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ENHANCING DATA INTEGRITY AND REGULATORY COMPLIANCE IN BIOMANUFACTURING USING PAS-X MANUFACTURING EXECUTION SYSTEM

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Abstract

Background: Data integrity and regulatory compliance a major issues in biomanufacturing and of specific concern with the rise of ever-more complicated biologics and personalized medicines. The conventional paper-based systems are unable to effectively adhere to the high requirements of Good Manufacturing Practice (GMP) and Good Automated Manufacturing Practice (GAMP5), and this causes transcription mistakes, bad traceability, and non-compliance with the regulations.

Objective: The paper is an assessment of Werum PAS-X Manufacturing Execution System (MES) and its capability of improving data integrity, facilitating regulatory compliance and enhancing efficiency of operations in biopharmaceutical manufacturing facilities.

Methods: Analytical research was used to evaluate the implementation of PAS-X MES through literature studies, regulatory and industry case reports. The main parameters analysed were the goal of compliances with the ALCOA+, the compliance with 21 CF Low-level roadmap and EU Annex 11, the efficiency of work indicators, including the minimisation of deviations and release of batches.

Results: PAS-X MES succeeded in the elimination of data integrity issues as the tool established contemporaneous electronic capture of data, secure recorded audits, and role access restrictions. The system eased the FDA and EMA inspections, minimised deviations and enabled validation in compliance with GAMP 5. Right-first-time production, ease of interchange of information with the ERP and LIMS systems, as well as a 20-30% decrease in the time scales of releasing batches are operational advantages. Case studies in biologics, vaccines and cell & gene therapy manufacturing illustrate its adaptability and effectiveness across diverse manufacturing models.

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Conclusion: PAS-X MES shows itself as a strong, compliance-able technology that is in par with Pharma 4.0. It must be adopted by the manufacturers who desire to promote data integrity, have a regulatory readiness, and improve operational excellence applications in contemporary biomanufacturing.

Keywords: Data Integrity, Werum PAS-X MES, Biomanufacturing, Regulatory Compliance, FDA 21 CFR Part 11, EU Annex 11, GAMP 5, Pharma 4.0, Electronic Batch Records, Operational Efficiency.

1. Introduction

A highly regulated environment is associated with the biomanufacturing of developing and production of biologics, vaccines, biosimilars and advanced therapies, including cell and gene-based medicines. Good Manufacturing Practice (GMP) codes of FDA Title 21 CFR Parts 11, 210, and 211, and EU Annex 11 are binding on regulatory bodies such as the FDA, EMA and MHRA. The most important aspect of compliance is data integrity, as data needs to be Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring and Available to guarantee the integrity of patient safety, the quality of products, and confidence in pharmaceutical outputs (Singh & Solanki, 2022). The complexity of biomanufacturing workflows has become a growing concern, with traditionally used paper-based systems unable to cope with the growing complexity of those processes (Drobnjakovic *et al.,* 2023). The manual record-keeping and manual transcription depend on a lot of human interaction, and it exposes the data to the means of transcription errors, where some data is missed and the logs are illegible, and the audit trails are fragmented. Such gaps lower the compliance level and increase the threat of an unsatisfactory regulatory inspection, such as warning letters, and production stoppage (Isoko *et al.,* 2024).

In order to avert these hazards, the sector has resorted to digital systems. A more recent digital tool has been the Manufacturing Execution Systems (MES), which are specifically constructed to capture data digitally in an automated fashion, keep contemporaneous records, enforce procedural compliance, create digital records of audit, etc., by their design and nature as compared to the traditional forms of capturing data. MES platforms enable the following functions: electronic batch records (EBR), workflow configurations, review by exception, and ERP, LIMS and automation integration (Futschik, 2018; 2016). According to Pharm Manufacturing: “Manufacturers of pharmaceuticals are doing away with paper batch records in favour of electronically based batch recording and MES to enhance performance and compliance” (Stafford, 1998; Kranjc, 2021).

This digital transformation can be seen in Werum PAS X MES, a uniquely pharmaceutical and biopharmaceutical manufacturing end-to-end solution. The PAS X has undergone validation and can satisfy regulatory requirements (FDA 21 CFR Part 11, EU Annex 11, GAMP 5), and it is already in use by more than 50 percent of the leading 30 pharma/biotech companies worldwide. It has modular architecture to aid the electronic Master Batch Record (MBR) design, directed implementation via EBR, operator decision support in real time, identity tracking through barcodes, and audit trail integration (Malheiro *et al.,* 2023; Frolov *et al*.,

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2025). As in the case of advanced therapy (including cell and gene production), PAS X has demonstrated its capability to facilitate streamlined operations, retain chain-of-identity/custody, and facilitate review-by-exception processes (Smith, 2012).

In the present paper, the existing issues of data integrity in biomanufacturing is introduced, cover the way digital MES tools resolve them, and, lastly, dwell upon the advantages and opportunities of Werum PAS X. The enhancing process of PAS X on data integrity, reinforcement of regulatory compliance, audit preparedness and operational excellence in pharmaceutical manufacturing facilities can be explored.

2. Review of Literature

2.1 Regulatory Framework for Data Integrity

International regulations, including the FDA 21 CFR Part 11, EU Annex 11 and GAMP 5, strictly regulate data integrity in the biomanufacturing process, as they define what electronic records and signatures usages have to be, particularly: system validation, audit trail, levels of user's access control to the system, and attribution of the signatures, thus becoming legally binding (Hock *et al.,* 2020; Ullagaddi, 2024). Annex 11 EU, in a similar manner, requires risk-based validation of computerized systems under which the systems are to be authentic, have integrity and have traceability data lifecycle.

The GAMP 5 strengthens these requirements by reinforcing the use of lifecycle approach of validation, encouraging system design and maintenance in a way that facilitates the regulatorily compliant operating system. unity of these frameworks is summarized within the ALCOA+ model Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring and Available that acts as the foundation of valid and audit-friendly data⌈Kabir *et al.,* 2024).

2.2 Challenges in Maintaining Data Integrity

Manual systems and hybrids have still remained prevalent in biomanufacturing although there is a regulatory requirement of these systems, causing multiple points of vulnerability to data integrity. It hinders the contemporaneity, traceability, and completeness by transcription mistakes, lags, record illegibility, incomplete records and inadequate linkage as fundamental ALCOA principles (Sabale *et al*., 2024; Zhang, 2020). Not only that, paper-based systems do not have uniform audit trails which fails to capture the details of who, what, when and why of the data activities which are a common incident on FDA inspection leading to generation of Form 483 calls and warning letters (Miller *et al.,* 2024). According to analyses of warning letters, data manipulation, absence of metadata, and records destroyed are serious non-compliance elements, and they have a devastating effect on being ready to audit, and they pose threats to product quality and the safety of people.

2.3 Role of Electronic Systems in Regulatory Compliance

These weaknesses are directly solved by electronic systems, most of which are achieving compliance by design, especially MES systems. MES systems log the user identity and changes in records and reasons, time-stamped and using a secure audit trail without any manual

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intervention (Sargiotis, 2024). Electronic signatures have non-repudiable approval features in full agreement with the Part 11 demands (Sarkis *et al.,* 2021; Saidi *et al*., 2022). Contemporaneous recording, which is enforced by workflow rules, prevents backdating of data, whereas access controls will allow separation of duties and limit the data manipulation to those with the proper authorisation. Data integrity and the results of predictable behaviour of the system are ensured when MES is checked against GAMP5 and Annex 11. A proper review of the GMP regulations considers MES capabilities in detail to include electronic batch records, real-time monitoring and audit trails and access controls, and all of this can be used to demonstrate how MES can facilitate in bridging the compliance gaps (Passi *et al.,* 2023; Kayes *et al*., 2020).

2.4 Werum PAS-X MES in the Context of Data Integrity

Werum PAS X MES is an example of a system of the next generation intended to meet data integrity requirements in the regulated space. Its main functionalities are guided electronic batch record (EBR) performance, configurable master batch records (MBR) design through content libraries and automatic audit trails) (Charoo *et al.,* 2023; Yaqoob *et al.,* 2019). The system with the mandatory implementation of ALCOA+ performs actions to initiate operator discussions during execution, time-stamped data, automation integration (e.g., OPC UA), and central management of records to ensure record tracking and right-first-time production (Misal, 2024; Assiri & Humayun, 2023; Bakhshi & Ghita, 2021). There are also such features as review-by-exception, which could make sure that out-of-spec or critical process parameters get flagged and reviewed as soon as possible, which minimizes manual processes and strengthens compliance. Such resilient pharmacist-focused capabilities render PAS X a mighty empowered towards data integrity, regulatory compliance, and biomanufacturing best practice.

3. Materials and Methods

3.1 Study Design

This project employs an analytical framework to look at the effectiveness of Werum PAS X Manufacturing Execution System (MES) against the enhancement of data integrity and regulatory compliance in a biomanufacturing environment. The steps involve the inspection of the PAS X's features and their alignment to the regulation requirements of the FDA 21CFR Part 11, the EU Annex 11 and the GAMP 5 practices. To prevent bias, it was implemented in terms of a qualitative approach was implemented to assess the documented case studies, peer-reviewed articles and regulatory reports regarding MES implementation in biopharmaceutical and pharmaceutical plants. Further, the comparative analysis of manufacturing procedures was performed when there was no PAS X provided and after the realisation of the latter to draw the parallels with the elevation of data integrity and efficient completion of the processes (Koerber *et al.,* 2023; Mullard, 2022).

3.2 Data Sources

The research has been carried out using data obtained using several sources, such as:

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• Peer-reviewed journals indexed on PubMed, Science Direct and Web of Science that concentrate on MES and GMP compliance.

• Industry case studies on the application of PAS X MES in the industry facts of biologics and vaccine production.

• Regulatory inspection agencies (FDA, EMA, and MHRA) report that mentioned regarding the data integrity concerns and how to address the same through electronic systems.

Technical whitepapers by Koerber Pharma and other associated MES providers about the system features and alignment to Pharma 4.0. This triangulation method of data collection provided a full scope of technical, operational, and compliance points of view (Koerber *et al.,* 2023; Popa *et al.,* 2023).

3.3 valuation Criteria

The productivity of PAS X MES is evaluated with the help of the following assessment

parameters:

• Parameters of Data integrity:

o Existence of secure and time-stamped audit trails to record actions of all users.

o Use of access control rules in order to have role-based permitting and segregation of duties.

o Electronic signatures that should be by ": 21 FDA CFR part 11".

- **Compliance Metrics:**

o System validation convention within the GAMP 5 standards and compliance with EU annex 11 for computerized systems.

o Lessened deviations, mistakes and manual activities on electronic batch records (EBRs).

o Regulatory audit, readiness and inspection.

Parameters were based on the regulatory guidance documents and the available frameworks of assessing computerized systems within the GMP setting (Yadav & Suryawanshi, 2025; Pedro *et al.,* 2023).

3.4 Method of Analysis

Comparative analysis took place in order to evaluate operations before and after the implementation of PAS X MES. Important highlights were:

• Detecting manual process weaknesses (e.g. transcription errors, data loss) of pre-MES processes.

• Examining post-MES performance statistics like batch release cycle time, deviation rates and levels of audit preparedness.

• Assessing how PAS X helps in the production of right first time and subsequent review by exception.

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The framework of operational efficiency was used to measure efficiency in terms of data accuracy, compliance with regulations, and increased productivity in manufacturing (Ghosh, 2023).

Results and Discussion

The use of Werum PAS X Manufacturing Execution System (MES) is a new paradigm to biomanufacturing as it includes the solutions to the most troubling issues of data integrity and regulatory compliance. The findings signify that the PAS X not only help to minimize manual errors and improve traceability but also helps in operational efficiency and audit readiness. Such results correspond to other reports that focus on the contribution of MES, which is considered to enable the compliance-by-design approach in Good Manufacturing Practice (GMP) settings (Sargiotis, 2024).

4.1 Impact of PAS-X MES on Data Integrity

It has been proven that the appropriation of Werum PAS X MES has mitigated human errors and increased the traceability of data in bio manufacturing settings. An example of this is the adapter of production equipment through OPC and barcode scanning which totally avoided manual data entries in weigh/dispense steps which is a major issue to experience transcription errors (Hass, 2003). Another feature of PAS X is real-time enforcement of contemporaneous data capture, the element which makes operators timely and inhibits any loss of recording of an essential element of ALCOA compliance. In addition, centralized, time-stamped audit trails, make every data interaction traceable to an individual user, greatly enhancing accountability and making inspection preparation much easier.

4.2 Regulatory Compliance Improvements

PAS X MES makes it easier to prepare against FDA and EMA inspections through the implementation of critical regulatory requirements. Electronic signatures allowed separate controls, which were created to meet the requirements of the FDA 21 CFR Part 11 and the role-based limitations that maintain data authenticity and separation of duty. It has a validated framework that is developed on the basis of GAMP 5 and EU Annex 11 to provide a safe and compliant system life cycle. As an example, Dr. Reddy in Visakhapatnam went live at a green field site that was able to deliver FDA-ready documentation in five months (Duan, 2022). The audit trails and exception logging features and review-by-exception features in the system have worked together to minimize regulatory 483 observations and validate the entirety of audit readiness by fully documenting all data lineages.

Regulatory agencies like FDA and EMA are still concerned with data integrity, and they insist that strict rules have to be followed regarding ALCOA+. In the manual paper-only systems, the data are vulnerable to the kinds of mistakes, skipping, and even modification of the data by unauthorized individuals (FDA, 2021). PAS X MES addresses these challenges due to its enforcement of real-time data capture, guided workflows and secure audit trails. The system capacity in keeping contemporaneous, accurate as well and attributable data goes a long way in decreasing the vulnerability witnessed in manual systems. This is in line with FDA policy

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regarding electronic records, 21CFR Part 11 and can help in adhering to EU GMP Annex 11 guidelines.

4.3 Operational Benefits of PAS-X Implementation

There are great advantages of operational efficiency after deploying PAS X. The use of its right-first-time production design, guided workflows, automated plausibility checks, and even notifications in EBR processes has enabled manufacturers such as AstraZeneca to keep operating without a hitch even in seasons of the COVID-19 disruption (Ratnayake, 2013). Connectivity with ERP (e.g., SAP), LIMS and automation systems (ABB, OPC UA) improves the smooth passage of information and uniformity in operations (Pare & Trudel, 2007). Such as in the scenario seen in the Mustafa Nevzat Pharmaceuticals kind of facility, when end-to-end MES was configured simply in half a year, leading to paper records being removed and replaced by electronic working.

Table 1: Impact of PAS-X MES on Data Integrity, Compliance and Operational Efficiency

Section	Key Findings
Impact on Data Integrity	-Removed errors of data transcription with auto-data capture and bar code reading. -Increased traceability having time-stamps and secure audit trails. -Duelled real-time input of data through embedded processes.
Regulatory Compliance Improvements	- Made FDA and EMA inspections easier using strong electronic batch records (EBR). - Decreased variations and enhanced auditable readiness. - System validation according to GAMP 5 and Annex11 of EU reporting.
Operational Benefits	-Saving on time and effort through right-first-time production and reduced batch release time delivery. - Smooth connection to ERP, LIMS and DCS systems. It is 20 to 30 percent in implementation to operate.
Case Study Examples	- Cell and Gene Therapy: Advancement of chain-of-identity and custody management. - Biologics Production: Global uniform workflows of the paperless operations. Greenfield Sites: In less than 6 months, attained FDA compliant readiness.

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4.4 Case Study Examples

4.4.1 Cell & Gene Therapy Manufacturers

A closer control of chain-of-identity and custody is made possible by PAS X MES, using workflows with barcode-based controls and barcode-based scanning of patients and materials essential to personalized therapies (Mimura & Fujii-Kuriyama, 2003). According to Lyell and Takeda, the digitalization of the processes and review-by-exception ability enable better batch consistency, confidence in meeting the compliance requirements, and speed of moving scale-up from clinical to large-scale production (Lobry, 1970).

The research proves that PAS X MES facilitates inspection of the regulatory body and minimizes deviations. The compliance capacities and technologies inherent to the system guarantee compliance with the regulatory requirements concerning the authenticity and privacy of data in the form of electronic-signatures and access management by roles. Moreover, GAMP 5-based validation of PAS X supports stable and vulnerable operation, which is the key to regulatory confidence. The case studies, of companies like that of Dr. Reddy, and Mustafa Nevzat Pharmaceuticals, affirm what has been said about MES implementation, that it is the vehicle to achieve right first time manufacturing and support the overall compliance posture.

4.4.2 Biologics and Vaccine Production

At Walvax Biotechnology in Yuxi, PAS X was adopted with the view of ensuring the aim of achieving a paperless factory, global standardization, faster batch release and support to compliance (Gu *et al.,* 2000). In the meantime, other manufacturers, such as AstraZeneca, involved in preparations of data integrity reported taking a serious shot upwards towards better data integrity, reporting that they had achieved the same through analogy of PAS X MES enabled digital workflows, despite the limitations of a pandemic setting (Hatleberg *et al.,* 2018).

4.4.3 Greenfield Pharmaceutical Sites

At Visakhapatnam, Dr. Reddy utilized their MES implementation called MES rollout that made it possible to align regulations on the first day of implementing the MES in full scope to capture as much data as possible and control the process (Stadhouders *et al.,* 2010). In the same line, the new plant of Sakamoto Yakuhin Kogyo managed to become paperless and compliant with manufacturing that tightly combined EBR, audit trail capture, and linkage with ERP and DCS systems.

In addition to being compliant, PAS X MES has major operational benefits. The system lowers the cycle times, boosts productivity and promotes the harmonization of manufacturing practices as it digitizes and standardizes the manufacturing processes. Its ease of fitting well with ERP, LIMS and automation systems highlights its appropriateness in the Pharma 4.0 environment. As an example, chain-of-identity and custody control supplied by PAS X is essential to patient-specific therapy in cell and gene therapy manufacturing.

Co-existence with MES such as PAS-X is a strategic move that the biomanufacturers are operating within an environment that is becoming more digitalized and regulated. With the

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shift of regulatory authorities toward a data-focused approach to auditing, the systems that bear the principles of data integrity and compliance in will prove invaluable. Also, it is possible that in the future, MES will be combined with artificial intelligence (AI) and advanced analytics, further expanding the predictive potential, optimising processes, and real-time decision-making.

Conclusion

The adoption of Werum PAS X MES in the bio manufacturing industry shows a great progress in providing an efficient solution to major concerns which surround data integrity and regulatory problems. Incorporation of ALCOA+ principles into its architecture provides PAS-X with secure, contemporaneous and traceable information management, successfully removing the drawbacks of earlier systems that used paper-based and hybrid systems. Compliance with FDA 21CFR Part 11, EU Annex 11 and GAMP 5 standards leads to the use of the system as a robust solution to readiness of audit and inspections by regulators. In addition to ensuring compliance, PAS-X facilitates efficiency through workflow automation, simplified procedures that minimize the occurrence of manual errors, improved batch release cycles through electronic batch records, audit trails, ERP and LIMS integration and so on. Real activities in biologics, vaccines and cell and gene therapy production encompassing case studies show its success in helping with Pharma 4.0 efforts and facilitating paperless manufacturing on a global scale.

In general, despite automation and technology challenges associated with quality assurance and patient safety enhancement, PAS X MES has the potential to ensure manufacturers are ready to scale in a digitally transforming regulatory environment in the future. It is therefore a strategic requirement of organizations in their quest to meet sustainable compliance levels and competitive edge in the contemporary biopharmaceutical production.

References

1. Assiri, M., & Humayun, M. (2023). A blockchain-enabled framework for improving the software audit process. *Applied Sciences*, *13*(6), 3437.
2. Bakhshi, T., & Ghita, B. (2021). Perspectives on Auditing and Regulatory Compliance in Blockchain Transactions. In *Trust Models for Next-Generation Blockchain Ecosystems* (pp. 37-65). Cham: Springer International Publishing.
3. Charoo, N. A., Khan, M. A., & Rahman, Z. (2023). Data integrity issues in pharmaceutical industry: Common observations, challenges and mitigations strategies. International journal of pharmaceutics, 631, 122503.
4. Drobnjakovic, M., Hart, R., Kulvatunyou, B., Ivezic, N., & Srinivasan, V. (2023). Current challenges and recent advances on the path towards continuous biomanufacturing. *Biotechnology Progress*, *39*(6), e3378.
5. Duan, C. (2022). On the appeal of drug patent challenges. Am. UL Rev., 72, 1177.
6. Frolov, T., Wossnig, L., & Jung, A. (2025). Digital Transformation in the Biopharmaceutical Industry: Rebuilding the Way We Discover Complex Therapeutics. In Biopharmaceutical Informatics (pp. 11-39). CRC Press.

Received: August 09, 2025

Volume 38 No. 7s, 2025
ISSN: 1311-1728 (printed version); ISSN: 1314-8060 (on-line version)

7. Futschik, M. (2016). Comparison of Electronic Batch Recording Systems in the pharmaceutical industry. TechnoPharm, 6(6).
8. Futschik, M. (2018). *Electronic Batch Recording Solutions*. Wiesbaden: Springer Fachmedien Wiesbaden.
9. Ghosh, P. K. (2023). Status of the Indian biopharmaceutical industry and way forward to be a dominant global player. MGM Journal of Medical Sciences, 10(2), 317-326.
10. Gu, Y. Z., Hogenesch, J. B., & Bradfield, C. A. (2000). The PAS superfamily: sensors of environmental and developmental signals. Annual review of pharmacology and toxicology, 40(1), 519-561.
11. Hass, V. C. (2003). Prozess automation in der Bioverfahrenstechnik. *Chemie Ingenieur Technik*, *75*(12), 1887-1887.
12. Hatleberg, C. I., Ryom, L., El-Sadr, W., Mocroft, A., Reiss, P., De Wit, S., ... & Franck, P. F. H. (2018). Gender differences in the use of cardiovascular interventions in HIV-positive persons; the D: A: D Study. Journal of the International AIDS Society, 21(3), e25083.
13. Hock, S. C., Kian, S. M., & Wah, C. L. (2020). Global challenges in the manufacture, regulation and international harmonization of GMP and quality standards for biopharmaceuticals. *Generics and Biosimilars Initiative Journal*, *9*(2), 52-64.
14. Isoko, K., Cordiner, J. L., Kis, Z., & Moghadam, P. Z. (2024). Bioprocessing 4.0: a pragmatic review and future perspectives. *Digital Discovery*, *3*(9), 1662-1681.
15. Kabir, M., Rana, M. R. H., & Debnath, A. (2024). The Role of Quality Assurance in Accelerating Pharmaceutical Research and Development: Strategies for Ensuring Regulatory Compliance and Product Integrity. Journal of Angiotherapy, 8(12), 1-11.
16. Kayes, A. S. M., Kalaria, R., Sarker, I. H., Islam, M. S., Watters, P. A., Ng, A., ... & Kumara, I. (2020). A survey of context-aware access control mechanisms for cloud and fog networks: Taxonomy and open research issues. Sensors, 20(9), 2464.
17. Koerber, S. A., Röhrich, M., Walkenbach, L., Liermann, J., Choyke, P. L., Fink, C., ... & Giesel, F. L. (2023). Impact of 68Ga-FAPI PET/CT on staging and oncologic management in a cohort of 226 patients with various cancers. Journal of Nuclear Medicine, 64(11), 1712-1720.
18. Kranjc, T. (2021). Introduction to laboratory software solutions and differences between them. Digital Transformation of the Laboratory: A Practical Guide to the Connected Lab, 75-84.
19. Lobry, C. (1970). Contro labilite des syste mes non lineaires. SIAM Journal on Control and Optimization, 8(4), 573.
20. Malheiro, V., Duarte, J., Veiga, F., & Mascarenhas-Melo, F. (2023). Exploiting Pharma 4.0 Technologies in the Non-Biological Complex Drugs Manufacturing: Innovations and Implications. Pharmaceutics, 15(11), 2545.
21. Miller, R., Whelan, H., Chrubasik, M., Whittaker, D., Duncan, P., & Gregório, J. (2024). A Framework for Current and New Data Quality Dimensions: An Overview. Data, 9(12), 151.

Received: August 09, 2025

Volume 38 No. 7s, 2025
ISSN: 1311-1728 (printed version); ISSN: 1314-8060 (on-line version)

22. Mimura, J., & Fujii-Kuriyama, Y. (2003). Functional role of AhR in the expression of toxic effects by TCDD. Biochimica et Biophysica Acta (BBA)-General Subjects, 1619(3), 263-268.
23. Misal, J. (2024). Blockchain-Enabled Incident Management Systems: A Framework for Immutable Audit Trails and Enhanced Security Controls. *Available at SSRN 5125047*.
24. Mullard, A. (2022). 2021 FDA approvals. Nat. Rev. Drug Discov., 21(2), 83-88.
25. Pare, G., & Trudel, M. C. (2007). Knowledge barriers to PACS adoption and implementation in hospitals. *International journal of medical informatics*, *76*(1), 22-33.
26. Passi, I., Salwan, S., & Kumar, B. (2023). US-FDA approved drugs in 2020 and 2021: a review. Mini Reviews in Medicinal Chemistry, 23(12), 1273-1297.
27. Pedro, F., Veiga, F., & Mascarenhas-Melo, F. (2023). Impact of GAMP 5, data integrity and QbD on quality assurance in the pharmaceutical industry: How obvious is it? Drug Discovery Today, 28(11), 103759.
28. Popa, A., Barbu, C. A., & Ionascu, A. E. (2023). The New Paradigm of Online Marketing: A Study of Generation Z Consumers' Behaviour and Their Attitude Towards Brands. In The 9th BASIQ International Conference on New Trends in Sustainable Business and Consumption (pp. 359-368).
29. Ratnayake, R. C. (2013). Sustainable performance of industrial assets: The role of PAS 55-1&2 and human factors. *International Journal of Sustainable Engineering*, *6*(3), 198-211.
30. Sabale, M. M., Pande, V. A., Tagalpallewar, A. A., Swami, A. G., Pawar, A. T., & Baheti, A. M. (2024). Maintaining data safety and accuracy through data integrity (DI): A comprehensive review. Research Journal of Pharmacy and Technology, 17(5), 2431-2440.
31. Saidi, H., Labraoui, N., Ari, A. A. A., Maglaras, L. A., & Emati, J. H. M. (2022). DSMAC: Privacy-aware Decentralized Self-Management of data Access Control based on blockchain for health data. *IEEE Access*, *10*, 101011-101028.
32. Sargiotis, D. (2024). Data Governance in Different Industries: Case Studies and Applications. In Data Governance: A Guide (pp. 327-337). Cham: Springer Nature Switzerland.
33. Sargiotis, D. (2024). Data Governance in Different Industries: Case Studies and Applications. In Data Governance: A Guide (pp. 327-337). Cham: Springer Nature Switzerland.
34. Sarkis, J., Kouhizadeh, M., & Zhu, Q. S. (2021). Digitalization and the greening of supply chains. Industrial Management & Data Systems, 121(1), 65-85.
35. Singh, M., & Solanki, P. R. (2022). An overview of legal and regulatory challenges of biological products. *Biomedical Product and Materials Evaluation*, 275-286.
36. Smith, S. A. (2012). A network planning process and inventory strategy for high-mix low-volume markets (Doctoral dissertation, Massachusetts Institute of Technology).
37. Stadhouders, R., Pas, S. D., Anber, J., Voermans, J., Mes, T. H., & Schutten, M. (2010). The effect of primer-template mismatches on the detection and quantification of nucleic

Volume 38 No. 7s, 2025
ISSN: 1311-1728 (printed version); ISSN: 1314-8060 (on-line version)

acids using the 5′ nuclease assay. The Journal of Molecular Diagnostics, 12(1), 109-117.

38. Stafford, J. E. H. (1998). LIMS: an automating or information technology?. Laboratory Automation & Information Management, 33(3), 163-168.
39. Ullagaddi, P. (2024). A Framework for Cloud Validation in Pharma. *Journal of Computer and Communications*, *12*(9), 103-118.
40. Yadav, S., & Suryawanshi, S. J. (2025). 3 Integration of cGMP &. Understanding Pharmaceutical Standards and Regulations: Insights Towards Best Practice, 40.
41. Yaqoob, T., Abbas, H., & Atiquzzaman, M. (2019). Security vulnerabilities, attacks, countermeasures, and regulations of networked medical devices—A review. IEEE Communications Surveys & Tutorials, 21(4), 3723-3768.
42. Zhang, Y. (2020). Mitigating Insider Threats in Enterprise Storage Systems: A Security Framework for Data Integrity and Access Control. International Journal of Trend in Scientific Research and Development, 4(4), 1878-1890.

Received: August 09, 2025