

# DSCSA serialization track and trace

Comply with regulations and eliminate counterfeit goods

**Körber's innovative track and trace application enables organizations to comply with government regulations – such as the Drug Supply Chain Security Act (DSCSA serialization) in the USA and the Falsified Medicines Directive (FMD) in the EU – that are designed to eliminate counterfeit goods across supply chains, particularly in pharmaceutical, medical devices and tobacco.**

## **DSCSA serialization regulatory challenges**

Counterfeit drugs, medical devices and tobacco products are a major challenge for governments around the world, especially in emerging markets. To comply with various government regulations designed to eliminate counterfeit items, manufacturers, wholesalers and retailers must adopt serialization and traceability, and report serial numbers as products pass through each node in the supply chain.

To add to further complexity, manufacturers in one country may be shipping drugs to another country where compliance regulations are different. Furthermore, serial numbers must be reported to various repository organizations, including private companies in the US and government agencies in the EU.

Total pharmaceutical manufacturer compliancy, whereby items can be tracked, traced and recorded from the manufacturer all the way through to the retail partner, is expected in US by year-end 2023. Tobacco regulations in the EU went into effect in 2019.

## **Key benefits**

### **Easy to integrate**

Our solution will easily integrate with your current WMS and any other existing operational systems you are running within your facility.

### **Easy to personalize**

Track and trace is built into our own software development platform, which means you can easily develop your own code to personalize settings and align the solution with your business operations.

### **Repository friendly**

The software also integrates with any repository systems that you may need to use. For example, in Europe, each country will use a local agency repository system.



**The EU loses approximately €10 billion in unpaid tax annually for counterfeit and smuggled tobacco products.**

**The World Health Organization estimates that 50% of drugs sold online are fraudulent.**

Source: [Fighting counterfeit pharmaceuticals](#)



## Tracking and tracing across the entire supply chain

With Körber's DSCSA serialization track and trace software, you can track, trace and manage serial numbers on pharmaceutical drugs or medical devices, as well as tobacco products, as the products pass through your facility. These numbers can then be aggregated and reported to the various repository organizations.

If you run a distribution center, our software can easily be implemented to make your facility compliant. When it comes to the real-time distribution space, Körber's experts have a wealth of experience. Over the years, working with the world's top global pharmaceutical manufacturers and third-party logistics providers, we've developed an in-depth understanding of how warehouses work and the most effective solutions to control inventory.

By eliminating counterfeit products from the supply chain, you'll also be saving money within your organization and, in the case of pharmaceutical supplies, improving people's lives in terms of the medical treatment they receive.

We can provide your organization with consultancy expertise to help you understand compliance regulations and formulate a plan of action. Our experts can implement and test your DSCSA serialization software solution and train your staff – although most customers find our system very easy to use.

Beyond the pharmaceutical industry, there are comparable regulations in other industries. For instance, we work with tobacco and electronics companies to help them meet their track and trace compliance requirements. Looking to the near future, track and trace regulations are set to impact more and more industries – and eventually this will also be a requirement for the food and drink industry.

### The Körber difference

We don't believe in a one-size-fits-all approach, because each node in the supply chain has its own unique compliance requirements. We'll provide your organization with a highly adaptable and flexible solution that has the right track and trace capabilities to address your current and future DSCSA serialization compliance requirements (or equivalent regulations outside the USA), while optimizing your productivity levels.

**“The work Körber carries out is vital in terms of ensuring sick people receive the correct drugs. I'm very proud of that, plus the fact that we're helping organizations across the pharmaceutical supply chain to address their FDA serialization challenges.”**

**Bob Kennedy**  
Körber

## DSCSA serialization track and trace in use



### Johnson & Johnson

Enabling DSCSA compliance, our solution was integral to the first fully serialized pharmaceutical warehouse in the US. In addition, the Council of Supply Chain Management Professionals presented us with a Supply Chain Innovation Award for the Johnson & Johnson serialization project.

