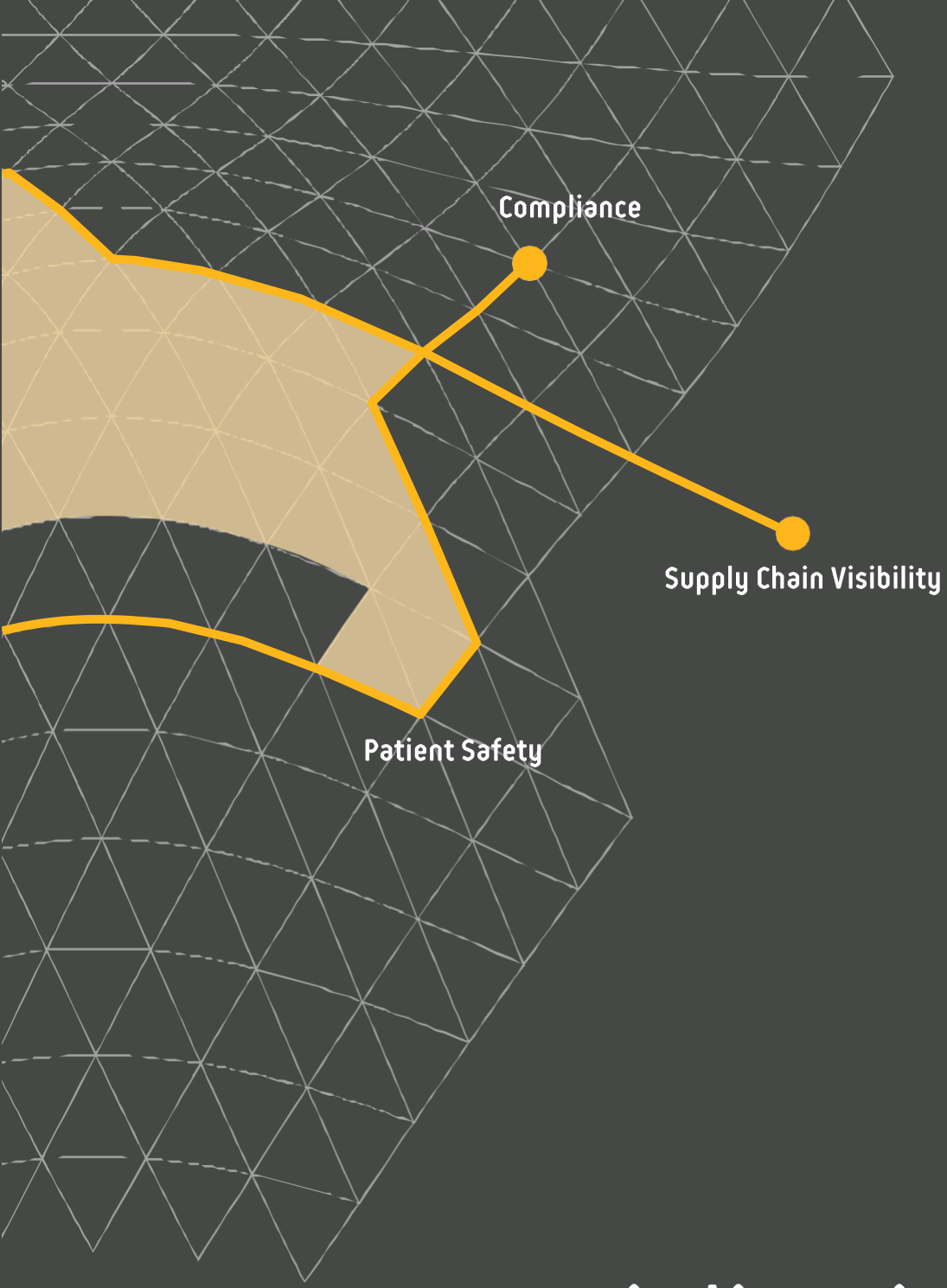


modis

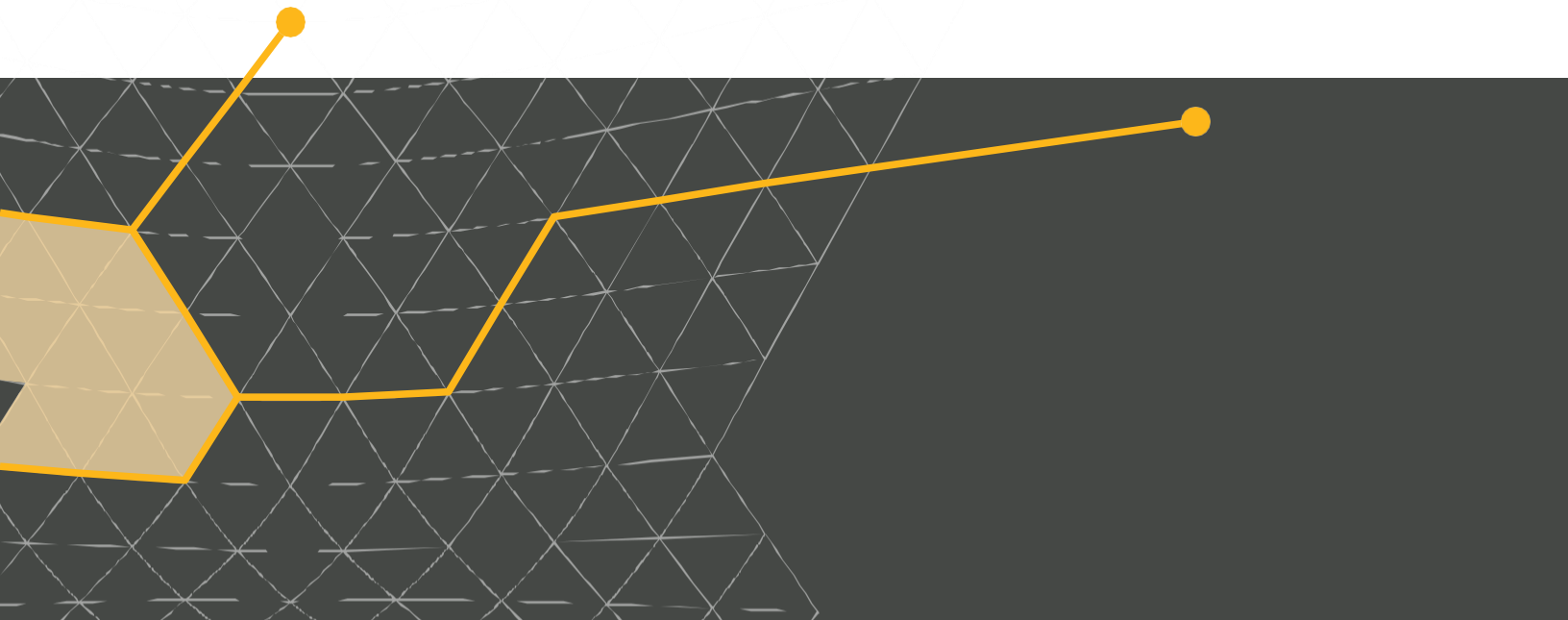
Serialization in Life Sciences

Case Study

Introduction

The circulation of counterfeit drugs is a genuine danger for the safety of patients. To fight against this threat, many countries have developed – or are in the process of developing – a regulatory roadmap for serialization. The implementation of safety and control features, such as a unique serial number, ensures the recognition of product authenticity. It is important to note that serialization extends beyond compliance with a legislation. It improves supply chain visibility and efficiency, makes it easier to track returns or recalls, and can even be used in data-driven analytical tools (*e.g.* to predict consumption behavior) as a foundation of Industry 4.0.

The regulatory landscape for serialization is continuously evolving, meaning the implementation of serialization in your business is not a one-off. Regulations are constantly updated, and new legislations are emerging. As an example: Since the implementation of the Falsified Medicines Directive (FMD) in 2019, serialization has become mandatory in Europe for pharmaceutical supply chain members. Next in the run is a similar legislation for Medical Devices, called the European Medical Devices Regulation (EU MDR). This regulation entails the implementation of a device traceability system based on Unique Device Identification (UDI), which will come into force in May 2020. We expect that more regulations and legislations will follow to secure the supply chain in the life sciences industry, and beyond.



Case Study: Serialization in the Pharmaceutical Industry in Europe

Counterfeit and falsified medicines entering the pharmaceutical supply chain can carry major health and safety related risks. They might be ineffective or can cause adverse reactions, putting the life and safety of patients in danger. These events impair the brand equity of pharmaceutical companies, and the pharmaceutical industry loses tremendous amounts of revenue due to the presence of falsified medicines on the market. In order to counteract unauthorized parallel supply chains and the circulation of falsified drugs, the European Union has put a legal framework in place: the Falsified Medicines Directive (FMD). This directive has gone into force on February 9th, 2019 and aims at preventing falsified medicines entering the supply chain by introducing several safety and control features.

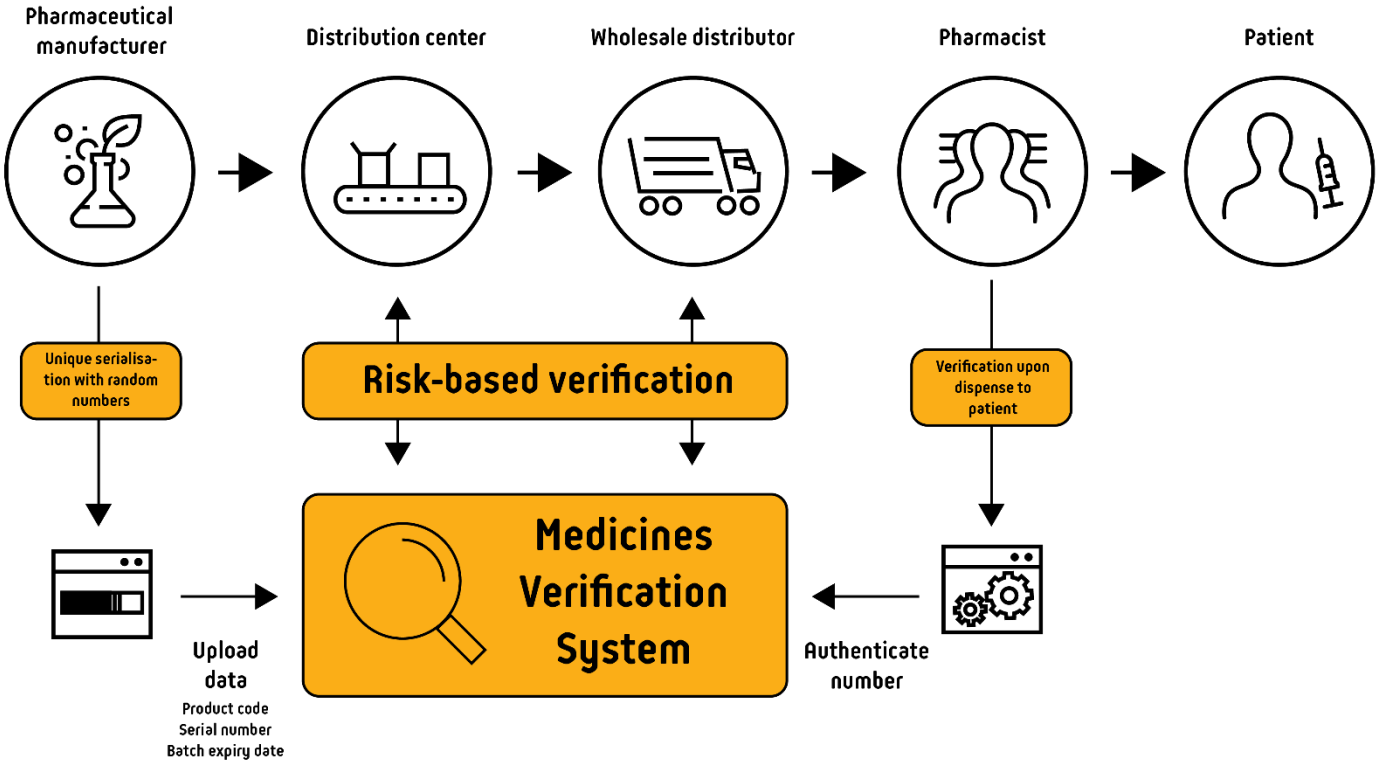
Each saleable unit of most prescription and certain non-prescription drugs needs to be serialized, *i.e.* needs to display a unique serial identifier. Furthermore, these units also need to hold an anti-temper evidence. These safety features will guarantee the authenticity of the product which can be verified before supplying it to the patient.

Implementing serialization affects the entire supply chain, impacting manufacturers, distributors, wholesalers and retailers:

- Artwork needs to be updated and might require a full redesign due to lack of space for the safety features.
- Software has to be implemented to create, store and process a large amount of randomized serial numbers, and to ensure an integrated flow of data.
- Production lines need to be altered, involving new print and scan devices.

All these changes need to be realized without disrupting the delivery of drugs to the market. Therefore, the implementation of serialization across the enterprise is an interdisciplinary project and requires thorough preparation and planning. A cross-functional team is essential – ranging from experts in IT and labeling to specialists in regulatory and quality assurance – and vigorous project management is key.

> "The implementation of serialization across your enterprise is an interdisciplinary project, during which vigorous project management is key"



Expertise at Modis

In the context of the Falsified Medicines Directive, Modis has helped one of its clients to ensure end-to-end functional compliance and technical connectivity from the client (SAP Advanced Track and Trace for Pharmaceuticals (ATTp)) to the National Medicines Verification Systems (NMVS) via the EU-Hub, across 30 countries in the European Economic Area (EEA):

- Alignment and follow-up on serialization readiness status for 30 EEA countries
- SAP ATTp readiness: User Acceptance Testing
- Master Data validation and uniformization
- Ensure connectivity between client and EU-Hub (third party system)

Modis' Project Managers and subject matter Experts have profound knowledge in Industry 4.0, Serialization, and Compliance & Regulatory Management. In close collaboration with your team, Modis will be your partner to successfully guide your serialization project towards success.

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