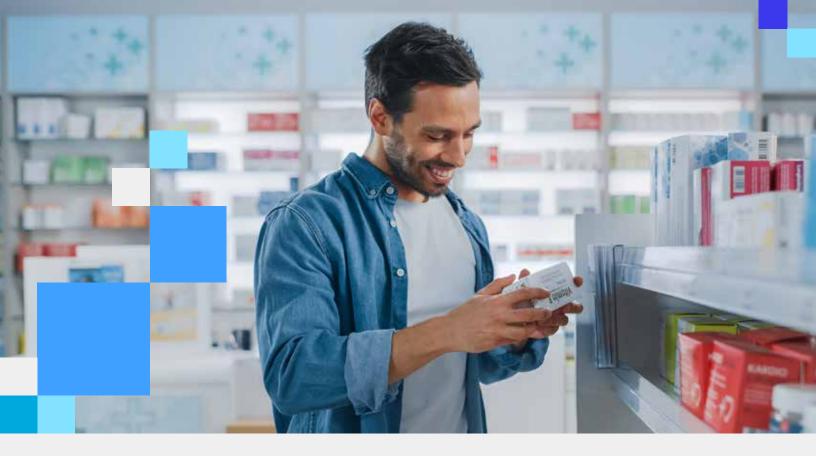


Pharma serialization for greater data visibility and traceability

Prevent counterfeiting, waste, and pharma supply chain disruption







What is pharma serialization?

While operating in the most regulated industry and constantly evolving global supply chain landscape, pharmaceutical manufacturers are more susceptible to costly logistical disruptions. Regulatory requirements for label accuracy are increasingly stringent, with severe penalties for any company that fails to meet them.

According to global management consultancy, McKinsey, it is estimated that half of all product recalls are caused by <u>labeling or packaging artwork errors</u>, with the average cost of distributing a recall notice standing at \$8 million. Additionally, pharmaceutical product recalls occur as often as 20 times per week in the U.S. alone¹.

In order to adapt, it is important for pharma companies to consider their supply chains a valuable component in delivering vital pharmaceutical products in a safe and timely manner. In a 2023 survey of the top five trends in labeling and packaging artwork, results showed that the effective management of supply chains is front of mind for many professionals, with 70% of companies listing global traceability as a priority².

- 1. Visit: www.manufacturingchemist.com/news/article_page/Overcoming_the_challenge_of_accurate_supplier_labelling/174689
- 2. Visit: www.loftware.com/resources/reports/2023/2023-top-5-trends-inlabeling-and-packaging-artwork

Supply chain traceability

When it comes to managing global supply chain products throughout the lifecycle, it is critically important for the pharma sector to consider their operations, exercising caution and ensuring accuracy at every stage of the supply chain. It is vital for pharma companies to have full traceability and accuracy of every prescription drug on the market where public health and safety are core concerns, and the consequence of a single mistake is quite serious. In fact, the trends research also suggests that 49% of professionals believe not being able to effectively manage recalls is the biggest risk due to the inability to track products throughout the supply chain.

Serialization technology is of paramount importance in enabling pharma companies to adapt to this dynamic environment. Serialization involves the allocation of a unique serial number to each product unit, which contains information about the product's origin, batch number, and validity date. By printing this code on the packaging itself, a product can be tracked and traced throughout the supply chain. By facilitating greater accuracy and traceability within the supply chain, serialization technology is helping pharma companies tackle challenges including counterfeit and substandard drugs.



Managing logistical disruptions

Logistical disruptions that plague supply chains have garnered significant unwanted media attention in recent years. As a result of these challenges, pharma companies have struggled to obtain the raw materials needed to manufacture their products, which, in turn, has led to a shortage in some countries of several critical medicines including penicillin and amoxicillin3. The channels traditionally used to collect and share data throughout the various touchpoints of the global supply chain have faced significant disruption, in part due to the rise of remote work. The limitation of face-to-face interactions has frustrated communication and coordination between suppliers, manufacturers, and logistics providers. Consequently, visibility throughout the supply chain has been impacted and it has become difficult to identify and resolve issues to ensure that products reach their intended destinations in a timely manner.

Incorporating technology into the management of pharma supply chains has empowered the industry to respond to disruptions with greater agility. Smart barcode labeling, which utilizes cloud-based RFID (radio-frequency identification) technology, provides traceability through real-time tracking and monitoring of pharmaceutical products as they are manufactured, packaged, shipped, warehoused and, ultimately, delivered to customers. The data collected from the RFID tags (small chips with unique identification

numbers attached to drug packaging) are then transmitted to a cloud-based platform, where it can be analyzed and used to identify bottlenecks, optimize logistics, and improve overall supply chain efficiency. In this way, serialization technology is instrumental in managing inventory, limiting waste, and improving forecasting.



Common use cases involve equipment that requires attachments or cartridges to perform patient-specific tasks such as blood test assays, as well as single-use surgical equipment that is attached to a larger device. In both examples, brand owners are encoding embedded RFID tags with product information, serial numbers, batch, and use-by details during manufacture. When the hospital or clinic inserts the device into its equipment, a scan of the RFID tag is completed to verify its authenticity and that it is the correct component. This method of serialization and verifying authenticity provides high accuracy and traceability in the supply chain for customers.

Expired and counterfeit medications

Serialization technology also provides a remedy to the problem of counterfeit and expired drugs infiltrating the market.

Counterfeit medication has emerged as a critical global issue in recent times, despite stricter regulations governing the entry of counterfeit drugs into the supply chain, the market continues to thrive. According to Fortune Business Insights' 'The Global Anti-Counterfeiting Packaging Market Size' reported that the anti-counterfeiting packaging market from 2018 is expected to grow 47% by 2026⁴.

Pharma companies are demanding greater brand protection and are looking to serialization technology for the answer. The cloud-based RFID encoding of serialization technology offers a rigorous approach to drug authentication. This works by the reader devices comparing the information on each tag to a central database, thereby authenticating and verifying each drug package before it leaves the manufacturing facility, as well as further down the supply chain.

Cloud-based RFID traceability also simplifies the process of detecting and removing counterfeit products. The technology allows specific information, such as product type, batch number, expiration date and manufacturer to be encoded, allowing real-time tracking and monitoring. This heightened visibility makes it possible to monitor the movement of drugs. This is helpful in identifying packages that have been tampered with when responding to counterfeiting attempts.

Furthermore, serialization technology can help pharma companies with regulatory cloud-based compliance. Cloud computing stores and manages data securely, while also enabling remote access. Regulatory bodies such as the FDA, EMA, and WHO require certain documentation, and serialization technology allows them access to the data in their jurisdictions. The secure, cloud-based environment in which this RFID data is stored ensures that only authorized individuals or devices can access the information.

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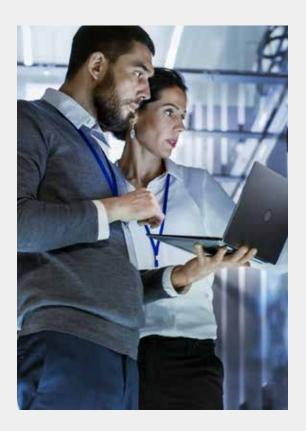
Sustainability with digital traceability

As the threat of climate change looms large, incorporating sustainable practices into a company's long-term business model is no longer optional. In support of this notion, research shows 76% of professionals already have a sustainability initiative in place². The pharma industry is taking steps to improve its sustainability credentials and align operations with the United Nations Sustainable Development Goals. This often involves initiatives like introducing waste reduction targets and increased investment in energy-efficient technology.

Serialization technology plays a crucial role here. The real-time tracking and monitoring enabled by cloud-based RFID tags helps improve a company's sustainability credentials by increasing the efficiency of logistics and transportation. Additionally, the tags track and monitor expiration dates and, as such, help reduce the number of expired products that need to be discarded. This, in turn, helps to minimize the environmental impact of waste disposal within the pharma supply chain.

RFID tags can also provide a valuable link to information about the raw materials and suppliers used in the manufacturing of products. By utilizing this data, companies can ensure that they are sourcing materials from suppliers that align with their own sustainability goals, as well as identifying

areas for improvement within their supply chains. As sustainability initiatives become more mainstream, pharma companies must consider how they can improve labeling and packaging strategies. Part of the equation is around how social, ethical, and environmental performance factor into the process of selecting suppliers. With sustainability at the forefront, digital traceability can help companies deliver on their commitment. Being able to trace products both upstream and downstream will become important for managing the product life cycle and ensuring sustainable sourcing.



2. Visit: www.loftware.com/resources/reports/2023/2023-top-5-trends-inlabeling-and-packaging-artwork

Leveraging serialization technology

Recent years have highlighted the pharmaceutical industry's resilience to disruptive shocks in the global supply chain. Pharma companies have responded adeptly to additional complications with agility by leveraging technology to adapt to evolving needs. A pivotal aspect of the industry's adaptation strategy has been its utilization of serialization technology, which has facilitated greater data visibility and traceability across supply chains. With the likely possibility of future disruptions looming, integrating cloudbased serialization technology into operations not only facilitates the tracking of goods, but also mitigates the risks of counterfeiting and waste.

Obviously, pharmaceutical companies have a lot to consider when it comes to labeling and packaging artwork. They need to shorten time to market without sacrificing accuracy and compliance all while striving to gain a competitive edge. The right solution can make a world of difference – offering new efficiencies, streamlining ability to scale, and extending labeling operations while reducing time to market.

Loftware offers all-in-one centralized cloud-based labeling solutions that redefine how enterprises create, manage and print labels. Our solutions enable pharma companies to seamlessly implement, deploy, maintain, and scale labeling operations across the entire global network while enabling customers to meet rigorous regulatory requirements. Available in the cloud or on-premise. Loftware provides a comprehensive digital platform which integrates with business applications and serialization solutions to offer unrivaled performance, and ensures accuracy, consistency, and compliance.



Loftware

The world's largest cloud-based Enterprise Labeling and Artwork Management provider



Loftware is the world's largest cloud-based Enterprise Labeling and Artwork Management provider, offering an end-to-end labeling solution platform for companies of all sizes. Maintaining a global presence with offices in the US, UK, Germany, Slovenia, China, and Singapore, Loftware boasts over 35 years of expertise in solving labeling challenges. We help companies improve accuracy, traceability, and compliance while improving the quality, speed, and efficiency of their labeling. As the leading global provider of Enterprise Labeling and Artwork Management, along with Clinical Trials Labeling and Content Management, Loftware enables supply chain agility, supports evolving regulations, and optimizes business operations for a wide range of industries. These include automotive, chemicals, consumer products, electronics, food & beverage, manufacturing, medical device, pharmaceuticals, retail, and apparel.