

Original Article

# From Plant to Patient: Study on SAP Advanced Track and Trace Solution for the Life Science Industry

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**Abstract** - Counterfeit drugs have become a significant challenge in the pharmaceutical industry, causing harm to patients, damaging the reputation of pharmaceutical companies, and costing the global economy billions of dollars. This paper offers insight into the pharmaceutical industry's challenges of counterfeit drugs and studies SAP Advanced Track and Trace solutions to combating this problem.

This article describes the benefits and 360-degree analysis of SAP Advanced Track and Trace solution, including compliance with regulatory requirements, improved supply chain efficiency, and patient safety. It also highlights the challenges pharma companies may face when implementing this solution, such as integration, cost, complexity, data security, privacy, and regulatory compliance. Finally, this paper offers several ways to overcome these challenges.

**Keywords** - Counterfeit drug, Track and Trace, Digital Transformation, Life Science, Pharmaceutical Industry, SAP S/4HANA.

## 1. Introduction

Counterfeit drugs pose a significant threat to the safety and health of patients worldwide. The global counterfeit drug market is estimated to be worth billions of dollars, a rapidly growing problem in the pharmaceutical industry. As per the estimation by the World Health Organization (WHO), approximately 10% of drugs sold globally are counterfeit. This percentage is more pronounced in developing countries, where regulations and enforcement may be less stringent [1].

Counterfeit drugs can be ineffective or harmful to patients, as they may contain incorrect or insufficient amounts of active ingredients or even toxic substances. Counterfeit drugs have sometimes been responsible for serious health consequences and deaths [2] [3].

Serialization has been adopted as a critical tool by the pharmaceutical industry to combat the problem of counterfeit drugs. Serialization requires allocating a unique code to every product unit, which facilitates tracking it throughout the supply chain, from its manufacturing stage to its dispensing point. By incorporating serialization, pharmaceutical companies can identify and prevent the distribution of counterfeit drugs and ensure the credibility and safety of their merchandise [4].

Track and Trace solutions have become increasingly important for pharmaceutical companies in recent years as

they face increasing pressure to ensure the safety and quality of the products throughout the supply chain. SAP has developed a comprehensive Advanced Track and Trace solution that enables pharmaceutical companies to comply with regulatory requirements, improve supply chain efficiency, and ensure patient safety [5].

According to a report by ResearchAndMarkets.com, Global Track and Trace Solutions Market was valued at USD 4.8 billion in 2021 and is expected to reach USD 8.6 billion by 2027, at a CAGR (Compound Annual Growth Rate) of 10.21% from 2022-2027, indicating a significant level of investment by pharmaceutical companies in this area [6].

## 2. Literature Review

Several studies have been conducted on the SAP Track and Trace solution, highlighting its benefits and limitations. In their study, Kumar et al. (2018) explore the impact of traceability solutions on supply chain performance [7].

They found that SAP Track and Trace solution positively influences the supply chain's performance by improving inventory management, reducing lead times, and increasing product quality. Similarly, Tiwari et al. (2019) conducted a case study on implementing SAP Track and Trace in a pharmaceutical company. The solution improved supply chain transparency and reduced costs [8].



Similarly, Bo Zhou et al. (2020) examined the use of SAP Track and Trace in the logistics industry and found that it improved operational efficiency, reduced costs, and increased customer satisfaction [9].

However, despite the benefits of SAP Track and Trace, its implementation has some limitations.

The authors of this article have identified the solution's limitations, such as the high cost of implementation, integration challenges, and the need for extensive personnel training, which have yet to be extensively discussed in previous studies. Therefore, this study comprehensively explains SAP Track and Trace's benefits and limitations in supply chain and logistics management and the mitigation plan.

### **3. Exploration of the Advantages and Potential Benefits Associated with the Implementation of the SAP Track and Trace Solution in the Life Science Industry**

#### **3.1. Compliance with Regulatory Requirements**

The SAP Track and Trace solution empowers pharmaceutical companies to adhere to regulatory mandates, including the USA's DSCSA (Drug Supply Chain Security Act) and the FMD (Falsified Medicines Directive) in European Union. These regulations require pharmaceutical manufacturers and distributors to implement serialization and track and trace systems to ensure the safety and authenticity of products throughout the supply chain.

#### **3.2. Uplifting Supply Chain Efficiency**

SAP Track and Trace solution enables pharmaceutical companies to manage inventory levels better, reduce the risk of product shortages, and optimize logistics operations. By providing real-time supply chain visibility, companies can make better decisions and improve overall efficiency.

#### **3.3. Ensuring Patient Safety**

The SAP Track and Trace solution assists in preventing counterfeit drugs from infiltrating the supply chain, consequently diminishing the likelihood of harm to patients. In addition, pharmaceutical companies can guarantee the receipt of secure and efficient medications by verifying the legitimacy of every product.

### **4. Capabilities of SAP Advanced Track and Trace (ATT) Solution**

#### **4.1. Serialization**

SAP Track and Trace solution starts with serializing each product with a unique identifier such as a barcode or RFID tag. In the pharmaceutical industry, unique identifiers such as barcodes or RFID tags are applied to each product unit, including individual items and larger containers such as boxes or pallets. Barcodes are typically printed on product

labels or packaging using specialized equipment, while RFID tags are embedded in product packaging or labels. Next, these unique identifiers are linked to a database that contains relevant product information such as the manufacturer, product type, batch number, and expiration date.

This unique identifier is recorded in the database and can be used to track the product through the supply chain. The serialization process also enables verification of the authenticity of the product, as counterfeit products will not have a valid unique identifier.

The use of unique identifiers in the pharmaceutical industry is regulated by various international standards, including the ISO/IEC 15415 standard for barcodes and the ISO/IEC 18000 standard for RFID tags. Compliance with these standards ensures that the unique identifiers can be read and recognized by different types of equipment and systems used throughout the supply chain. In addition, tracking and tracing every serial number requires sophisticated techniques and technology to deal quickly with billions of transactions. Serialization begins with printing a randomized serial number on packaged vials at 50-150 per minute. As a result, high-speed printing and number verification equipment has also become necessary.

Given that more than 6.47 billion prescription drugs were filled at pharmacies in the US alone (in 2021), one can imagine the volume of drugs that need to be serialized worldwide. Such compliance would have been unthinkable a decade ago when information systems were not as advanced [10].

#### **4.2. Data Capture**

In the SAP Advanced Track and Trace solution, data capture is a critical component that enables pharmaceutical companies to track their products through the supply chain. Throughout the product's journey within the supply chain, data pertaining to its geographic location and real-time status is captured and meticulously recorded within a database. This data is captured through various means, such as barcode scanning, RFID tag reading, or manual data entry.

The captured data can include information such as the date and time of shipment, the shipment's location, and the parties' identity. This data is stored in a centralized database, which can be accessed by authorized personnel throughout the supply chain. This allows for real-time visibility and tracking of the product's movement and status from the point of manufacture to the end of dispensing.

Additionally, the data captured can be analyzed to identify trends and patterns in the supply chain, enabling pharmaceutical companies to optimize their operations and improve supply chain efficiency. The data can also identify potential issues or risks, allowing for proactive measures to mitigate them.

#### 4.3. Verification

SAP Track and Trace solution provides real-time verification of product authenticity and enables the tracking of products throughout the supply chain. This verification is essential in preventing counterfeit products from entering the supply chain, ensuring patient safety and brand protection.

The SAP Track and Trace solution integrates various technologies, such as scanners, mobile devices, and software applications, into the supply chain network to enable real-time verification. These technologies allow for the scanning of unique identifiers at various points in the supply chain, such as at the end of manufacture, during transportation, and at the point of dispensing.

The system then checks the product's authenticity by comparing the unique identifier to the information stored in the database, such as product data, shipment data, and other relevant information. If the information matches, the product is considered genuine, and the system allows it to continue through the supply chain. If the information does not match, the system flags the product as counterfeit and alerts the relevant parties, such as the manufacturer or regulatory authorities, for further investigation.

#### 4.4. Reporting and Analytics

Integrating the SAP Advanced Track and Trace solution with other SAP solutions, such as SAP EWM and SAP Ariba, facilitates seamless data transfer and real-time visibility of the supply chain, enhancing supply chain transparency and enabling better decision-making due to data sharing.

EPCIS (Electronic Product Code Information Services) is an internationally recognized GS1 Standard that facilitates the generation and exchange of serialization event data for drug and medication products, allowing for tracking and tracing within and across global enterprises. In addition, this Standard provides valuable visibility into physical objects such as clinical, drug, and medical products.

To streamline the integration of integrated serialization processes in SAP's WM (Warehouse Management) and EWM (Extended Warehouse Management) solutions, there are Warehouse Integration add-ons available. Out of the different deployment models available, the SAP deployment model highly recommended for Advanced Track and Trace system is establishing a single centralized repository system and connecting it with all internal and external systems. This includes integrating it with EWM to handle warehouse processes that may affect serialized products.

The technical integration of WM with the Advanced Track and Trace system can be achieved by exposing the out-of-the-box provided FMs using OData API web services, which is a best practice.

Simultaneously, WM can fetch the serialized product data from ATTP for seamless integration using Remote Function Call (RFC). Whenever warehouse transactions involve serialized products, EWM transmits several EPCIS events to Advanced Track and Trace system. These events encompass a range of activities, such as alterations in the HU (Handling Unit) hierarchy resulting from the consolidation and deconsolidation of serialized handling units, as well as events like loading and unloading and inbound returns to the warehouse.

To ensure the accuracy of the Advanced Track and Trace system, any changes in the HU (Handling Unit) hierarchy due to the consolidation or deconsolidation of serialized handling units should be promptly communicated from EWM. This communication occurs through aggregation events that indicate packing and unpacking business steps. By reporting these changes, the Advanced Track and Trace system can track and trace serialized products effectively and maintain compliance with regulations. Failure to report such changes accurately and promptly can lead to data inconsistencies and create operational and regulatory issues.

EWM is crucial in reporting loading and unloading events to the Advanced Track and Trace solution. Specifically, EWM communicates essential information to Advanced Track and Trace solutions, such as validating EWM outbound delivery orders and inbound delivery orders linked to the top-level HU, which is often a Shipping Handling Unit (SHU). This information is transmitted through object events containing the relevant details of the transaction, such as the date and time of the event, the location of the transaction, and the relevant serialized product information. In addition, the possibilities are tagged with the business steps of loading and unloading, allowing the Advanced Track and Trace system to accurately track and trace serialized product movement within the supply chain. Any status changes in these events, such as order fulfillment or cancellation, are promptly reported to the Advanced Track and Trace system via object events, allowing it to maintain an up-to-date record of all serialized products within the supply chain. This is critical for ensuring compliance with regulations and maintaining the safety and quality of pharmaceutical products.

Inbound returns to the warehouse are also considered Advanced Track and Trace system events. They occur when customers or other external entities return serialized products to the warehouse. When such returns occur, the related serialized products must be processed and updated within the Advanced Track and Trace system to ensure accurate tracking and tracing. EWM typically generates EPCIS events to report such inbound returns to the Advanced Track and Trace system, which allows the system to maintain an up-to-date inventory of serialized products and their movements throughout the supply chain.

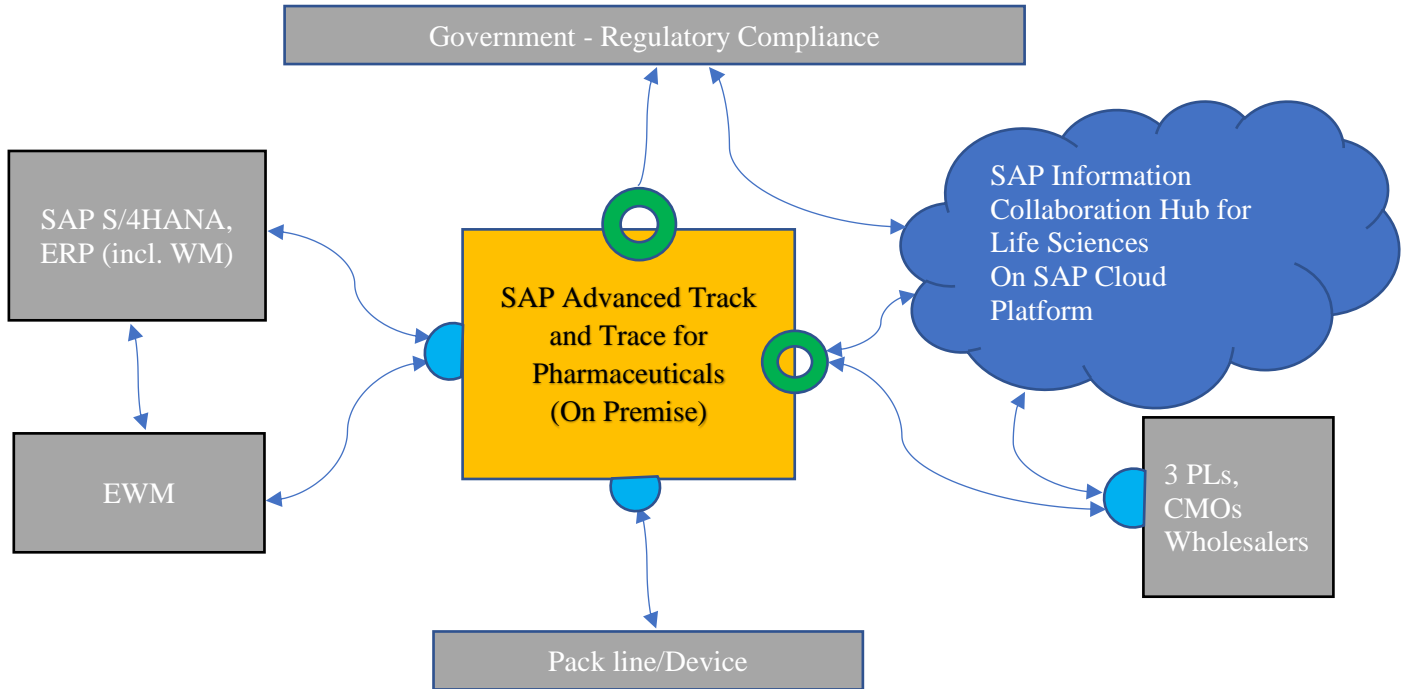


Fig. 1 Sample Architecture for SAP ATTP



**Application Interface Framework (AIF – restricted license included in SAP Advanced Track and Trace for Pharmaceuticals)**  
 AIF Content shipped for regulatory reporting and 3PLs, CMO (Contract Manufacturing Organization) /Wholesaler messaging

## 5. Challenges of Implementing SAP Track and Trace Solution and Mitigation Plan

While SAP Track and Trace solution offers many benefits for the pharmaceutical industry, there are several challenges that companies may face when implementing this solution.

According to a European pharmaceutical manufacturer media report, the European Medicines Verification System (EMVS) implementation was delayed by six months due to data synchronization and system integration challenges. The delay increased costs for stakeholders, including pharmaceutical manufacturers and wholesalers [11].

A study by HDA Publications – Serialization Readiness Survey 2022 found that 33% of pharmaceutical companies surveyed experienced delays in implementing serialization solutions due to system compatibility and data synchronization issues [12]. The delays resulted in increased costs and compliance risks for the companies.

A report by Supply Chain Brain found that incomplete and inaccurate data in traceability systems can result in operational disruptions and compliance risks. For example, in the case of a pharmaceutical wholesaler, inaccurate data resulted in delays and disruptions in the shipment of

products, which affected customer satisfaction and revenue [13].

These data points highlight the importance of careful planning and execution in implementing traceability solutions to minimize the risk of delays, increased costs, and compliance risks.

Below are some of the critical challenges with the mitigation plan:

### 5.1. Complex Project Execution Hurdles

The successful implementation of an Advanced Track and Trace solution is a complex endeavor that necessitates the cooperation and coordination of all stakeholders involved in the project. Achieving the organization's objectives requires a collaborative and well-coordinated effort from all parties, including IT, operations, and regulatory compliance teams.

Effective communication, collaboration, and a well-coordinated effort are essential to ensure the project is completed on time and within budget. Careful planning and execution are also critical, as is ongoing monitoring to ensure the system functions correctly and meets all regulatory requirements for pharmaceutical serialization and

traceability. By following these best practices, organizations can achieve a successful Advanced Track and Trace solution implementation and reap the benefits of improved supply chain visibility, enhanced regulatory compliance, and increased operational efficiency.

#### 5.1.1. Mitigation Plan

- Conducting a thorough risk assessment can help to identify potential risks and challenges associated with the implementation process, allowing to develop a plan to mitigate these risks. For example, a study by McKinsey found that organizations that conducted a thorough risk assessment before an effective technology implementation were 80% more likely to meet their objectives and stay on schedule [14].
- Developing a comprehensive project plan that includes clear timelines, milestones, and deliverables can help ensure that the implementation is completed on schedule. For example, a study by the Project Management Institute found that organizations with a well-defined project management process were 2.5 times more likely to complete projects on time and within budget [15].
- Assigning a dedicated project team with the necessary expertise and resources can help manage the implementation process effectively. For example, a study by PMI found that organizations that provided adequate resources and expertise to their project teams were 60% more likely to achieve their project objectives [16].
- Developing contingency plans can help to address any unforeseen challenges or issues that may arise during the implementation process. For example, a study by the Standish Group found that organizations that developed contingency plans for their projects were six times more likely to achieve their project objectives than organizations that did not [17].

#### 5.2. Integration Challenges

Implementing a new SAP Track and Trace solution may require integration with logistics management software, such as Warehouse Management Systems (WMS) or Transportation Management Systems (TMS). Ensuring that all systems are compatible and data is appropriately synchronized can be a complex and time-consuming process, requiring expertise in SAP and logistics management software. Ensuring all systems are compatible and adequately synchronized data can take time and effort.

##### 5.2.1. Mitigation Plan

- Conducting a thorough analysis of the existing IT systems can help to identify potential compatibility issues and determine the best approach for integrating them with the new system. For example, according to a

study by the Healthcare Distribution Alliance, 35% of pharmaceutical companies surveyed reported that system compatibility was a significant challenge in their serialization implementation.

- Developing a comprehensive integration plan that outlines the data flow, mapping, and transformation between systems can help ensure that all systems are properly integrated. For example, a study by MuleSoft found that organizations with a well-defined integration strategy are 2.5 times more likely to achieve their project objectives than organizations without [18].
- Using industry-standard integration techniques such as web services, APIs, and message queues to enable seamless communication between systems can help ensure that data is accurately transmitted between systems. According to a survey by Cleo, 88% of respondents cited web services as the most popular method for integrating applications [19].
- Performing extensive testing to ensure that all systems are correctly integrated can help identify any issues or inconsistencies before they become problematic. A study by Capgemini found that organizations that invest in testing and quality assurance see a 75% reduction in project defects and a 50% reduction in the cost of rework [20].
- Implementing monitoring tools to detect and resolve any data inconsistencies or issues with the integrated systems can help ensure that the system operates smoothly over time. According to a report by Gartner, proactive monitoring and problem resolution can reduce downtime by up to 90% [21].

#### 5.3. Cost

The cost associated with deploying an Advanced Track and Trace (ATT) solution for pharmaceutical serialization and traceability is subject to various factors, including the scale of the organization, the extent of the deployment, the intricacy of the IT architecture, and the degree of regulatory adherence needed.

According to a report by the Healthcare Distribution Alliance, the cost of implementing an ATT solution can range from \$2 million to \$5 million for a small to mid-size pharmaceutical company.

In comparison, larger companies may incur costs ranging from \$10 million to \$20 million. These costs may include hardware and software fees and IT infrastructure investments and staff and consultant costs [22].



Additionally, ongoing maintenance and support costs should be considered, as the system must be updated and maintained to ensure that it continues to function correctly and meets regulatory requirements. Therefore, implementing an ATT solution can be a significant investment for pharmaceutical companies. Still, it is necessary to ensure compliance with regulatory requirements and to achieve improved supply chain visibility, enhanced regulatory compliance, and increased operational efficiency.

#### 5.3.1. Mitigation Plan

- Considering a phased implementation approach can help minimize upfront costs and allow the organization to realize benefits from the system before entirely investing in the solution. According to a study by the Standish Group, organizations that implemented projects in more minor phases saw a success rate of 78%, compared to 40% for projects implemented all at once [23].

Phased implementation can also allow the organization to learn from each phase and adjust to improve the implementation process. This can help to minimize risks and costs associated with a large-scale implementation. For example, according to a study by PMI, organizations that incorporate feedback and lessons learned into their implementation process see a 50% reduction in project failures [24].

- Considering a cloud-based ATT solution rather than investing in hardware and IT infrastructure can help to reduce upfront costs and provide greater flexibility and scalability. According to a study by Gartner, organizations that use cloud-based solutions can see a 15-20% reduction in infrastructure costs and a 30-40% reduction in support and maintenance costs [25].

Opting for a cloud-based ATT solution can offer more flexibility and agility to an organization, enabling it to respond to evolving market conditions and business requirements swiftly. According to a study by Accenture, organizations that use cloud-based solutions see a 22% increase in time to market and a 23% increase in customer satisfaction [26].

### 5.4. Data Security and Privacy

Pharmaceutical data's sensitive nature requires companies to implement strong data security and privacy measures to prevent unauthorized access and protect patient privacy. In addition, the SAP Track and Trace solution involves technology and data transfer, which can make it vulnerable to cybersecurity risks such as data breaches and hacking attacks.

#### 5.4.1. Mitigation Plan

- Implementing strong data security and privacy measures can help to protect patient privacy and prevent unauthorized access to sensitive pharmaceutical data.

According to a study by IBM, the healthcare industry's average data breach cost is \$10.1 million [27].

- Implementing data encryption and secure data transfer protocols can help to protect sensitive information from unauthorized access. For example, a study by Ponemon Institute found that using encryption can reduce the cost of a data breach by up to \$370,000 [28].
- Implementing access controls and regular security audits can help to identify vulnerabilities and potential threats before they result in a data breach. According to a study by Accenture, companies that conduct regular security audits and risk assessments see a 70% reduction in cybersecurity incidents [29].
- Complying with regulatory requirements such as GDPR and HIPAA can help protect patient privacy and reduce the risk of legal liabilities. For example, a study by the National Institute of Standards and Technology found that compliance with regulatory requirements can reduce the likelihood of a data breach by up to 50% [30].

### 5.5. Regulatory Compliance

While SAP Track and Trace solution is designed to enable compliance with regulatory requirements, keeping up with changing regulations can be a challenge. As a result, companies may need to continually update their systems to ensure compliance with new rules or changes to existing laws.

Examples of regulations include the DSCSA and DQSA in the United States, the FMD in the European Union, and the PMD Act in Japan.

#### 5.5.1. Mitigation Plan

Staying informed about regulatory changes and developing a plan to adapt systems can help pharmaceutical companies to minimize the costs and complexity of compliance. A study by PwC found that 58% of organizations with a comprehensive compliance plan saw a positive impact on their business operations [31].

- Working with technology providers and regulatory bodies can help companies to understand the impact of regulatory changes on their systems and develop a roadmap for implementation. A study by Accenture found that collaboration between organizations and external stakeholders can increase the success rate of digital transformation initiatives by up to 55% [32].
- Investing in flexible and scalable solutions can help pharmaceutical companies quickly adapt to regulatory changes and continue to ensure patient safety. A study by Deloitte found that companies that invest in flexible solutions see a 32% reduction in IT costs and a 26% improvement in IT efficiency [33].
- Conducting regular compliance audits can help pharmaceutical companies ensure their systems comply with regulatory requirements. According to a study by

Compliance Week, 71% of companies surveyed reported that compliance audits were an effective tool for managing regulatory risks [34].

### 5.6. Standardization

Standardization is essential in ensuring the SAP Trace and Track solution is effective across the entire supply chain [35]. To overcome this challenge, pharmaceutical companies must work with suppliers and various business partners to ensure the processes and systems are standardized.

#### 5.6.1. Mitigation Plan

- Achieving standardization can help to improve efficiency and reduce errors in the supply chain. According to a study by McKinsey, standardization can reduce operating costs by up to 20% and improve quality by up to 50% [36].
- Developing standard data exchange formats and processes can help ensure that data is accurately recorded and shared between different systems and partners. For example, a study by GS1 found that using common data exchange standards can reduce errors by up to 50% [37].
- Aligning systems to ensure that data is accurately recorded and shared between partners can help to improve visibility and transparency in the supply chain. According to a study by Accenture, companies that will enhance supply chain visibility see a 10-15% reduction in inventory costs [38].

### 5.7. Training and Education

Ensuring employees are trained to use SAP Trace and Track solutions is critical to success. To overcome this challenge, pharmaceutical companies must invest in training and education programs to ensure all employees are fully trained to use the system.

- Effective training and education programs can help to minimize errors and improve the accuracy of data recorded in the system, ensuring compliance with regulatory requirements and improving patient safety. For example, a study by PwC found that companies that invest in employee training see a 24% increase in productivity [39].

Leveraging e-learning platforms, online courses, and webinars can provide training and education to employees cost-effectively and efficiently. According to a study by eLearning Industry, e-learning can reduce training costs by up to 50% and increase retention rates by up to 25-60% [40].

- Developing a training and education plan that outlines the training needs of each employee and provides a clear roadmap for delivering the necessary training can help to ensure that all employees receive the training they need to use the system effectively. According to a study by Training Industry, companies that develop a comprehensive training plan see a 40% increase in employee engagement [41].
- Providing ongoing training and education can help employees stay updated with the latest system updates. An Association for Talent Development study found that companies that provide ongoing training and education see a 218% increase in income per employee [42].
- Investing in practical training and education programs for employees is critical in ensuring the success of SAP Trace and Track solutions in the pharmaceutical industry. By providing comprehensive training and education, companies can potentially improve the accuracy of data recorded in the system, ensure compliance with regulatory requirements, and enhance patient safety. Utilizing cost-effective and efficient training methods, as well as providing ongoing training and education, can further maximize the value of this investment in employee training.

## 6. Conclusion

The study results show that counterfeit drugs pose a substantial risk to patients worldwide, highlighting the need for practical solutions. Serialization has emerged as a critical weapon in combating this issue. By adopting the SAP Track and Trace solution, pharmaceutical companies can efficiently address this problem. This approach assists these organizations in complying with regulatory requirements and streamlines their supply chain operations, ensuring patient safety. The mitigation solution findings suggest that the SAP Track and Trace solution is a promising strategy to overcome the challenge of counterfeit drugs, offering a comprehensive solution to this complex issue.

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