an AI integrated electronic Batch Manufacturing Record (e-BMR) system. Predictive analytics is used by this advance digital platforms to proactively detect possible deviations and instantly improve manufacturing procedures. Features that automate compliance reporting make it easier to submit information to regulatory agencies like the FDA and EMA, ensuring quicker and more precise approvals. Furthermore, the cloud-based architecture of the system promotes international cooperation and allows for smooth technology transfer between Moderna's foreign locations. Moderna's e-BMR initiative, which combines AI with digital documentation, is a prime example of the upcoming generation of intelligent, scalable, and compliant biopharmaceutical manufacturing systems.[33]

CHALLENGES IN ADAPTATION

Legacy systems and infrastructure: Many pharmaceutical businesses use outdated MES, LIMS, or ERP platforms, which might make it difficult for them to integrate with contemporary e-BMR/e-BPR systems. In order to guarantee smooth data flow and process continuity, integrating various systems might be technically challenging and demand for specialized middleware, data migration plans, and substantial IT resources.[34]

Need for System Validation and Audit Readiness: For e-BMR/e-BPR systems to meet regulatory requirements like 21 CFR Part 11 and EU Annex 11, they must go through a thorough validation process. This is a resource intensive procedure that needs constant upgrades, thorough documentation, and testing to stay audit ready. It is an ongoing task to make sure the system is always in compliance with evolving regulations.[35]

Resistance to change and organizational culture: Digital transformation in pharmaceutical companies often brings significant changes to processes and roles, which can lead to resistance from employees. Challenges such as lack of awareness, limited trust in new systems, and rigid organizational cultures can hinder adoption. To ensure successful implementation, companies must foster a culture of innovation, provide clear communication, and actively involve employees through training and support. Effective leadership and

structured change management are key to building trust and driving acceptance of digital initiatives.[36]

High Initial Investment: When switching to digital documents, significant upfront expenditures are needed for infrastructure modifications, software licenses, hardware, and thorough employee training. Even while these expenses are usually justified by long term savings and improvements in compliance, many businesses, particularly smaller ones, may find them prohibitive.[37]

REGULATORY FRAMEWORK FOR DIGITAL DOCUMENTATION IN PHARMACEUTICAL QA

21 CFR Part 11–(US FDA): This FDA regulation outlines the conditions under which electronic records and signatures are considered as valid as their paper counterparts in regulated industries. It requires systems to be properly validated for consistent and accurate performance, maintain secure audit trails tracking user actions and timestamps, and enforce electronic signatures that are uniquely assigned and traceable. Additionally, strict access controls and routine system checks are mandated to protect data integrity and prevent unauthorized access.[38]

EU Annex 11–Europe: Annex 11 outlines the expectations for computerized systems used in GMP regulated processes across Europe. It emphasizes a risk based approach throughout the system's lifecycle, including planning, validation, and decommissioning. Key requirements include validated performance based on risk assessments, secure data handling with audit trails and electronic signatures, defined user roles and responsibilities, and formal agreements with suppliers. Regular reviews and updates of validation records help ensure ongoing system integrity and compliance.[39-40]

Schedule M–India's GMP Framework: Schedule M under the Drugs and Cosmetics Rules, 1945, defines GMP standards for pharmaceutical manufacturing in India. While focusing mainly on facility design, equipment, and operational procedures, it also stresses the importance of thorough documentation across all quality and production activities. The use of electronic systems is allowed, provided they maintain data integrity, security, and auditability. For companies targeting global markets, alignment with international guidelines like 21 CFR Part 11 and EU Annex 11 is encouraged.[41-44]

FUTURE PERSPECTIVES OF DIGITAL DOCUMENTATION IN PHARMACEUTICALS

AI Based Document Review and Trend Detection: Artificial Intelligence (AI) and Machine Learning (ML) are reshaping batch record review and quality oversight. These technologies can identify anomalies, uncover patterns in deviations, and predict compliance issues before they occur. By enabling real time trend analysis, they support proactive quality assurance, continuous improvement, and faster root cause identification.[45]

Blockchain for Tamper-Proof Batch Records: Blockchain introduces a decentralized, tamper-proof system for managing batch records and audit trails. Each transaction or update is securely timestamped and cryptographically signed, ensuring transparency and data integrity. This technology is especially beneficial in contract manufacturing, supply chain traceability, and regulatory inspections where trust and verification are critical.[46]

Pharma 4.0 and Smart Manufacturing Integration: Pharma 4.0 marks the shift toward fully connected, data driven pharmaceutical manufacturing by integrating technologies like IoT, AI, robotics, and advanced analytics. e-BMR/e-BPR systems are evolving to interact with smart sensors, automated machinery, and enterprise platforms (MES/ERP), enabling real time control, predictive maintenance, and adaptive manufacturing. This digital convergence enhances quality, efficiency, and operational agility.[47-49]

IoT based real time monitoring and predictive maintenance: The Internet of Things (IoT) connects devices and sensors across pharmaceutical manufacturing and logistics to enable real-time monitoring of critical parameters like temperature, humidity, and pressure. This data, when combined with AI and advanced analytics, provides actionable insights into equipment health and process efficiency. As a result, companies can implement predictive maintenance, reduce downtime, minimize manual errors, and ensure consistent regulatory compliance—all key drivers of digital transformation in pharma.[40-51]

CONCLUSION

Pharmaceutical quality assurance has undergone an enormous transformation with the adoption of electronic Batch Manufacturing Records (e-BMR) and electronic Batch Packaging Records (e-BPR), which replace conventional paper based systems with digital documentation. This evolution greatly improves operational efficiency, data integrity, and traceability while strengthening compliance with international regulatory frameworks like

FDA 21 CFR Part 11, EU Annex 11, and Schedule M. Digital platforms are increasingly incorporating advanced technologies such as blockchain, IoT, and AI, which allow for tamper-proof audit trails, real time monitoring, and predictive quality control. The long term advantages, which include quicker batch releases, fewer human errors, increased sustainability, and improved global competitiveness, outweigh the initial implementation's challenges such as high costs, system validation, and resistance to change. Going forward, digital documentation will be essential to accomplishing Pharma 4.0 goals, promoting intelligent manufacturing, and ensuring the safe, effective, and scalable distribution of high-quality medications in a challenging regulatory and commercial landscape.

ABBREVIATIONS

AI – Artificial Intelligence

ALCOA+ – Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available

BMR – Batch Manufacturing Record

BPR – Batch Packaging Record

cGMP – Current Good Manufacturing Practices

CTD – Common Technical Document

DMF – Drug Master File

e-BMR – Electronic Batch Manufacturing Record

e-BPR – Electronic Batch Packaging Record

EMA – European Medicines Agency

ERP – Enterprise Resource Planning

EU – European Union

FDA – Food and Drug Administration

GMP – Good Manufacturing Practice

IoT – Internet of Things

LIMS – Laboratory Information Management System

MES – Manufacturing Execution System

ML – Machine Learning

MFR – Master Formula Record

QMS – Quality Management System

QA – Quality Assurance

SOP – Standard Operating Procedure

WHO – World Health Organization

REFERENCES

1. Kumar K. Good documentation practices (gdps) in pharmaceutical industry. Journal of Analytical & Pharmaceutical Research, 2017; 4(2): 00100.
2. Thanuja R, Kumar KV, Sree BD, Karthick S, Reshma T. A Comprehensive Review on Documentation Practices in the Pharmaceutical Manufacturing Industry. Jordan Journal of Pharmaceutical Sciences, 2024 Dec 20; 17(4): 829-47.
3. Søren Ventegodt MD, Joav Merrick MD. The pharmaceutical industry and documentation. Journal of Alternative Medicine Research, 2011 Oct 1; 3(4): 453.
4. Ismael A, Okumus I. Design and implementation of an electronic document management system. Mehmet Akif Ersoy Üniversitesi Uygulamalı Bilimler Dergisi, 2017; 1(1): 9-17.
5. Wisniewski CS, Pummer TL, Krenzelok EP. The implementation of an electronic document management system at a drug information center. Journal of Pharmacy Technology, 2010 Mar; 26(2): 66-70.
6. Kumar S. *Implementation of an Integrated Document Management System at ACMIT and Croma Pharma* (Doctoral dissertation, University of Applied Sciences Technikum Wien).
7. Amrih P, Damayanti RW. Pharma 4.0 Quality Management Challenge: A Literature Review. Inproceedings of 12th Annual International Conference on Industrial Engineering and Operations Management (IEOM) Conference, 2022; 606-615.
8. Hinojosa-Amaya JM, Rodríguez-García FG, Yeverino-Castro SG, Sánchez-Cárdenas M, Villarreal-Alarcón MÁ, Galarza-Delgado DÁ. Medication errors: electronic vs. Paper-based prescribing. Experience at a tertiary care university hospital. Journal of evaluation in clinical practice, 2016 Oct; 22(5): 751-4.
9. Buckland M. What is a" digital document"?. Document numérique, 1998; 2(2): 221-30.
10. Venkatesh MP. Digital Pharma: How Software Solutions are Shaping the Pharmaceutical Industry.
11. Reinhardt IC, Oliveira JC, Ring DT. Current perspectives on the development of industry 4.0 in the pharmaceutical sector. Journal of Industrial Information Integration, 2020 Jun 1; 18: 100131.
12. Söderlund Carlborg A. How to Fully Obtain the Potential Benefits of a Digital Document Management System–A Guide to Successful Implementation.

13. Borghoff UM, Rödig P, Schmitz L, Scheffczyk J. Long-term preservation of digital documents: principles and practices. Berlin, Heidelberg: Springer Berlin Heidelberg; 2006 Oct 1.
14. Schmidt A, Frey J, Hillen D, Horbelt J, Schandar M, Schneider D, Sorokos I. A framework for automated quality assurance and documentation for pharma 4.0. Ininternational Conference on Computer Safety, Reliability, and Security, 2021 Aug 25; 226-239. Cham: Springer International Publishing.
15. Thanuja R, Kumar KV, Sree BD, Karthick S, Reshma T. A Comprehensive Review on Documentation Practices in the Pharmaceutical Manufacturing Industry. Jordan Journal of Pharmaceutical Sciences, 2024 Dec 20; 17(4): 829-47.
16. Futschik M. Electronic Batch Recording Solutions. Wiesbaden: Springer Fachmedien Wiesbaden, 2018.
17. Sprague Jr RH. Electronic document management: Challenges and opportunities for information systems managers. MIS quarterly, 1995 Mar 1: 29-49.
18. Aamir M, Rasid SZ, Baskaran S, Manzoor F. Effect of personality traits on dysfunctional audit behaviour. International Journal of Academic Research in Business and Social Sciences, 2018 Dec; 8(12): 1189-202.
19. Abacı K, Medeni IT. Efficiency of electronic document management systems: a case study. Sci. Educ. Innov. Context Mod. Probl., 2022; 5: 75-86.
20. Champagne D, Hung A, Leclerc O. The road to digital success in pharma. Mckinsey &Company pharmaceuticals and medical products, Article, 2015 Aug.
21. Han Y, Makarova E, Ringel M, Telpis V. Digitization, automation, and online testing: The future of pharma quality control. Mckinsey & Company Report, 2019 Jan.
22. Van Rossum HH. Technical quality assurance and quality control for medical laboratories: a review and proposal of a new concept to obtain integrated and validated QA/QC plans. Critical Reviews in Clinical Laboratory Sciences, 2022 Nov 17; 59(8): 586-600.
23. Burcham RL. INTRODUCTION TO FDA 21 CFR PART 11. The Pharmaceutical Regulatory Process, 2008 Dec 2: 429.
24. U.S. Food and Drug Administration. *21 CFR Part 11 – Electronic Records; Electronic Signatures*. Silver Spring (MD): FDA, 2003.
25. Lopez O. EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP. CRC Press, 2015 Apr 6.
26. Riska K. Digital Calibration Certificate as part of an ecosystem.

27. Kulkarni P, Kothari C. Documentation and data integrity in pharmaceutical industry. Inmodern Aspects of Pharmaceutical Quality Assurance: Developing & Proposing Application models, sops, practical audit systems for Pharma Industry, 2024 Mar 12; 381-403. Singapore: Springer Nature Singapore.
28. Ullagaddi P. Safeguarding data integrity in pharmaceutical manufacturing. Journal of Advances in Medical and Pharmaceutical Sciences, 2024 Aug 17; 26(8): 64-75.
29. Sarkis M, Bernardi A, Shah N, Papathanasiou MM. Emerging challenges and opportunities in pharmaceutical manufacturing and distribution. Processes, 2021 Mar 3; 9(3): 457.
30. Raviteja MN, Gupta NV. A review on electronic data management in pharmaceutical industry. Asian J Pharm Clin Res., 2013; 6(2): 38-42.
31. Folorunso O. *AN OPEN-SOURCE MANUFACTURING EXECUTION SYSTEM* (Doctoral dissertation).
32. Franzosa R, Hestermann C. Magic quadrant for manufacturing execution systems. Gartner Inc., Stamford, 2019.
33. Iansiti M, Lakhani KR, Mayer H, Herman K. Moderna (A). Harvard Business School Case, 2020 Sep 15: 621-032.
34. Steinwandter V, Borchert D, Herwig C. Data science tools and applications on the way to Pharma 4.0. Drug discovery today, 2019 Sep 1; 24(9): 1795-805.
35. Mackey TK, Nayyar G. A review of existing and emerging digital technologies to combat the global trade in fake medicines. Expert opinion on drug safety, 2017 May 4; 16(5): 587-602.
36. Chen Y, Yang O, Sampat C, Bhalode P, Ramachandran R, Ierapetritou M. Digital twins in pharmaceutical and biopharmaceutical manufacturing: a literature review. Processes, 2020 Sep 2; 8(9): 1088.
37. Keyhani A. Coping with the digital shift: four of the thorniest issues. The Serials Librarian, 1999 Mar 1; 36(1-2): 149-62.
38. Mazan KD. FDA's Electronic Records and Electronic Signatures Rule: Structuring a Risk-Based Approach. FDLI Update, 2003; 12.
39. Mcdowall RD. Is GMP Annex 11 Europe's Answer to 21 CFR 11?. Spectroscopy, 2011 Apr 1; 26(4): 24-33.
40. Lopez O. EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP. CRC Press, 2015 Apr 6.

41. Chingale ND, Walunj SD, Kikale MS, Devade OA, Redasani V. DOCUMENTATION ESSENTIALS IN THE PHARMACEUTICAL INDUSTRY: A REGULATORY PERSPECTIVE.
42. Moalla N, Bouras A, Neubert G, Ouzrout Y. Data compliance in pharmaceutical industry, interoperability to align business and information systems. Arxiv preprint arxiv: 1811.07693. 2018 Oct 31.
43. Rana A, Sarkar B, Parida RK, Adhikari S, Anandha Lakshmi R, Akila D, Pal S. A Data-Driven Analytical Approach on Digital Adoption and Digital Policy for Pharmaceutical Industry in India. Ininternational Conference on Micro-Electronics and Telecommunication Engineering 2023 Sep 22; 509-521. Singapore: Springer Nature Singapore.
44. Venkatesh MP. Digital Pharma: How Software Solutions are Shaping the Pharmaceutical Industry.
45. Mahadevkar SV, Patil S, Kotecha K, Soong LW, Choudhury T. Exploring AI-driven approaches for unstructured document analysis and future horizons. Journal of Big Data, 2024 Jul 5; 11(1): 92.
46. Shekhtman L, Waisbard E. Engravechain: A blockchain-based tamper-proof distributed log system. Future Internet, 2021 May 29; 13(6): 143.
47. Arden NS, Fisher AC, Tyner K, Yu LX, Lee SL, Kopcha M. Industry 4.0 for pharmaceutical manufacturing: Preparing for the smart factories of the future. International journal of pharmaceutics, 2021 Jun 1; 602: 120554.
48. Kumar SH, Talasila D, Gowrav MP, Gangadharappa HV. Adaptations of Pharma 4.0 from Industry 4.0. Drug Invention Today, 2020 Mar 15; 14(3).
49. Marsh JL, Eyers DR. Increasing production efficiency through electronic batch record systems: a case study. Insustainable Design and Manufacturing, 2016 Apr 2; 261-269. Cham: Springer International Publishing.
50. Dubey R, Gunasekaran A, Childe SJ, Bryde DJ, Giannakis M, Foropon C, Roubaud D, Hazen BT. Big data analytics and artificial intelligence pathway to operational performance under the effects of entrepreneurial orientation and environmental dynamism: A study of manufacturing organisations. International journal of production economics, 2020 Aug 1; 226: 107599.
51. Pugna A, Negrea R, Miclea S. Using Six Sigma methodology to improve the assembly process in an automotive company. Procedia-Social and Behavioral Sciences, 2016 Jun 7; 221: 308-16.