

Article

# Critical Success Factors of Adopting an Enterprise System for Pharmaceutical Drug Traceability

Gaurav Kumar <sup>1,\*</sup><sup>1</sup> Maryland, USA

Correspondence: Gaurav Kumar (gka.gaurav@gmail.com)

**Abstract:** For conducting advanced analytics initiatives to acquire in-depth data into usage habits, regional access, sales, and promotional success, etc., unique identification of packaged pharmaceuticals will be a fantastic enabler. The main objective of this study is to prevent and reduce the production of erroneous and counterfeit drugs using the enterprise system, which has become a serious threat because it damages the reputation of legitimate drug manufacturers by trying to produce and market placebo medications that are identical to the real thing. Due to federal government procedures and priorities that frequently change over time, the majority of implementation takes time. To achieve compliance with numerous federal regulatory authorities, including drug traceability for patient safety, the pharmaceutical industry must implement a systematic procedure in an ERP environment. The goals would be to guarantee medical drug traceability and provide real-time warnings to supply chain stakeholders and regulatory bodies to maximize the benefit of integrating a drug traceability system into an ERP environment. Additionally, manufacturers are compelled to maintain product costs on the higher side due to a heavy burden of unchecked manufacturing cost spikes. As a result, innovative marketing schemes must be introduced in order to increase the reach to consumers by putting into practice successful strategies.

**How to cite this paper:**

Kumar, G. (2023). Critical Success Factors of Adopting an Enterprise System for Pharmaceutical Drug Traceability. *Universal Journal of Pharmacy and Pharmacology*, 2(1), 3–10. Retrieved from <https://www.scipublications.com/journal/index.php/ujpp/article/view/738>

**Academic Editor:**

Shambhu Sarkar

**Received:** May 31, 2023**Accepted:** July 28, 2023**Published:** July 29, 2023

**Copyright:** © 2023 by the author. Submitted for possible open access publication under the terms and conditions of the Creative Commons Attribution (CC BY) license (<http://creativecommons.org/licenses/by/4.0/>).

**Keywords:** Drug Traceability, Drug Counterfeit, Pharmaceutical Serialization, Supply chain, Blockchain, Track and Trace System, Enterprise System

## 1. Introduction

An ERP system is a computer system created to combine the units and functions of every department into a single computer system that can handle the needs of every department. In fact, the core objective of ERP is to manage the business while enhancing information flow throughout all facets of a company's internal activities. ERP is a group of unique but connected modules that can be implemented as a whole for any firm. (Ogechi, 2018) [1]. Whereas, drug counterfeiting is a potential threat to the pharmaceutical industries. (Mackey, 2017) [2]. Critical success factors for adopting ERP for drug counterfeiting are not technical system implementation procedures; instead, they promote highly effective enterprise system implementations for drug traceability and support the organization in focusing on the most important aspects. The development of an effective strategy for enterprise systems is dependent upon the development of acceptable functionality to meet key attributes of a drug traceability system, which can be measured by success factors of systems that have been successfully implemented and their interactions (Khan, 2018) [3].

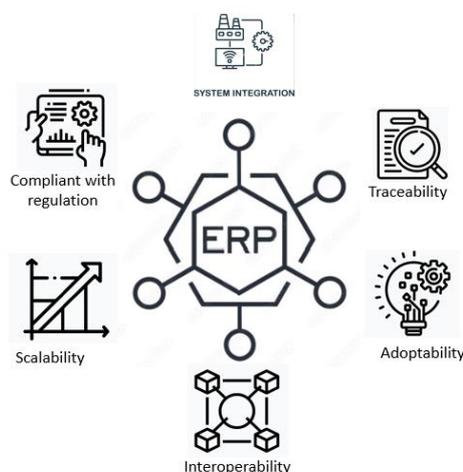
The suppliers, raw material, manufacturers, retailers, hospitals, distributors, clinics, and patients are contained as an agent in the healthcare supply chain. The difficulty in

supply throughout the process is brought on by the need for data, centralized organizations, market competition amongst partners, and other considerations. It is not difficult because of the COVID-19 (Chambliss et al. 2012) [4], yet it is difficult to combat bogus pharmaceuticals because they can quickly infiltrate the healthcare industry.

Pharmaceutical businesses use a technological platform called enterprise resource planning for "drug traceability requirements" that makes it easier to manage everyday corporate operations, distributions, manufacturing, and accounting. It assists with coordinating efforts to better manage your everyday operations while simplifying processes. Both small and large enterprises view ERP as essential. ERP software, a crucial element of daily operations, productivity, and record-keeping, improves efficiency and accuracy to prevent costly errors and delays. ERP systems can offer data integrity and get rid of duplicate data with a single source of truth. You will be able to attain process efficiency and more data visibility with this software's possibilities.

ERP systems serve a variety of business kinds, but their main function is to centralize all of your company's drug traceability information's. You can be certain that everything you require is fully integrated, structured, safe, and accessible in this manner. Getting a comprehensive picture of your organization is simple with the aid of an ERP system. Additionally, it clarifies every aspect of your business operations for drug serialization compliance and aids in finding opportunities to increase productivity. This can also assist you in making sound financial decisions to setup infrastructure for adopting drug track and trace system, which can be difficult if you lack a general understanding of your company. If a corporation aspires to reach new heights, the system's clarity regarding how it operates is essential.

Technology now affects practically every aspect of our behaviour and personal lives. The commercial and economic ecosystem is undergoing a great deal of change every day. The pharmaceutical industry, like all other major and small sectors, is undergoing significant adjustments to keep up with these changing times. Pharma companies face a variety of challenges for adopting drug traceability compliance, such as increasing process complexity, changing consumer behaviour, healthcare reforms, an expanding amount of data without the infrastructure to exploit it, and much more. Ultimately, drug serialization regulatory compliance is a top priority for all pharmaceutical companies. These restrictions affect consumer trust and brand reputation, but there is also a safety concern. There are regional variances in both legislation and standards. A comprehensive solution for drug serialization in ERP can alter the game in terms of maintaining international standards, safety, and medical best practices. Drug manufacturers can monitor these metrics and stay up with adherence thanks to its customisable interface, centralized networking capabilities, and automated solutions, which allow pharma businesses to keep up with the always changing standards and laws. With an ERP solution integrated with drug traceability system in businesses can be sure that tight laws will be followed. In this review article, we are explaining the key attributes of an ERP system required for drug traceability. In this article, we explain the key attributes of the ERP system in [Figure 1](#).



**Figure 1.** Key attributes of ERP System

## 2. Adaptability

The pharmaceutical industry creates, produces, and sells drugs as prescription medications that patients can self-administer or have prescribed for them to cure, prevent, or relieve symptoms. Pharmaceutical companies can sell both name-brand and generic medicines, as well as medical supplies. Consider an enterprise system as a way of gathering all the data about finished goods or final medications from manufacturing, stock storage, quality testing and release, and shipment to consumers or distributors. The ERP system should be compatible to adopt emerging drug traceability systems. The system should also be simple to use and flexible enough to accommodate all users inside the company. The capacity of an enterprise system for pharmaceutical drug traceability to adapt to all of its users is one of the key success criteria in its adoption. The followings are some features of Enterprise System:

- Strict quality checks
- The capacity to follow ingredients from raw materials to finished goods throughout the production process.
- Inventory tracking to ensure effective order fulfilment and on-time delivery.
- Accurate sales operation and planning for manufacturing.
- Digital transparency in the supply chain.
- Strict security measures are required to comply with various government requirements. Visibility into the financial performance of every part of the organization.
- Compatible to integrate with internal MES and external customer and regulatory system

## 3. Scalability

Drug serialization process generates millions of record every day. These data is critical for further drug traceability in the supply chain. The ability of enterprise resource planning (ERP) systems to integrate the key components of manufacturing to improve workflows and boost overall productivity has made them very popular today, especially in the manufacturing sector. However, you must carefully choose your ERP system to make sure it meets the needs of your company. When choosing the best ERP for manufacturing, there are several factors to take into account. Consider the scalability choices offered by your desired ERP system, for example. Because you anticipate that your firm will continue to expand, the scalability of your system is crucial.

### 3.1. What Is ERP System Scalability

Scalability in relation to ERP systems refers to the system's capacity to accommodate business expansion and change. This implies that your ERP system should be able to manage various business entities and have full access to on-demand automation resources. Most pharmaceutical companies have multiple business lines, or they have a global presence. ERP systems integrated with track-and-trace systems should be scalable due to their applicability to most prescribed drugs. Its capacity to manage increasingly complicated elements of your workflows and extra rules for local and global expansion is the basis for its scalability.

Most ambitious manufacturing companies will soon outgrow their current ERP system, necessitating an upgrade to suit their current business requirements. Due to the bother and agony involved in replacing your current ERP system with a new one, which may cost you hundreds of thousands of dollars, you need an ERP system that is fully scalable. Organization must ask yourself a number of crucial questions when you assess the scalability of your ERP system. These inquiries will enable you to determine whether the ERP system you select will be beneficial to your company for an extended period of time. The following are the key inquiries you should make while evaluating the scalability of your ERP software:

- How well does your company's ERP system handle the increasing volume of information and transactions?
- Can your ERP system accommodate new functions and features as your company grows and changes?
- How does scalability play a role in multi-location or multi-national setups supported by the ERP system?
- Can your ERP software help your company grow globally as a single entity?

### 4. Interoperability

Interoperability between enterprise systems for electronic data exchange is a regulatory requirement for the US market. As per the drug traceability regulation, all partners in the supply chain must exchange unit-level serialization data between stakeholder groups, including the manufacturer, wholesaler, distributor, and dispenser. Opportunities to enhance patient care and gain valuable insights from healthcare data have increased dramatically in recent years as a result of the boom in investment in digital health technologies. A complex ecosystem of interoperability providers has emerged from start-up and large IT organizations as complementing offers to the ever-growing number of creative solutions. Despite the fact that many interoperability vendors advertise plug-and-play, one-size-fits-all, and simple button solutions, I can attest from personal experience that things are rarely as straightforward as sales and marketing personnel would have you believe. In order to make sure that you (as a technology, supplier, the payer, pharmaceuticals, or other healthcare consumer of these services) are maximizing the benefit of your investment, there are a number of important things to achieve.

Work with an interoperability vendor who was created to manage healthcare systems and all of their numerous (not so) endearing interoperability quirks. This is their area of expertise and industry focus. In a continuously changing, industry-neutral environment, working with an interoperability vendor who is an integration innovation will pay off in the long run by enabling you to stay ahead of the curve when it comes to new legislation, regulatory standards, and client feature requirements. The capacity to support your use case successfully and efficiently at scale, the amount of time and effort required to execute the solution, the overall cost at scale, and many other factors are among the top

priorities for buyers. **Business Objectives:** An organization building out a core interoperability capability will have different considerations than one attempting to improve its digital footprint across the company or adapt to certain changes in its main business.

## 5. Usability

Drug traceability solutions integrated with ERP systems should be user-friendly. The user interface (UI) should not be designed to be cumbersome and difficult to understand for business users. Many products aim to be plug-and-play devices that can be rapidly set up and need little technical knowledge. However, those who are well-versed in healthcare interoperability know that this is rarely the case. Unless you have a large staff of technical FTEs with little to do (and if you have, we should chat as soon as possible) **Supported Modalities:** API-to-API interfaces are supported by a large number of interoperability vendors, but other modalities, such as HL7, FHIR, X12, and flat files, to mention a few, are widely used in healthcare and can provide major functional difficulties for otherwise simple workflows.

**Supported Deployment Types:** Healthcare data is increasingly being migrated to the cloud. However, a lot of interoperability suppliers in the healthcare sector got their start when patient data was only ever held locally. Given the significant effort needed to set up an interoperability solution between each participant in your solution's ecosystem, having a thorough understanding of how your interoperability vendor's solution may or may not work depending on your deployment strategy today and in the future may be a deciding factor.

## 6. Drug Traceability

Pharmaceutical drug traceability is a regulatory process that is the core component of serialization. All drug traceability systems integrated with ERP must be capable of storing events and transaction data. As per the National Institute of Health, the ability to trace the history, application, or location of a medicine is one of the key attributes of the drug traceability process. The source of the medicine must be traceable through the key elements of data encoded into barcodes or in human-readable forms. In essence, traceability is a component of quality management. The effort to enhance and boost the effectiveness of data collection, plant control, and quality assurance can also serve as a catalyst for the development of a cutting-edge internal traceability system. Additionally, according to (Moe, 1998) [5], a data model must be developed in order to track the history of process activity or the variation in the amount of unit-traceable resources through time. Since data flow happens across several firms, traceability systems demand the sharing of information and the usage of a common language. The main goal of implementing a traceability system is to reevaluate the duties and goals of the entire supply chain management.

### 6.1. *Compliant with Internal and External Auditing*

As per US regulation 21 CFR Part 11, the enterprise system should have all change logs with electronic signatures. All events and transactions impacting drug serialization must be available for internal and external audit. A simple audit is just a look at the books, money, and physical inventory of a business. Double checking everything is essential because tax money, government compliance, and the reputation of the organization are all at stake (Schenker, 2018) [6]. Anyone working for the company who is familiar with basic financial concepts including creating financial statements, bookkeeping, and how to assess internal business processes can conduct an internal audit. Internal audits are conducted for a number of reasons, including to make sure that the company's financial figures add up, that the records are kept accurately, that the operations are in order, and that the financial controls are operating as intended. An effective internal audit is one of the four components of corporate governance, according to the Institute of Internal Auditors

corporate governance model. The ERP system should be seen as a significant factor influencing internal audit performance since information technology advancements, in all of their forms, quickly affect auditing (Wang, 2013) [7]. Internal audit is viewed as a service provided by auditors to make sure the figures in the financial statements of the company produced by the accountants are not materially misrepresented. (Tsipouridou, 2014) [8] explained that the most significant IT project affecting the accounting function in the preceding 15 years has been the implementation of ERP systems.

### ***6.2. Easy to Integrate with other Business applications.***

Pharmaceutical business processes are very dynamic and complex. Due to business requirements, Enterprise applications must integrate with internal and external systems, including drug packaging lines, traceability systems, regulatory systems, and customer systems. For many of their services and product offerings, pharmaceutical businesses rely on partnerships or outside vendors. For instance, organizations that do clinical research, clinical trials, and pharmacovigilance are known as clinical research organizations (CROs). Organizations are collaborating with one another to create new skills, including novel medicines or commercialization services, that would normally take them years to develop internally. Although these more frequent partnerships may contribute to scalability and success, they also raise the demand for backend IT data sources to be connected. Integrated data between businesses is necessary for business-as-usual tasks like financial reporting and compliance or regulatory requirements. Additionally, there is a growing requirement for real-time access to and viewing of this data.

### ***6.3. Compliant with federal regulations***

Drug traceability is a key regulation for the United States DSCSA and the European Union Falsified Medicine Directive (EU-FMD). Hence, it is mandatory for drug traceability solutions to be built into ERP to comply with existing regulations. It is also essential that whatever ERP you select has features in place to help you ensure that records, electronic signatures, and handwritten signatures are each accounted for and can be followed throughout the manufacturing process in order to be in compliance with title 21 CFR part 11, a crucial FDA regulation governing the pharmaceutical industry. Even though using an ERP by itself won't help you comply with this law, many of them have features like workflows, approval controls, and audit trails that can. The DEA or EPA may be actively monitoring your business depending on the things you create. If that's the case, you'll want to be sure the software you buy can help you keep track of your inventory of hazardous or controlled substances.

### ***6.4. Compliant with Emerging Technologies***

Over the past few decades, the world has seen a significant transformation. Emerging technologies drew the most attention in the pharmaceutical industry for drug traceability and cold chain, especially blockchain technology. Organizations used and continue to adopt a variety of technological applications in an effort to thrive and gain a competitive advantage. ERP, or enterprise resource planning, is one of the results of progress (Salur, 2021) [9]. Cloud ERP solutions are delivered using the SaaS approach. Numerous providers in the industry offer cloud-based ERP solutions (Cheng, 2020) [10]. The most common ERP modules, which can be used separately or in combination to create an integrated system: finance & accounting, inventory, production, sales, human resource, supply chain management, and ultimately the CRM module (Abdullah, 2017) [11]. Software as a service (SaaS) and cloud computing are revolutionizing how companies distribute and use project programming. SaaS, which gained popularity in the latter half of the 1990s, has expanded quickly and is now the industry standard for distributing new applications throughout IT businesses. (Fauscette, 2013) [12]. Using technological tools like storage, memory, and processing on-site is no longer necessary thanks to the cloud computing paradigm. Instead,

service providers control and manage these online services and client access (Sadeeq, 2021) [13]. Utilizing this type of machine platform would be profitable for the business. Some advantages include decreasing the initial capital expenditure, shortening the start-up phase, lowering operational and running costs, and productive virtualization (Rashid, 2019) [14]. If the cloud computing capability affects ERP systems, then they are cloud-based. An internet-based browser can be used to access a cloud-based ERP system, so the end-user is not required to set up or install any software. In the software sector, SAP Business by Design is a well-known Cloud ERP. With the shift to this computing paradigm, the availability of online cloud storage for ERP poses a number of security issues, including intrusion detection. The attacks and intrusions seem to be able to bypass traditional intrusion prevention systems, resulting in a lack of network security (Iqbal, 2016) [15]. AI in ERP is a modern innovation that eliminates the need for human machinery. But there's no denying that AI is a useful tool for enhancing the ERP framework's computing power (Madakam, 2019) [16]. In addition to significantly changing the environment and way of life, digital advancements impact every aspect of business and society. Better interactions and innovation are enabled by new digitally based market models, which unlock knowledge value (Morris, 2016) [17]. In order to improve internal management, create a more intelligent technology platform, and maximize business processes within a single organization, AI makes best use of intelligent software systems (Juma, 2020) [18]. Artificial intelligence programs are more likely to perform routine human tasks. Therefore, the adoption of new technology is also driven by the need to reduce operational expenses for businesses by improving employee workflows and the overall effectiveness of business operations (Marshall, 2018) [19]. Following Figure 2, explain the benefits of cloud computing adopted in an ERP environment.



**Figure 2.** Benefit of Cloud computing in ERP environment

## 7. Conclusion

ERP systems provide the entire business with a wide range of advantages and services, including pharmaceutical drug traceability. ERP systems assist the business by exchanging information and data amongst all functional areas both internal and external the business to align with current drug serialization compliance. ERP systems offer a wide range of benefits and services to the entire firm to compliant with drug traceability regulations. ERP systems help the company by facilitating information and data exchange across all functional divisions both inside and outside the company. There is a wealth of evidence in the literature that suggests integrating AI could increase productivity, and there has also been considerable discussion of how AI may affect the security and privacy of SaaS and cloud-based ERP systems. ERP systems offer a wide range of benefits and services to the entire firm. ERP systems help the company by facilitating information and

data exchange across all functional divisions both inside and outside the company. Small manufacturers can use some best practices to reduce the danger of breaking the law. As the scale of generating serializing products is minimal, they can alter or improve their current Base ERP system and develop an internal serialization process. The in-build serialization program will have a very low sustainability rate and can be integrated with the support of the current ERP system.

## References

- [1] Ogechi, Anyanwu, (2018). The Role of Enterprise Resource Planning Systems in Continuous Auditing of A Selected Organization in the Western. Unpublished Master Thesis in Technology in Business Information Systems in the Faculty of Business and Management Science, University of Technology.
- [2] Mackey, T.K.; Nayyar, G. A review of existing and emerging digital technologies to combat the global trade in fake medicines. *Expert Opin. Drug Saf.* 2017, 16, 587–602.
- [3] Khan, S.; Haleem, A.; Khan, M.I.; Abidi, M.H.; Al-Ahmari, A. Implementing traceability systems in specific supply chain management (SCM) through critical success factors (CSFs). *Sustainability* 2018, 10, 204.
- [4] Lu, M., Chambliss, D., Glider, J., & Constantinescu, C. (2012, June). Insights for data reduction in primary storage: a practical analysis. In *Proceedings of the 5th Annual International Systems and Storage Conference* (pp. 1-7).
- [5] Moe, T. (1998). Perspectives on traceability in food manufacture. *Trends in Food science & technology*, 9(5), 211-214.
- [6] Schenker, J. (2018). Overview of audit - Audit and Due Diligence Foundations. Retrieved from <https://www.linkedin.com/learning/audit-and-due-diligence-foundations/overview-of-audit>
- [7] Wang, B., Li, B., & Li, H. (2013). Panda: Public auditing for shared data with efficient user revocation in the cloud. *IEEE Transactions on services computing*, 8(1), 92-106.
- [8] Tsipouridou, M., & Spathis, C. (2014, March). Audit opinion and earnings management: Evidence from Greece. In *Accounting Forum* (Vol. 38, No. 1, pp. 38-54). No longer published by Elsevier.
- [9] Salur, M. N., & Kattar, W. K. (2021). The impact of enterprise resource planning (ERP) on the audit in the context of emerging technologies. *Ekonomi Maliye İşletme Dergisi*, 4(2), 115-123.
- [10] Chen, X., Cheng, L., Liu, C., Liu, Q., Liu, J., Mao, Y., & Murphy, J. (2020). A WOA-based optimization approach for task scheduling in cloud computing systems. *IEEE Systems journal*, 14(3), 3117-3128.
- [11] Abdullah, A. M. A. (2017). "Evolution of Enterprise Resource Planning Excel". *Journal of Engineering Technology and Management Science*, 1(11). Retrieved from: <http://excelpublication.com/index.php/current-issue-8/>.
- [12] Fauscette, M. (2013). ERP in the Cloud and the Modern Business. IDC White Paper, 1-16.
- [13] Sadeeq, M. M., Abdulkareem, N. M., Zeebaree, S. R., Ahmed, D. M., Sami, A. S., & Zebari, R. R. (2021). IoT and Cloud computing issues, challenges and opportunities: A review. *Qubahan Academic Journal*, 1(2), 1-7.
- [14] Rashid, A., & Chaturvedi, A. (2019). Cloud computing characteristics and services: a brief review. *International Journal of Computer Sciences and Engineering*, 7(2), 421-426.
- [15] Iqbal, S., Mat Kiah, M. L., Dhaghighi, B., Hussain, M., Khan, S., Khan, M. K., & Raymond Choo, K. K. (2016). On cloud security attacks: A taxonomy and intrusion detection and prevention as a service. *Journal of Network and Computer Applications*, 74, 98–120.
- [16] Madakam, S., Holmukhe, R. M., & Jaiswal, D. K. (2019). The future digital work force: robotic process automation (RPA). *JISTEM-Journal of Information Systems and Technology Management*, 16.
- [17] Morris, H. D., Rizza, M. N., Mahowald, R. P., Hayward, D., Jimenez, D. Z., Motai, Y., & Stratis, A. (2016). i-ERP (Intelligent ERP): The new backbone for digital transformation. *Industry Development and Models*.
- [18] Juma, M., & Shaalan, K. (2020). Cyberphysical systems in the smart city: Challenges and future trends for strategic research. In *Swarm intelligence for resource management in Internet of things* (pp. 65–85). Elsevier.
- [19] Marshall, T. E., & Lambert, S. L. (2018). Cloud-based intelligent accounting applications: Accounting task automation using IBM Watson cognitive computing. *Journal of Emerging Technologies in Accounting*, 15(1), 199–215.