

AI-Augmented SAP EWM For Predictive Warehouse Optimization In Life Sciences Supply Chains

Nikhil Kumar

Jawaharlal Nehru Technological University, Kakinada, AP, India

Abstract

The supply chains of life sciences are very controlled and entail sensitive products and complicated procedures, which greatly determine the functions at the warehouse. This has facilitated the SAP Extended Warehouse Management (EWM) to become popular in such settings in that it allows standard, auditable and compliant operations to be deployed in the warehouse. Nevertheless, optimization systems developed by SAP EWM are predominantly rule-based, which prevents the opportunity to predict changes in the processes occurring in warehouses, and respond proactively to disruption. Artificial intelligence offers predictive and reactive decision support on the basis of past and current warehouse data. This review describes the ways in which artificial intelligence can be implemented to enhance SAP EWM to provide predictive warehouse optimization within the supply chains in the life sciences. The conceptual framework is based on the synthesis of peer reviewed research on the sphere of warehouse management systems, logistics analytics and controlled supply chain activities. The implications on the operational performance are also discussed in the review, and compliance assurance and adoption by the organizations are also discussed in the review. Lastly, the research directions are also discussed for future research wherein the explainability and validation are proposed as the conditions of scalable and reliable warehouse management using AI-enhanced warehouse management. The results can be summarized as offering an academic unified view of the implementation of artificial intelligence within the warehouse system in life sciences indicating both the opportunity and the barriers of predictive warehousing in controlled supply chains.

Keywords: Artificial Intelligence; SAP Extended Warehouse Management (EWM); Predictive Warehousing; Life Sciences Supply Chain; Regulatory Compliance (21 CFR Part 11)

Introduction

Life sciences supply chains are among the most complex and strictly regulated logistics systems. The compliance requirements, product integrity and operational efficiency meet at the main control points in the operation of the pharmaceutical, biotechnology and medical device warehouse operations in the control points of the pharmaceutical, biotechnology and medical device supply lines warehouse operations. The facilities must deal with high value and temperature sensitive products, batch and serial traceable products, and extensive documentation in order to satisfy the regulatory audit and recall preparation [1]. Computer systems in regulated life sciences environments must comply with highly restrictive regulations e.g 21 CFR Part 11 that regulates electronic records and electronic signatures in pharmaceutical operations. These policies impose data integrity, traceability, auditability, and system validation requirements, which in its turn influences how AI-based decision-support systems can be developed and implemented into warehouse management systems. It possesses a greater variability of demand globally, user-designed drugs and multi-channel distribution models thus placing a lot of strain on the activities of the warehouse to act in a timely manner without affecting the discipline in the process. Enterprise warehouse management systems SAP Extended Warehouse Management (EWM) have been extensively applied to structured and controlled settings to fulfill these needs, since they encompass all processes, audit and integrate with enterprise resource planning systems. SAP EWM can maintain inbound, outbound and internal operations within the warehouse and enable the traceable and validated

operations depending on the regulatory requirements [2]. In spite of these advantages, most of the operational decisions in SAP EWM are preset and prescribed by rules and set parameters that affect most of these including replenishment planning, labour allocation and exceptions. These strategies do have shortcomings with regard to disruptions, fluctuation of demand and real time performance optimization.

AI has become one of the major facilitators of predictive and adaptive decision-making within the supply chain and logistics. The studies have proposed that machine learning and enhanced analytics can improve predictive accuracy, resource consumption and operational resilience in extremely demanding situations [3], [4]. AI has been applied to demand forecasting, cold-chain monitoring, and risk detection in a supply chain of life sciences, which indicates that it can also become useful in improving the effectiveness of operations and regulatory compliance [5]. The academic sources however have never found a review that aims to concentrate on the methodical synthesis of the AI and SAP EWM under the life-sciences context of predictive warehouse optimization. To fill this gap, this paper focuses on the analysis of the available research, identification of the trends of integration, and a conclusion about the opportunities and challenges of AI-based SAP EWM solutions.

Literature Review

The long-standing interdependence among receiving, storage, picking, and shipping decisions shows that warehouse performance depends on closely connected operational choices; however, many studies have examined these decisions separately, and this limits the generalizability of end-to-end findings in real warehouse settings [6]. Other review articles on warehouse design and performance evaluation, also indicated that the computational decision support needed to integrate layout, capacity and control policies together, but not to optimize each of the layers independently [7]. Order picking is the most significant cost driver in this literature; conventional literature review studies have found the interaction between batching, zoning, routing, and storage assignment and have noted that real systems in the world rarely adopted globally optimal combinations of these elements because of shifting demand and labour constraints [8].

These problems have been repackaged in high-velocity, time-constrained fulfillment, variability and short-horizon planning where the premium of predictive control (e.g. forecasting the congestion, replenishment needs, and wave release timing increases (according to recent surveys of warehousing) [9]. Reviews focused on automation, such as AS/RS reported that the performance of the static design assumptions during dynamic operation is poor as well as the learning-based policies, which is to learn an adaptive policy to stochastic arrivals and equipment conditions, was encouraged [10]. At the same time studies on supply-chain analytics also found that information asymmetry and nonlinearity of performance (i.e. exactly the qualities desirable to predict workload, slotting pressure, and exception risk) in the task orchestration of EWM can be effectively modelled using machine-learning approaches [11].

Conceptual Framework for AI-Enabled SAP EWM in Life Sciences Warehousing

Internet-of-Things-enabled supply chains have improved real-time observability through RFID and telemetry, thereby supporting closed-loop control; however, they have also introduced major data quality, integration, and governance challenges, which are critical when extending AI services to SAP EWM transactions and event logs [12]. Better bibliometric evidence is required to confirm the reality of accelerated expansions of AI applications in the supply chain processes and reiteratively indicate gaps in maturity of deployment, consistency in evaluation and interpretability as used in the operational decision making [13]. Such developments in Industry 4.0 architectures are also seen by

the industrial AI views by saying that the quantifiable value is offered in matching data streams, model lifecycle operations, and shop-floor / warehouse implementation loops rather than deploying differentiated predictive models [14]. Finally, interpretability has become an operationalized need (not an ethical ideal) in high-stakes logistics settings, as opaque models can also create brittle automation, inadequate auditability, and inadequate exception handling weaknesses, which are even more dire in regulated life-sciences supply chains [15].

Although this review takes a system-level perspective, it needs to be contextualized the items of artificial intelligence methods that are commonly implemented within such settings. Gradient boosting models and random forests are examples of supervised machine learning algorithms that have been used in demand forecasting and workload prediction in warehouse applications and supply chain applications; time-series forecasting of inventory and replenishment demand is offered by deep learning models, such as recurrent neural networks (RNNs) and long short-term memory (LSTM) networks. Reinforcement learning methods have also been used to solve dynamic decision problems such as finding routes and allocating tasks in stochastic environments. Additionally, computer vision techniques that utilize convolutional neural networks (CNN) are also used in warehouse management with the objective of automated identification problems, such as pallet label reading and product integrity verification. All these examples indicate that AI use with SAP EWM is not a particular field of abstract analytics but may take into account numerous, task-related structures depending on operational demand.

Specifically, the enterprise systems such as SAP have also begun to be enhanced with the computer vision capabilities in a way that they can automatically facilitate warehouse operations, e.g., labeling the pallets with the aim of facilitating automated registration of the goods receipt, which demonstrates the feasibility of the AI augmentation in real EWM environment.

Conceptual Framework for AI-Powered SAP EWM in Life Sciences Warehousing

Since it is a review article, the framework will not require the creation of a new algorithm or a new system but it is expected to be grounded on the already existing research and report on the research. It is oriented on the abstract clarity, compliance, and reality. The AI in SAP EWM should also be implemented in accordance with the regulatory requirements such as 21 CFR Part 11 in particular, audit trail, system behavioural control, and validation of the model. To enable the use of AI models in such environments, they must be explainable, version-controlled and subjected to validation procedures similar to those of the standard software systems to guarantee that their outputs can be relied upon in the process of auditing by the regulatory bodies.

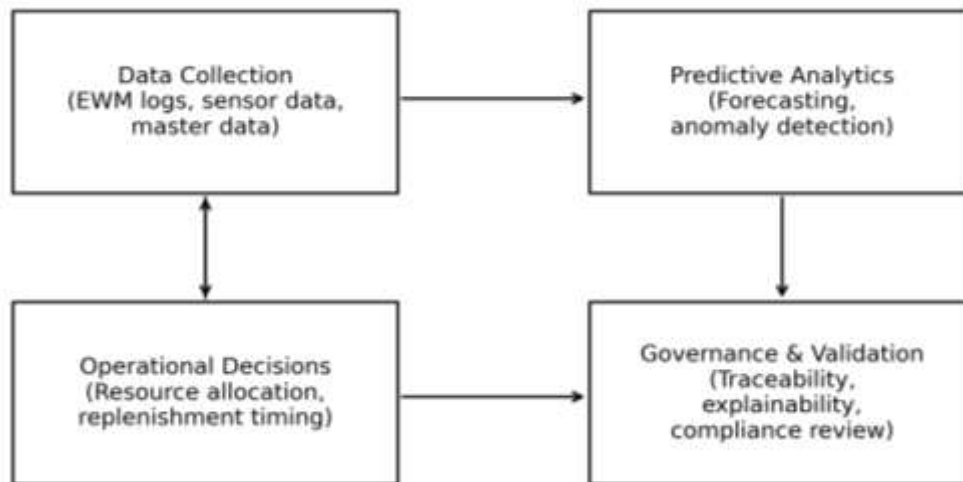
In addition to the technical integration, regulatory compliance is one of the characteristic components of AI application in SAP EWM in the context of a life science. The 21 CFR Part 11 and the extended GxP guidelines requires that digital systems have validated states and that they preserve data integrity” “record advisory measures” is unclear; likely “advisory controls as well as furnishing full audit trails. AI models should be structured as such and deployed to controlled settings with record advisory measures, version control and explainability measures to provide audit readiness. These criteria have a profound impact on system design and prefer advisory AI systems to systems that make independent decisions. In the light of such considerations, the conceptualization of AI-driven SAP EWM in life sciences warehousing can be depicted as shown below.

Figure 1. Conceptual framework for AI-enabled SAP EWM



Figure 1 presents the positioning of AI at the high level around SAP EWM. SAP EWM is the implementation and transaction layer wherein real warehouse operations such as inventory flows, warehouse operations along with those compliance-based events are recorded [16], [19], [20]. They can then be fed into an analytics and AI layer where they are predictive models that forecast the trends based on the historical trends and near real-time trends. The decision-support insights of this layer are the workload predictions, replenishment risk warnings, and exception forecasts. Above all the deliverables pushed by AI are advisory rather than autonomous, which preserves the role of SAP EWM as system of record, as well as meets regulatory expectations.

Figure 2. Predictive warehouse optimization lifecycle for AI-augmented SAP EWM



The simplified predictive warehouse optimization lifecycle is depicted in figure 2. The cycle begins with a structured process of data collection from SAP EWM and related sources. Predictive analytics transform these data into forward-looking insights. These insights are applied to operational decision-making, such as resource scheduling and replenishment. A governance and validation layer also offers both traceability and explainability and compliance analysis before insights influence implementation. This lifecycle reflects best practices in enterprise analytics and managed supply chain research [23] -[29].

Insights and Implications for Predictive Warehousing in Life Sciences

It is a literature review synthesis that gives an overview of operational and governance implications of AI-enhanced SAP Extended Warehouse Management (EWM) in life sciences supply chains. Among the findings of the studies to which the predictive decision

support can be attributed, one should mention the fact that when superimposed on the enterprise execution systems, it improves the functioning of warehouses by mitigating the uncertainty in the plans of labor, timeliness of replenishment, and the management of exceptions [25], [26]. Predictive models provide insight into changing operational risks and workload before they happen, which would not be the case in fixed rule-based environments, where a quick response is costly, particularly within the regulated environment.

Another important point emphasized in the literature is that value realization depends on the effective integration of AI insights into decision-making processes. The research shows that advisory integration when the results of AI are used to recommend or advise the planners and supervisors but not to direct the implementation is more acceptable and less risky in the operations [28]. This measure is in line with the role of SAP EWM as a proven system of record where forecasts may be used in order to complement and not supplant set compliance controls.

The laws of regulatory compliance (such as 21 CFR Part 11) in the fields of life sciences demand that systems based on artificial intelligence be well-equipped with an audit trail, ensuring that data integrity is maintained and the decision-making process is supported by the proven process. Therefore, explainability, traceability, and human control should be used to implement AI in SAP EWM to make predictive insights that can withstand regulatory scrutiny. This supports the necessity of keeping AI as a regulated decision layer as opposed to an autonomous implementation system.

The monitoring of the cold-chain and exception forecasting (when the early notification can prevent loss of products and regulatory violations [27]) is particularly put into productive use in the life sciences perspective as predictive analytics. Nevertheless, the analysis of evidence is also concerned with the existence of controlling tools, such as explainability, traceability, and human control, to make certain that the excessive dependence on the output of the models could be averted and audit acceptability could be ensured [29]. All these connotations collectively indicate that AI-augmented SAP EWM will become more efficient and compliant when deployed as a monitored decision-support layer, as opposed to a distinct optimization engine.

Future Research Directions

Even though the literature reviewed has a high discrepancy in the intelligence-driven SAP Extended Warehouse Management (EWM), certain gaps still exist in the literature that are subject to systematic research. One of the main directions is linked to the creation of explanation-ready and explainable AI models that would be customized to be introduced into the controlled warehouse setting. Even though explainable AI has been vigorously studied in the general context, not much effort has been undertaken to explain how model outputs is to be translated into feasible warehouse choices such as replenishment priority or allocation of labour, particularly when regulatory audits are at play [30], [31]. The study should consider conducting future research on domain specific mechanisms of explanation that are consistent with those of warehouses and compliance documentation practices.

The second is the constraint aware and hybrid optimization methods. Hard regulations on temperature, expiration, serialization and segregation control life sciences warehouses. These restrictions have not been as extensively explored, but treating them as a component of learning and optimization models, rather than post-processing restrictions, is one possibility. Theory-based and hybrid AI-based systems would boost the resilience and regulatory consistency and remain predictive [32].

Third, it is necessary to possess empirical research that will compare the features of organizational and human-AI interaction. Most existing studies focus on algorithmic

performance; however, successful implementation also depends on human factors such as planners' trust in the system, the interpretability of model outputs, and accountability in decision-making. Longitudinal case studies should be conducted on the collaboration of the staff at the warehouse with the AI-supported SAP EWM processes, which would be a useful tool to grasp the impediments to adoption and success criteria [33].

Finally, standardized evaluation systems of AI-enhanced warehouse systems could be developed in future research. The best measures that would capture efficiency, resilience, compliance impact and explainability would enable the comparison of studies with one another and make evidence-based deployment choices in life sciences supply chains.

Conclusion

The review has examined how artificial intelligence can be utilized to augment the SAP Extended Warehouse Management to enable predictive warehouse optimization in the life sciences supply chain. Based on the literature, product criticality, compliance requirements and operational uncertainty present some unique challenges facing warehouses in this regulated environment. SAP EWM has a robust and auditable implementation foundation, and the optimization is largely rule-based, and as such the rules do not allow a dynamic response to changing conditions.

The synthesis of the literature review shows that the work of warehouses can be optimized using predictive analytics relying on AI and significantly enhancing the ability to forecast the work, replenishment plans, and detect risks early. Remarkably, the evidence under analysis suggests that value realization is attained when AI is introduced as a controlled decision-support, which does not replace the SAP EWM implementation logic but complements it. Validated processes should incorporate predictive insights, which are traceable, explainable and human controlled to attempt to ensure compliance and operation reliability.

The illustrations and conceptual framework applied in this review bring together the fragmented bodies of research and outline how the AI augmentation can be established around SAP EWM when it is applied to the life sciences. The paper highlights both the fields of achieving efficiency gains and the compliance assurance by focusing on predictive capability, alignment of governance and regulation, and the issues of explainability, validation, and adoption by the organization would also be addressed in the future studies.

References

1. Shah, N. (2004). Pharmaceutical supply chains: Key issues and strategies for optimisation. *Computers & Chemical Engineering*, 28(6-7), 929-941. <https://doi.org/10.1016/j.compchemeng.2003.09.022>
2. Jacobs, F. R., & Weston, F. C. (2007). Enterprise resource planning (ERP)—A brief history. *Journal of Operations Management*, 25(2), 357-363. <https://doi.org/10.1016/j.jom.2006.11.005>
3. Waller, M. A., & Fawcett, S. E. (2013). Data science, predictive analytics, and big data: A revolution that will transform supply chain design and management. *Journal of Business Logistics*, 34(2), 77-84. <https://doi.org/10.1111/jbl.12010>
4. Choi, T.-M., Wallace, S. W., & Wang, Y. (2018). Big data analytics in operations management. *Production and Operations Management*, 27(10), 1868-1883. <https://doi.org/10.1111/poms.12838>
5. Badia-Melis, R., McCarthy, U., Ruiz-García, L., Garcia-Hierro, J., & Robla Villalba, J. I. (2018). New trends in cold chain monitoring applications—A review. *Food Control*, 86, 170-182. <https://doi.org/10.1016/j.foodcont.2017.11.022>

6. Gu, J., Goetschalckx, M., & McGinnis, L. F. (2007). Research on warehouse operation: A comprehensive review. *European Journal of Operational Research*, 177(1), 1–21. <https://doi.org/10.1016/j.ejor.2006.02.025>
7. Gu, J., Goetschalckx, M., & McGinnis, L. F. (2010). Research on warehouse design and performance evaluation: A comprehensive review. *European Journal of Operational Research*, 203(3), 539–549. <https://doi.org/10.1016/j.ejor.2009.07.031>
8. de Koster, R., Le-Duc, T., & Roodbergen, K. J. (2007). Design and control of warehouse order picking: A literature review. *European Journal of Operational Research*, 182(2), 481–501. <https://doi.org/10.1016/j.ejor.2006.07.009>
9. Boysen, N., de Koster, R., & Weidinger, F. (2019). Warehousing in the e-commerce era: A survey. *European Journal of Operational Research*, 277(2), 396–411. <https://doi.org/10.1016/j.ejor.2018.08.023>
10. Roodbergen, K. J., & Vis, I. F. A. (2009). A survey of literature on automated storage and retrieval systems. *European Journal of Operational Research*, 194(2), 343–362. <https://doi.org/10.1016/j.ejor.2008.01.038>
11. Carbonneau, R., Laframboise, K., & Vahidov, R. (2008). Application of machine learning techniques for supply chain demand forecasting. *European Journal of Operational Research*, 184(3), 1140–1154. <https://doi.org/10.1016/j.ejor.2006.12.004>
12. Ben-Daya, M., Hassini, E., & Bahroun, Z. (2019). Internet of Things and supply chain management: A literature review. *International Journal of Production Research*, 57(15–16), 4719–4742. <https://doi.org/10.1080/00207543.2017.1402140>
13. Riahi, Y., Saikouk, T., Gunasekaran, A., & Badraoui, I. (2021). Artificial intelligence applications in supply chain: A descriptive bibliometric analysis and future research directions. *Expert Systems with Applications*, 173, 114702. <https://doi.org/10.1016/j.eswa.2021.114702>
14. Lee, J., Davari, H., Singh, J., & Pandhare, V. (2018). Industrial artificial intelligence for Industry 4.0-based manufacturing systems. *Manufacturing Letters*, 18, 20–23. <https://doi.org/10.1016/j.mfglet.2018.09.002>
15. Rudin, C. (2019). Stop explaining black box machine learning models for high-stakes decisions and use interpretable models instead. *Nature Machine Intelligence*, 1, 206–215. <https://doi.org/10.1038/s42256-019-0048-x>
16. Tsai, W. T., Sun, X., & Chen, J. (2012). A scalable and self-manageable cloud service architecture. *IEEE Transactions on Services Computing*, 5(4), 508–521. <https://doi.org/10.1109/TSC.2012.25>
17. Akidau, T., Balikov, A., Bekiroğlu, K., Chernyak, S., Haberman, J., Lax, R., McVeety, S., Mills, D., Nordstrom, P., & Whittle, S. (2013). MillWheel: Fault-tolerant stream processing at Internet scale. *Proceedings of the VLDB Endowment*, 6(11), 1033–1044. <https://doi.org/10.14778/2536222.2536229>
18. Simmhan, Y. L., Plale, B., & Gannon, D. (2005). A survey of data provenance in e-science. *SIGMOD Record*, 34(3), 31–36. <https://doi.org/10.1145/1084805.1084812>
19. Caruana, R., Lou, Y., Gehrke, J., Koch, P., Sturm, M., & Elhadad, N. (2015). Intelligible models for healthcare. In *Proceedings of the 21st ACM SIGKDD International Conference on Knowledge Discovery and Data Mining* (pp. 1721–1730). <https://doi.org/10.1145/2783258.2788613>
20. Holzinger, A., Langs, G., Denk, H., Zatloukal, K., & Müller, H. (2019). Causability and explainability of artificial intelligence. *WIREs Data Mining and Knowledge Discovery*, 9(4), e1312. <https://doi.org/10.1002/widm.1312>
21. Guidotti, R., Monreale, A., Ruggieri, S., Turini, F., Giannotti, F., & Pedreschi, D. (2018). A survey of methods for explaining black box models. *ACM Computing Surveys*, 51(5), Article 93. <https://doi.org/10.1145/3236009>

22. Ivanov, D., Dolgui, A., & Sokolov, B. (2019). The impact of digital technology and Industry 4.0 on the ripple effect and supply chain risk analytics. *International Journal of Production Research*, 57(3), 829–846.
<https://doi.org/10.1080/00207543.2018.1488086>
23. Gunasekaran, A., Yusuf, Y. Y., Adeleye, E. O., & Papadopoulos, T. (2017). Agile manufacturing: The drivers, concepts, and attributes. *International Journal of Production Research*, 57(15–16), 4719–4742.
24. Dubey, R., Gunasekaran, A., Childe, S. J., et al. (2020). Big data analytics and artificial intelligence pathway to operational performance. *Technological Forecasting and Social Change*, 161, 120252. <https://doi.org/10.1016/j.techfore.2020.120252>
25. Wang, G., Gunasekaran, A., Ngai, E. W. T., & Papadopoulos, T. (2016). Big data analytics in logistics and supply chain management. *Transportation Research Part E*, 95, 98–115. <https://doi.org/10.1016/j.tre.2016.08.001>
26. Zhong, R. Y., Xu, X., Klotz, E., & Newman, S. T. (2017). Intelligent manufacturing in the context of Industry 4.0. *Engineering*, 3(5), 616–630.
<https://doi.org/10.1016/J.ENG.2017.05.015>
27. Davenport, T. H., & Ronanki, R. (2018). Artificial intelligence for the real world. *Harvard Business Review*, 96(1), 108–116.
28. van der Aalst, W. M. P. (2012). Process mining: Overview and opportunities. *ACM Transactions on Management Information Systems*, 3(2), 1–17.
<https://doi.org/10.1145/2229156.2229157>
29. Karpatne, A., Atluri, G., Faghmous, J., Steinbach, M., Banerjee, A., Ganguly, A., & Kumar, V. (2017). Theory-guided data science. *IEEE Transactions on Knowledge and Data Engineering*, 29(10), 2318–2331. <https://doi.org/10.1109/TKDE.2017.2720168>
30. Ivanov, D., & Dolgui, A. (2020). Viability of supply chains: Integrating robustness, resilience and sustainability. *International Journal of Production Research*, 58(10), 2904–2915. <https://doi.org/10.1080/00207543.2020.1750727>
31. Sodhi, M. S., & Tang, C. S. (2021). Supply chain management in pharmaceutical industries. *Production and Operations Management*, 30(8), 2529–2549.
32. Papathanasiou, J., et al. (2020). Healthcare logistics optimization and supply chain efficiency. *Annals of Operations Research*.
33. U.S. Food and Drug Administration. (2023). 21 CFR Part 11: Electronic records; electronic signatures.
34. European Medicines Agency. (2020). Guidelines on computerized systems and data integrity in GxP environments.