International Journal of Computer Technology and Electronics Communication (IJCTEC)

| ISSN: 2320-0081 | www.ijctece.com ||A Peer-Reviewed, Refereed and Bimonthly Journal |

|| Volume 8, Issue 4, July- August 2025 ||

DOI: 10.15680/IJCTECE.2025.0804018

Enterprise Asset Management Digitalization for Multi-Site Pharmaceutical Manufacturing a Transatlantic Oracle eAM Implementation

Sameel Syed

Principal I Application Analyst, Herbalife International of America, Inc., USA

ABSTRACT: Digitalization of enterprise asset management in pharmaceutical manufacturing is a strategic necessity for global companies. A unique case study on Oracle enterprise asset management was implemented in the manufacturing plants of a global pharmaceutical company in both Indianapolis, USA and the UK. The unified digital system established across these two sites provided synchronized schedules for preventative maintenance and spare parts inventory, while also ensuring 21 CFR Part 11 compliance for electronic records. The methodology used in this project included functional architecture design, cross-functional initiation management, and comprehensive change management amongst international sites. The results of this case study demonstrated how data-driven repair vs. replace decisions resulted in significant cost optimizations on both capital and operating expenditures; how there were no longer production shutdowns due to local stock outs; and how all 100% of employees were proficient in complying with electronic record management. This case study adds to the existing body of literature around Pharma 4.0 by offering an applicable framework to multi-site pharmaceutical companies wishing to harmonize asset management principles while remaining compliant on a global scale within their manufacturing operations.

KEYWORDS: Oracle eAM, enterprise asset management, digital transformation, pharmaceutical manufacturing, 21 CFR Part 11, preventative maintenance, multi-site manufacturing, Pharma 4.0, asset governance, predictive maintenance

I. INTRODUCTION

Because of how extensively regulated the pharmaceutical manufacturing industry is in the global economy, and because of the tremendous impact enterprise asset management has on product quality, patient safety, and the reliability of supply chains; it should be noted that only one out of five, or 20%, of biopharmaceutical firms have successfully achieved digital transformation to date compared to 35% of all businesses across all sectors [4]. The slow pace of digital improvements in this class of business can be attributed in part to the challenges of implementing new digital tools in an industry that has significant compliance requirements such as those prescribed by 21 CFR Part 11.

According to the International Society for Pharmaceutical Engineering (ISPE), for an organization to realize returns on their investment in digital transformation, a strategic approach to comprehensive enterprise asset management is essential. Precision and efficiency are critical to the production of life-saving medicines, from maintaining specific environmental parameters through HVAC systems to creating finished pharmaceutical goods. Organizations are increasingly implementing solutions for predictive maintenance and asset optimization that leverage real-time data analysis to maintain their competitive advantage.

In title 21 Regulations 11, the United States Food and Drug Administration sets forth the requirements for the use of electronic records and electronic signatures by pharmaceutical firms, which include creating time-stamped records that cannot be changed of all lifecycle events related to assets and quality. For multi-national firms that operate plants around the globe, implementing a unified strategy for governing assets that is compliant with regulations while accommodating specific local operational differences is extremely challenging.

A global pharmaceutical firm with flagship manufacturing plants located in Indianapolis, Indiana and the United Kingdom, addressed these challenges head-on. This firm was dependent on traditional, paper-based logbooks for tracking maintenance, validating equipment, and using spare parts inventory management systems. This method of record-keeping exposes an organization to risks including but not limited to human error, missing documentation, weaknesses due to the absence of audit trails, and a lack of visibility across sites. Preventive maintenance schedules were maintained in silos, there was a lack of coordination in spare parts inventory management between sites, and with

| ISSN: 2320-0081 | www.ijctece.com ||A Peer-Reviewed, Refereed and Bimonthly Journal |

|| Volume 8, Issue 4, July- August 2025 ||

DOI: 10.15680/IJCTECE.2025.0804018

increased regulatory focus, organizations are exposed to heightened compliance risks and challenges with traditional record-keeping methods.

This article describes the strategic digitalization effort to transform the organization's enterprise asset management with Oracle eAM implementation for the firm's transatlantic manufacturing footprint. As the primary functional architect responsible for leading this transformation effort, the author created and executed an integrated digital standard that synchronized preventive maintenance schedules and spare parts inventory across international borders while achieving compliance with the 21 CFR Part 11 requirements.

This article provides three primary objectives: first, to define the architectural approach and methodology for the implementation of Oracle eAM for multi-site pharmaceutical manufacturers; second, to evaluate the stakeholder management strategies that supported successful transatlantic alignment; and third, to showcase the measurable results achieved to develop a replicable structure for similar transformation projects within life sciences organizations.

II. LITERATURE SURVEY

2.1 Digital Transformation in Pharmaceutical Manufacturing

The pharmaceutical industry is being increasingly affected by the digital revolution. There are many partnerships between biotechnology firms and large pharmaceutical companies in Europe and the US. Research and development (R&D) is shorter now than ever before due to developments such as CRISPR technology and artificial intelligence, which have yielded both new methods of pharmaceutical manufacturing and innovative methods of conducting R&D. The need for better equipment and vast amounts of operational data is also increasing because of new requirements for virtual testing and digital documentation. Changes in population demographics globally (most notably among aging populations) along with continued focus on healthcare resilience because of COVID-19 are driving this change. Emerging markets are also increasing demand through globalization while more developed markets are putting increasing pricing pressure on companies. Companies are working to combat these pressures using state-of-the-art software to provide agility, compliance and efficiency via supply chain platforms using artificial intelligence; therefore digital transformation is key to success.

2.2 Pharma 4.0 and Asset Management

Pharma 4.0 is a term used to describe the evolution of the pharmaceutical manufacturing industry through the application of digital technologies. The most important element of Pharma 4.0 is that you must have "FAIR" Operational Data - FAIR means the Operational Data must be "Findable, Accessible, Interoperable, and Reusable" [1]. The Operational Data to support Pharma 4.0 will allow you to find, access, and share the data with others in a secure manner that meets compliance regulations, and will be structured to support compatibility between your systems to eliminate "silos" of Operational Data. The Operational Data will also be well-documented, which will provide opportunities for you to build a history of experiments or Artificial Intelligence (AI) models to validate your experimental or AI design they were developed using Operational Data.

2.3 Challenges in Traditional Pharmaceutical Asset Management

There are many challenges facing the pharmaceutical industry from communicating with patient care professionals via social media to streaming compliance regulations on their websites [7]. Digital Transformation is designed to address some of these issues. Pharmaceutical companies use many different types of equipment and grounds, over a long period of time. Some examples include, High-Performance Liquid Chromatography Systems, Centrifuges, Cleanroom Infrastructure and HVAC Units. Many of the challenges faced by pharmaceutical companies when managing their assets are as follows [2][5] :

- **Compliance Issues** - the pharmaceutical industry is one of the most highly regulated markets in the world, and is subject to strict certifications by the FDA, EMA and WHO. Companies who rely upon manual methods of tracking/material management are subject to potential; allowing for human error which could lead to non-compliance of at least one piece of equipment, leading to a product recall.
- **Lost Productivity vs. Equipment Downtime** - Unplanned equipment failures could cause unexpected shutdown of production and therefore cause unplanned downtime in the millions of dollars of lost production costs. In some cases, unplanned downtime of one production floor could delay an entire production batch's delivery, thus limiting the amount of product available to treat patients.
- **Data Silos** - Most companies keep their Maintenance Logs, Calibration data and Quality records in separate systems. Consequently, this lack of communication and lack of preventative maintenance creates a fragmented view of an asset's overall health and ultimately hampers effective management/decision-making. In a

| ISSN: 2320-0081 | www.ijctece.com ||A Peer-Reviewed, Refereed and Bimonthly Journal |

|| Volume 8, Issue 4, July- August 2025 ||

DOI: 10.15680/IJCTECE.2025.0804018

commissioned survey conducted by Forrester Consulting, 68% of all technology decisionmakers in pharmaceutical manufacturing indicated that their organization has significant issues with data silos that impede the effectiveness of the informed decision-making process.

- **Increasing Costs** - Reactive maintenance strategies create a significant burden for asset-heavy environments since they require an ever-increasing amount of maintenance to be performed, which leads to inefficiency in scheduling and leads to an increase in the cost of the overall asset maintenance program.

Benchmarking sessions conducted by the ISPE involving nine (9) peer pharmaceutical companies showed approximately half of the respondents had begun discussions with their contract manufacturing organizations on asset management, despite having their own internal asset management process. This represents a tremendous opportunity to maximize the level of integration of asset management throughout the pharmaceutical supply chain.

2.4 Enterprise Asset Management Systems and Integration

Pharmaceutical Manufacturing relies heavily on Enterprise Asset Management (EAM) systems to provide SaaS based work order management tools, maintenance scheduling (PM) tools, parts inventory management, and compliance with FDA regulations. The integration of IT systems with Product Lifecycle Management (PLM), Enterprise Resource Planning (ERP), and Manufacturing Execution System (MES) increases the level of traceability and provides the ability to schedule planned/proactive maintenance, thereby increasing the efficiency and transparency of the operation. However, asset assessment integration issues exist with Computerized Maintenance Management Systems (CMMS) due to poor data quality, lack of compatibility with other CMMS, or the existence of multiple CMMS as a result of Mergers & Acquisition.

2.5 AI and Predictive Maintenance in Pharmaceutical Asset Management

AI-Powered asset management is a significant leap for asset management because it uses algorithms and data analytics to solve the traditional problems associated with asset management. The main capabilities of AI-powered asset management include predictive maintenance by analyzing historical performance data of equipment to predict future equipment failures, automated compliance for maintaining accurate Audit-ready records of all asset management activities, holistic visibility through unified views of all the health of your Assets, and Optimizing Resources by providing recommendations for Maintenance and inventory management. 65% of the decision-makers in the pharmaceutical technology Industry have indicated that AI is their highest priority for predictive maintenance and that 59% of those surveyed will be increasing their spending on IoT for real-time tracking and auditing of assets.

2.6 Digital Twins in Pharmaceutical Manufacturing

The pharmaceutical industry is now adopting digital twin technology more and more, as it allows manufacturers to create virtual copies of their assets so that they can simulate, monitor and optimise them. Currently, only 17% of all manufacturers use digital twins at this time but 79% of all new projects include digital twins in order to improve collaboration between teams and improve the accuracy of product designs. Therefore, we can expect to see increased adoption in the future. Unfortunately, research has pointed out the challenges in implementing this type of technology for line manufacturing processes, necessitating an integrated approach to implementing these technologies, including people, infrastructure and operations [5].

2.7 Change Management in Manufacturing Digitalization

Digital transformation success hinges on people, making effective change management an important factor in manufacturing. As the complexity of each change increases, organizations must also adapt their existing change management processes to allow for greater flexibility and efficiency when implementing those changes. Existing manufacturing change management processes appear to be inadequate when trying to digitize or provide digital support for existing methods (e.g., digitizing asset management). A significant change management strategy is required to transition from paper to digital systems [4].

2.8 Research Gap and Contribution

This article provides an overview of how Oracle eAM has been implemented within pharmaceutical manufacturing sites in both the United States and United Kingdom. In addition, this article addresses existing literature gaps concerning the harmonization of EAM, stakeholder management, 21 CFR Part 11 compliance and change management strategy implementation within the pharmaceutical industry [6] [12]. The article contains a comprehensive case study as well as a methodology for replicating digital transformation within the pharmaceutical industry.

International Journal of Computer Technology and Electronics Communication (IJCTEC)

| ISSN: 2320-0081 | www.ijctece.com ||A Peer-Reviewed, Refereed and Bimonthly Journal |

|| Volume 8, Issue 4, July- August 2025 ||

DOI: 10.15680/IJCTECE.2025.0804018

III. METHODOLOGY

3.1 Research Approach

The method used in this research was a single-case study technique that is suitable for looking at current events in a non-experimental (real-world) setting, where it may sound difficult to distinguish between what is happening and where it is happening. Through this method, the details of how the implementation of Oracle eAM was carried out will be thoroughly evaluated, including the various types of technical architecture; how stakeholders were managed; and what strategies were put into place to achieve successful implementation (e.g. through use of change management).

3.2 Project Architecture and Planning

This transatlantic Oracle eAM implementation methodology utilized a structured phased approach that provides for technical robustness, regulatory compliance, and user acceptance at the two different international locations. The project architecture supports the creation of the Project-based Global Template (PBGT), which is an Oracle eAM standard configuration serving as the enterprise's one-source of truth while accommodating local operation conditions.

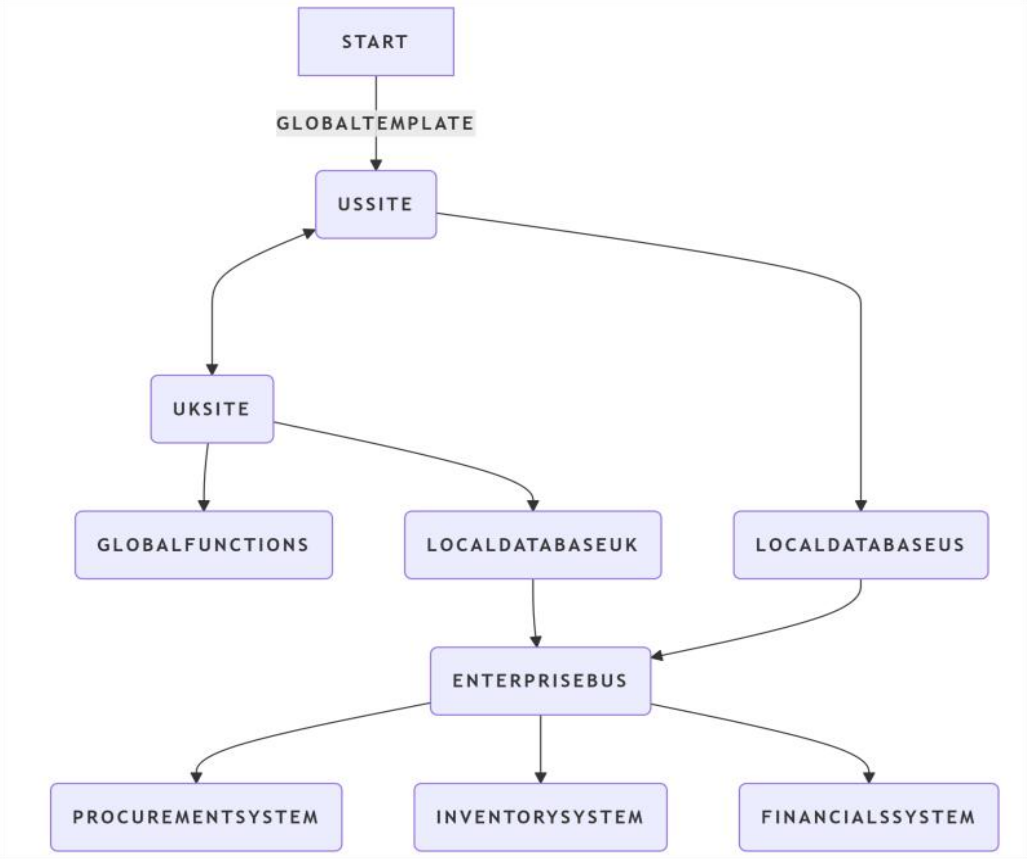

Figure 1: Oracle eAM Technical Architecture for Multi-Site Pharmaceutical Manufacturing

Phase 1 was a discovery phase that included multiple steps for collecting and documenting information. The steps for this phase included:

- Discovering the current preventative maintenance scheduling and procedures.
- Conducting an inventory analysis of spare parts at both locations.
- Observing and documenting the workflow for the physical logbook and any signature requirements.
- Finding any regulatory compliance gaps according to the requirements of 21 CFR Part 11.
- Interviewing maintenance engineers, plant managers, quality assurance staff, and production staff.
- Performing analysis of equipment hierarchies (how equipment is grouped together), Bills of Materials (the material required to build a piece of equipment), and Maintenance History (the record of when maintenance has been completed on a piece of equipment).

| ISSN: 2320-0081 | www.ijctece.com ||A Peer-Reviewed, Refereed and Bimonthly Journal |

|| Volume 8, Issue 4, July- August 2025 ||

DOI: 10.15680/IJCTECE.2025.0804018

The outcome of the discovery phase indicated there were significant variances in each of the site's maintenance documentation practices, spare parts coding, and equipment validation processes for each facility.

Phase 2 was the design of a global template, utilizing the information collected in phase 1. The following were included in the Oracle eAM system's configuration created from the Global Template:

- All equipment will have a common equipment numbering system and hierarchies at both facilities.
- All preventative maintenance schedules will be consistently defined based on the criticality of the equipment.
- All spare parts will be classified (i.e., coded) the same way at both facilities, with visibility to each other.
- There will be a common workflow structure for creating, approving, and executing work orders.
- The electronic signature requirements will be standardized and in compliance with 21 CFR Part 11.
- There will be integration points between existing Oracle ERP modules for purchasing and accounting.

The global template was designed to include configurable parameters so that each facility can maintain operational independence while allowing for the enterprise to maintain data consistency. This "configured not customized" design will allow for future upgrades and have continued compliance integrity.

Phase 3 was the implementation of Oracle E-Records functionality to allow for compliance with 21 CFR Part 11 regulations, which included:

- Unique User IDs and secured password authentication.
- Time-stamped audit trails for each date and time a record was created, changed, or deleted.
- Direct association between the system and records, which will not allow for the back-dating of records or undocumented changes in the records.
- Electronic signature requirements for specific transactions requiring explicit approval/signature.
- Authority check to ensure that only trained and authorized personnel could execute specific tasks.

The compliance architecture implemented has allowed us to comply with the "Digital Lockout" requirement—which states that all equipment must be validated before any manufacturing can take place.

3.3 Stakeholder Management Framework

A multi-layered stakeholder management framework was created to help government agencies coordinate their work. This created a multi-layered structure that most closely resembles the organizational structures in engineering, production, quality assurance, finance, and IT across two different countries. Global Steering Committee Liaison: The author served as the primary functional bridge between the Steering Committee of cross-functional executive members from Finance, Engineering, and IT to the users on the shop floor. The author translated the operational requirements of the users (shop floor) into strategic business cases. S/he reported regularly on the progress of implementation in relation to the 5-year business objectives. Additionally, the author facilitated decision-making regarding scope trade-offs/resource allocation; and presented risk assessments/mitigation strategies for the executive group to review.

- **Cross-Functional Orchestration:** The author implemented a "Quality-First" Digital Framework to resolve the conflicting objectives of Manufacturing Production's throughput objectives and Quality Assurance's "Digital Lockout" requirements for the validation of Equipment prior to release for production. The framework established appropriate workflows for validating equipment prior to release for production. The framework created real time visibility into the validation status of Equipment via Oracle eAM Dashboards. The framework defined appropriate escalation criteria that included a process for time-sensitive situations. The framework facilitated joint design sessions between representatives from Manufacturing Production and Quality Assurance for the purpose of reviewing the established workflows and developing the Equipment validation process.
- **International Operational Alignment:** The joint design sessions for functional expectations (e.g., design specifications) between the leadership in Indianapolis and the leadership in the UK occurred 50/50 between both locations (i.e., the U.S. and U.K.). Regulatory nuances (e.g., FDA vs. MHRA interpretations) required awareness of variances in regulatory requirements; and required the ability to accommodate terminology differences in manufacturing (e.g., enclosures vs. cages). The joint design sessions provided similar representation in both pilot groups and user acceptance testing.

3.4 Change Management and Training Strategy

A Comprehensive global user training program has addressed the various needs of maintenance engineers, plant managers and quality personnel, which is shown in below Table 1 [8]:

| ISSN: 2320-0081 | www.ijctece.com ||A Peer-Reviewed, Refereed and Bimonthly Journal |

|| Volume 8, Issue 4, July- August 2025 ||

DOI: 10.15680/IJCTECE.2025.0804018

Table 1: User Training Program Structure and Success Metrics

User Group	Training Focus	Delivery Method	Success Metrics
Maintenance Engineers	Work order execution, parts recording, electronic signatures	Hands-on workshops, job aids, floor walkthroughs	100% proficiency in electronic documentation
Plant Managers	Workflow approvals, reporting, team oversight	Instructor-led sessions, dashboard training	Accurate approval rates, team compliance
Quality Assurance	Audit trail review, exception management, validation verification	Specialized sessions, scenario-based training	Zero compliance findings
Production Staff	Equipment status visibility, validation verification	Just-in-time training, visual management	Proper handoff procedures

The cultural shift from being paper-based to using digital-only processes as a part of the change management program will be addressed by using early adopter programs, high visibility of leaders supporting the changes, reward and recognition programs, peer mentorship, and open internal communications connecting digitalization with quality and patient safety.

IV. RESULTS

4.1 Technical Architecture Outcomes

One of the successes of unifying preventative maintenance and spare parts inventory on a global scale has been to streamline both of these processes. Global harmonization of preventative maintenance has developed Resource Identification Standards that provide standardized maintenance schedules for all Critical Equipment, eliminate duplicate definitions of equipment, automate the generation of work orders, and consolidate Maintenance History records for equipment. Spare parts now have increased visibility through improved real-time visibility of inventory across US and UK locations, standardized categorization of spare parts, a reduction in duplicate spare parts inventory, and identification of opportunities to substitute spare parts across locations when necessary.

4.2 Financial Outcomes

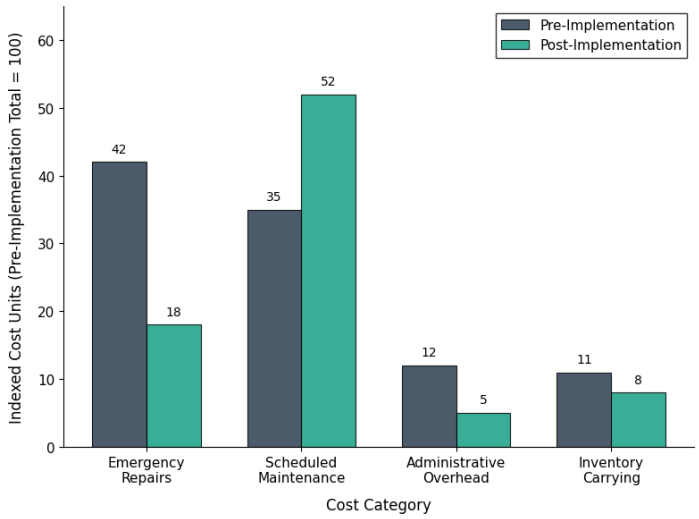

Figure 2: Maintenance Cost Distribution Pre- and Post-Implementation

4.3 Supply Chain Resilience Outcomes

The visibility of spare parts across the globe at multiple locations (specifically between America and England) has enhanced inventory control and supply chain robustness. Some of the advantages of this include reducing the carrying costs associated with holding duplicate critical spare parts and better optimizing the on-hand safety stock levels,

| ISSN: 2320-0081 | www.ijctece.com ||A Peer-Reviewed, Refereed and Bimonthly Journal |

|| Volume 8, Issue 4, July- August 2025 ||

DOI: 10.15680/IJCTECE.2025.0804018

resulting in less obsolete inventory on hand and a lower requirement for working capital. No shutdowns due to a lack of spare part availability, emergency cross-site shipments occurring within 1-2 days and identifying previously unknown substitute parts for the maintenance team.

4.4 Compliance and Security Outcomes

1. **No Documentation Errors:** No documentation errors/unsigned documents in regards to the digital architecture are completely gone; therefore, there have been no instances of back-dated records or undocumented modifications, as well as automated verification of an operator's training status before performing a critical action, and the use of the same workflow for approval of all maintenance procedures.
2. **Audit Readiness:** The use of a complete audit trail allowed for a quick response to under-inspection inquiries; therefore, the amount of time needed to prepare for an audit has decreased from several weeks to just hours! In addition to this, audits have not found any violations of documentation integrity and have allowed for greater confidence in data submitted to regulation agencies.
3. **Safeguarding the Manufacturing Process:** Only authorized, trained personnel are allowed to do maintenance; therefore, verification of all personnel doing maintenance is supported by implementing the above three principles. In addition to this, all activity is traceable, no unauthorized changes will happen, and duties are segregated according to what exists in the system.

V. DISCUSSION

5.1 Interpretation of Findings

The case study suggests that Oracle eAM has been implemented effectively (since 2011) to overcome challenges faced when managing multiple site pharmaceutical company assets. The use of a Global Template has enabled harmonized governance of assets across countries while respecting the differences in how each country operates. Evidence was presented in the form of a reduction in both emergency repairs and administration costs, similar to what is found in the literature regarding proactive maintenance strategies, and the successful achievement of full compliance with electronic records by the entire workforce due to the use of comprehensive strategies to manage change related to transformation of a workforce, further demonstrates how comprehensive management of change has enabled workforce transformation by the implementation of change management programs. Additionally, the success of the training program demonstrates how the value of peer leadership, alignment of the training program with the organizational goals, and ongoing support are critical components within digital transformation initiatives [11][13].

5.2 Comparison with Existing Literature

This case study's results both confirm and clarify previous studies about drug asset management. The implementation of FAIR (Findable/Accessible/Interoperable/Reusable) operational data aligns with ISPE's Pharma 4.0 framework. With regard to findability, this project provided standardized metadata to improve finding data; in terms of accessibility, secure role-based access controls enabled users to have access to what they needed it so as to facilitate out-of-operations data use.

The results from this project also validated the advantages of integrating IT systems. Numerous studies have shown that integrating EAM Systems with ERP systems and/or other enterprise technologies will provide traceability and reduce the effort of coordinating between these systems. The benefits of integrating EAM with ERP are supported by this case study provided empirical evidence in a pharmaceutical manufacturing environment demonstrating improvements in inter-site visibility and supply chain resilience.

This case study also shows the gap between current capabilities and the future of AI that are discussed in literature. The implementation project created a strong data foundation for future AI applications; however, among the initial goals of this project, there were no plans for predictive maintenance capabilities [9]. This suggests that organizations would benefit from taking a staged approach in adopting AI technology — laying the foundation for standardized operational data prior to deploying advanced analytics.

5.3 Theoretical Implications

This case study helps to advance our theoretical knowledge of the digitalization of enterprise asset management in multiple ways. The first is empirical evidence for using a Global Template as an architecture solution that provides a framework to balance standardization and localization in EAM multi-sited implementations. The second contribution is to demonstrate how rules regarding 21 CFR Part 11 compliance can be applied in a transatlantic scenario (e.g., integrating local regulatory compliance requirements [FDA vs. MHRA] into one framework) [10]. Thirdly, it

| ISSN: 2320-0081 | www.ijctece.com ||A Peer-Reviewed, Refereed and Bimonthly Journal |

|| Volume 8, Issue 4, July- August 2025 ||

DOI: 10.15680/IJCTECE.2025.0804018

contributes to the change management theory by identifying four specific workforce transformation enablers within a regulated manufacturing setting: respect for legacy practices; peer leadership; linking to organizational purpose; and providing support.

5.4 Practical Implications

This case study contains useful recommendations for pharmaceutical companies that are contemplating trying to function differently. The first recommendation is to conduct a comprehensive discovery process that identifies any gaps, so that those gaps can help influence the design of their Global Templates. Additionally, it is suggested to configure instead of customizing solutions – so that any future upgrades and modifications will be easier to implement as local changes are required on an ongoing basis.

To successfully manage stakeholders, it will be necessary to orchestrate all the different stakeholders and establish strong relationships with each of them, not just from a technical perspective but also from a social perspective. Second, workforce transformation should take a holistic approach and develop cultural transformations in addition to training, role model leadership among peers, and providing ongoing support. Finally, developing a solid data infrastructure will create the best opportunity for the future integration of AI-based asset management, even though AI-based asset management could not be implemented until predictive functions are available.

5.5 Limitations and Future Research

The current research faces a few constraints. To start, this case study covers two locations within one company that may not apply well to other situations. Second, there were no advanced prediction tools, nor was there the ability to use IoT tracking devices during implementation; therefore, there is no way to examine how these new technological advances could have changed implementation analysis; and finally, determining if the results of the program will last beyond the original time frame will need additional research. Future studies should explore how well the Global Template strategy could be applied to additional sites/companies, continue examining the integration of AI and IoT capabilities to Oracle eAM in the pharmaceutical industry and perform long-term studies on the sustainability of EAM digitalization and its effect on workforce transformation.

VI. CONCLUSION

In the case study of Oracle's eAM (Enterprise Asset Management) implementation at multiple manufacturing sites in the US and UK by a global pharmaceutical organization highlights the substantial importance of digitalize strategic enterprise asset management within multi-site enterprises (MSEs). As outlined, the establishment of a harmonized asset governance model can occur by utilizing a Global Template model, which provides a balance between the enterprise standards and operational conduct standards, in turn aligning with the active management of maintenance and inventory and synchronizing with maintenance schedules.

The compliance with 21 CFR Part 11 of the Federal Regulations not only demonstrates regulatory compliance but also enhanced operational efficiencies through the provision of detailed equipment history that will facilitate equipment analysis and planning. Successful transformation necessitates high-level stakeholder orchestration across cross-functional and cross-location stakeholders, thus utilizing appropriate relationship management and communication to align expectations and resolve issues. Additionally, transitioning employees to a digital-first approach from a traditional paper-based process requires a strong change management framework that will address the skills, culture, and purpose of the organization while also providing tailored training to support the experienced workforce.

The financial and operational benefits associated with digitalize enterprise asset management will also lead to improved decision-making through the allocation of capital and decreased costs because of data-driven decisions. As a replicable framework for multi-site pharmaceutical manufacturers, this case study provides an integrated approach to technical architecture, stakeholder engagement, regulatory compliance, and workforce development. The baseline foundation provided to the manufacturer will enable the organization to realize full benefits of future innovation, such as predictive maintenance, the Internet of Things (IoT), and artificial intelligence (AI), which in turn will continue to drive asset performance upon the global footprint of the manufacturer.

| ISSN: 2320-0081 | www.ijctece.com ||A Peer-Reviewed, Refereed and Bimonthly Journal |

|| Volume 8, Issue 4, July- August 2025 ||

DOI: 10.15680/IJCTECE.2025.0804018

REFERENCES

1. International Society for Pharmaceutical Engineering. (2025). Pharma 4.0: Smarter asset management in pharma manufacturing. ISPE Pharmaceutical Engineering.
2. International Society for Pharmaceutical Engineering. (2024). Peer companies share knowledge on CMO asset management and obsolescence management. ISPE Pharmaceutical Engineering.
3. ARC Advisory Group. (2025). Digital transformation accelerates growth in the pharmaceutical & biotech industrial software market. ARC Industry Research.
4. Nielsen, M. K., & Tambo, T. (2025). Line manufacturing engineering change management: Contrasting views on modelling and governance towards a research agenda. In Human-Centered Technology Management for a Sustainable Future (pp. 445-453). Springer.
5. GL Tec. (2025). Why biopharma needs AI-driven asset management for the future. GL Tec Industry Articles.
6. Rammo, J. P., Mujcinovic, S., & Zaeh, M. F. (2024). Manufacturing change management - A case study-based analysis of change processes in industrial practice. Proceedings of the Conference on Production Systems and Logistics (CPSL 2024).
7. HTF Market Intelligence. (2025). Pharmaceutical Asset Performance Management (APM) industry report. HTF Market Research.
8. Rammo, J. P., Stang, J., Agyekum, E., & Zaeh, M. F. (2024). Requirements elicitation for a flexible, digital, and methodological manufacturing change management based on a literature review and expert interviews. IFAC-PapersOnline, 58(27), 1090-1095.
9. Hexagon. (2025). Survey: European pharmaceutical manufacturers bet on AI, digital twins and automation to overcome silos and compliance challenges. Hexagon Press Release.
10. Food and Drug Administration. (1997). 21 CFR Part 11: Electronic records; electronic signatures. Federal Register.
11. Gartner, Inc. (2024). Magic Quadrant for enterprise asset management software. Gartner Research.
12. Deloitte. (2025). 2025 global life sciences outlook: Forging a bold path forward. Deloitte Insights.
13. PwC. (2024). Asset management 2026: The path ahead for pharmaceutical manufacturing. PwC Health Industries Reports.