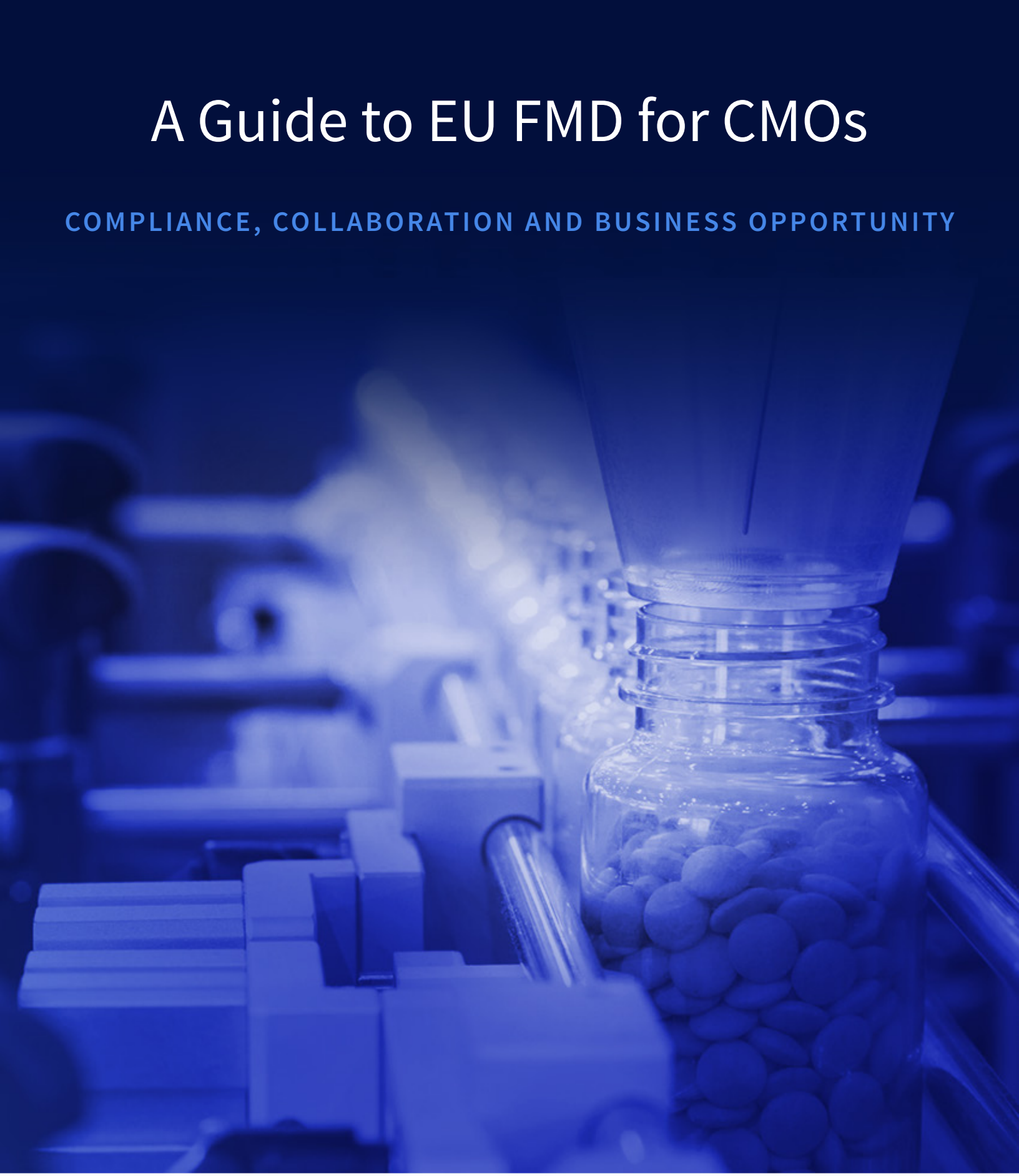
A Guide to EU FMD for CMOs

COMPLIANCE, COLLABORATION AND BUSINESS OPPORTUNITY



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Introduction

On the 9th of February 2019, the EU Falsified Medicines Directive (FMD) will come into effect, impacting both the manufacturing of prescription medicines sold in Europe and the way that pharmaceutical supply chain companies work together. For contract manufacturing organisations (CMOs), EU FMD introduces a paradoxical situation: you have no legal requirements under the regulations, and yet they will change how you operate and how you work with pharmaceutical company customers. EU FMD will also change the competitive landscape, as readiness for serialisation becomes a top criteria for how pharmaceutical companies select and retain CMO partners.

Most of your peers have already started preparation[1], with time fast running out to the deadline. If you are in the early stages of your journey, understanding FMD requirements and the challenges and opportunities they present is the first critical step. This eBook includes important concepts and considerations for moving forward, and explains what CMOs in the EU are—and aren't—required to do to succeed as part of a fully compliant supply chain.

[1] March 2017: 67% of companies surveyed were actively researching or planning, while another 15% were already at deployment stage. https://www.tracelink.com/insights/poll-4-of-5-companies-already-preparing-for-eu-fmd-compliance

SECTION 1

The Impact of EU FMD on Your Customers

EU FMD Overview

The aim of the new EU FMD requirements is to prevent falsified medicines from entering the supply chain by requiring safety features to be applied to individual packs of prescription medicines, and some over-the-counter medication considered to be at risk of falsification.

Those safety features are an anti-tamper seal and a unique identifier containing four pieces of data:

1. **Product Code:** A unique code that identifies a specific item and packaging level. Each EU Member State can choose between a GS1 GTIN, a GS1 NTIN, or a unique national code.
2. **Serial Number:** A randomly generated alpha-numeric code.
3. **Lot or Batch Number:** A unique combination of letters and numbers that identifies a set of products in a single unique production or packaging run.
4. **Expiry Date:** The date by which the medicine must be used.

All of this must be presented in both a GS1 2D DataMatrix code and in Human Readable Interpretation (HRI) form. Any medicine packs without the necessary safety features will not be able to be sold in the EU after 9th February 2019*.

> Want to know more about these terms and what they mean?
> Download our EU FMD Glossary

* Greece, Belgium and Italy have an additional 6 years to comply, as they already have national serialisation requirements in force.

Your Customers' Responsibilities

There are two verification systems under EU FMD: a central European Hub that works together with a separate National System for each EU Member State. Your customer, the Marketing Authorisation Holder (MAH), will be responsible for uploading its product data to the European Hub which, in turn, sends the data onto the National System of every market in which the medicines will be sold. Before a medicine is dispensed to a patient, it must be scanned and verified against the relevant National System.

Communication between the central European Hub and the National Systems is also intended to facilitate batch-information sharing, multimarket product movement, and secure parallel-trade activities across the EU.

SECTION 2

Connecting and Collaborating with Your Customers

EU FMD places no legal responsibilities on CMOs. However, there are requirements for your pharmaceutical customers, who will be turning to you as their outsourcing partner to help satisfy some of them. Pharmaceutical companies are likely to find new CMO partners if theirs are not ready in time for the deadline.[1]

Defining Business Requirements

It is critical to begin collaborating with your customers straightaway. Here are some of the questions to ask in order to understand the impact of EU FMD on your customer—and where it will affect you:

- Which products that we manufacture/package for you are impacted?
- Will you provide us with new artwork? When?
- What serialisation solution do you plan to use?
- Will you generate serial numbers centrally and distribute them to us? How do you plan to send them?
- Where will we fit in on your on-boarding schedule?
- When do you need to be ready for testing?
- Will you want us to participate in any pilot projects with you?

If your customer uses multiple CMOs, they will have to go through this process with each of them. Being an early mover will put your company ahead in the queue for integration and testing. Equally, if you have more than one customer impacted by EU FMD, you will need to work with them one by one to understand their unique requirements. Knowing their plans will help you make yours.

[1] May 2016: 37% of pharmaceutical companies surveyed said they are prepared to switch to a new CMO. https://www.tracelink.com/insights/poll-brands-willing-to-switch-cmos-to-meet-deadlines

Key Planning Considerations for CMOs

Planning for EU FMD compliance can be an entire project in itself. Once you have had an initial meeting with a customer, you will understand the financial and operational implications and how your production lines will be impacted. You can then research what equipment you need to purchase, how this will impact your operations, and, crucially, how long it will take you to be ready.

Here are the most important factors to include in your planning for EU FMD – and beyond:

- **Serialisation solution**: Determining how to connect to your customers in order to exchange the necessary data with them is a critical decision. Your choice has the potential to make a major difference to the time involved, as developing point-to-point connections to each customer takes far longer than one connection to an established network, which then allows you to interoperate with all network members.

- **Line equipment availability:** Before agreeing on a go-live date with a customer, it is vital that you speak to your line equipment vendors. The entire industry is working towards the same regulatory deadline, so new equipment is in very high demand. Be prepared for much longer lead times than usual and potentially higher prices due to higher demand. If you don't place your orders quickly, you risk not being ready in time for February 2019.

- **Physical space**: The equipment and systems you need for serialisation may take up more room than you have available, meaning that you may need to buy or rent more space. Factor in the time and logistics required to set up a new space in your planning.

- **Coordinated timing**: Going live can't be based purely around your equipment and systems all being in place, as a lot of third party systems need to also be ready. Your customer needs to have a serialisation solution in place, and be connected to the European Hub. That in itself can take many months, so you will need to collaborate closely with your customer to determine a testing date and a projected go-live date.

- **Downtime**: Your affected line(s) will have downtime when you install the new equipment or systems. If it is a shared line, you will need to communicate this to all affected customers in advance. They may insist that you increase production beforehand in order to meet your contracted targets.

- **Production speed**: After go-live, production speed is likely to be slower due to the additional requirements. Equipment may have to run at slower speeds in order to apply the anti-tamper seal, DataMatrix code and HRI data. Once you know projected production rates, you need to look at future run schedules and assess the impact on staffing and shipment times.

- **Headcount**: The new equipment and schedules may require more people, in which case you would need to allocate budget and time for on-boarding and training new staff. Temporary project teams may be an option in the run-up to February 2019, but be sure to retain specialist knowledge and resources.

Assessing and Addressing Your Costs

Once you know the extent of the changes you will need to make, you can start to think about how you will cover the costs, or share them with your customers. There is no set commercial model for sharing them, but common arrangements include:

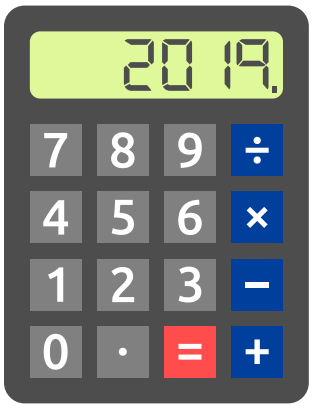
- **Capital cost**
  You ask your customers for upfront payment to help offset the cost of the initial outlay for either a shared or dedicated line.

- **Integration fee**
  You ask your customers to pay a fee towards the cost of integration and end-to-end testing.

- **Per-serial-number fee**
  You cover the upfront cost of the line upgrade, but charge the customers a certain amount per serial number once you are in production.

- **First in line, first to pay**
  You ask the first customer who asks you to upgrade to cover the cost.

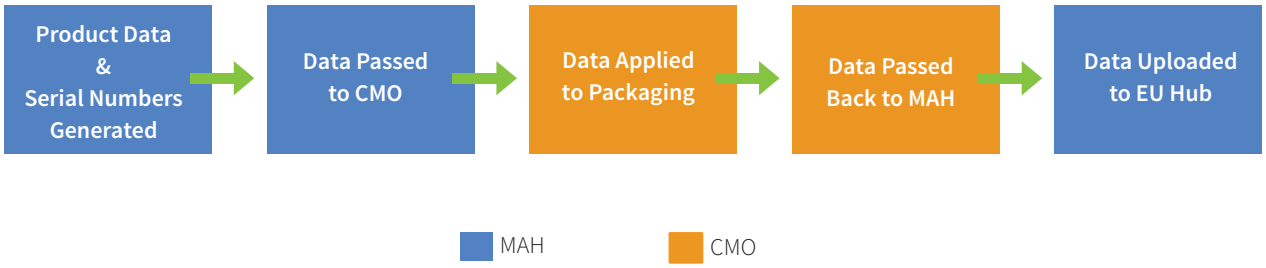
- **Contract price**
  You renegotiate your contract, increasing costs to cover regulation-related upgrades such as serialisation.



SECTION 3

How to Meet Your Customers' Requirements Under EU FMD

To understand what you will need to do once EU FMD is in force, let's look at how the typical process flow will work between the MAH and CMO:



Receiving the Data

Every application of the DataMatrix code and HRI data will be unique. Your line equipment will therefore need to be capable of receiving the data from your customer, unless you and your customer agree that you will generate it yourself.

We will go into more detail on data exchange in the next section, *Intelligent Data Exchange Using a Level 5 Solution*.

Applying the Data

Before you go live with applying the new data, the packaging design will need to be checked to make sure there is space for the DataMatrix code, HRI data and anti-tamper seal to be applied without covering up any other mandatory or desired information on the packaging. Bear in mind that additional data such as a national reimbursement number is required in some markets. If new packaging designs are needed, your customer will need to get these approved and provide them to you.

If you agree to generate the data for your customers rather than receiving it from them, be aware that there are strict rules on the format of the serialised data and the randomisation process for generating each serial number. Serial numbers must be randomised to a 1:10,000 sparsity rule: the probability of it being guessed must be less than 1 in 10,000. Each serial number must be unique, and the same number cannot be used within the longer of either the expiry date of the medicine +1 year, or 5 years. Detailed requirements such as this are why companies choose serialisation solutions purpose-built to meet the needs of EU FMD.

A pharmacist must be able to scan the GS1 2D DataMatrix code on the product to verify it before dispensing it to a patient. It is therefore critical that your equipment is capable of applying the data accurately and in such a way that it doesn't smear or blur.

Returning the Data

After the data has been applied to a pack of medicine, it needs to be returned to your customer and uploaded to the European Hub so that the product can be verified before being dispensed to a patient. Only an MAH is permitted to connect to the European Hub, so you will need to collaborate with your customer early on to decide how the data will be exchanged to allow them to upload it to the Hub in a timely manner and in the correct format—before the product moves onto the next point in the supply chain.

SECTION 4

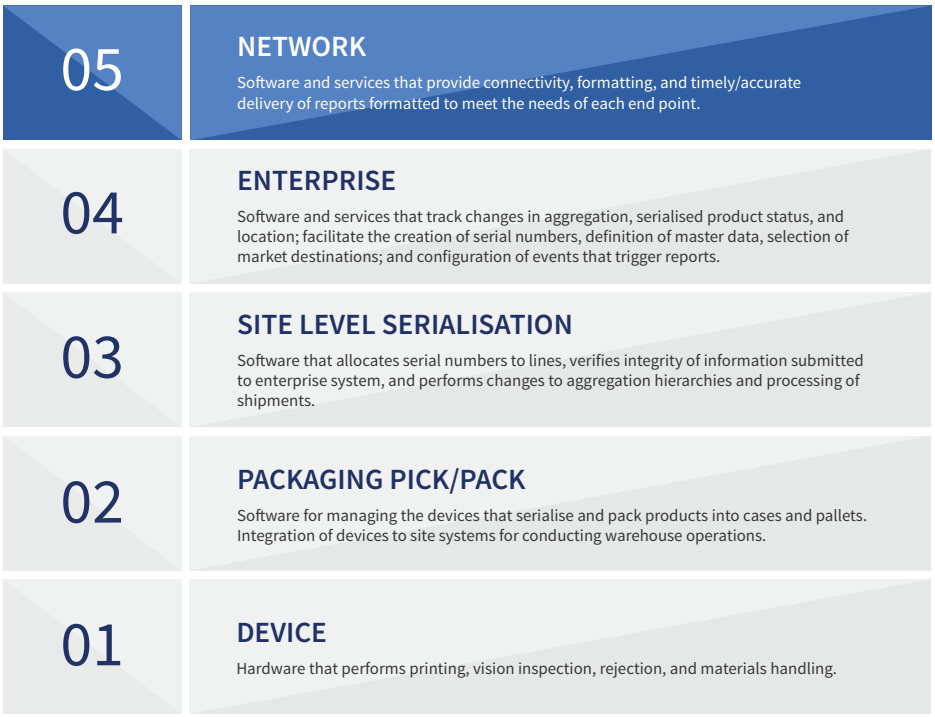
Intelligent Data Exchange Using a Level 5 Solution

One of the foundations of EU FMD is data exchange. You must be able to exchange data with your customers so they, in turn, can upload the data to the European Hub. Because of this, efficiently establishing reliable connections with each of your customers well in advance of the deadline is key.

Having a serialisation solution that can handle all of the data and reporting requirements of EU FMD without compromising your business efficiency is crucial. Even having one or two customers who need to comply with EU FMD will generate a huge quantity of data. Building a point-to-point connection with each customer represents a significant amount of development time and cost, and is simply not scalable. A network approach, also known as a Level 5 solution, is the only model capable of meeting the demands of serialisation. A common framework lets you connect to all customers and configure the workflows once the data connection has been established.

What is a Level 5 Solution?

There are 5 levels of technology in the serialisation packaging framework. Level 5 is the uppermost level, providing all of the connectivity and reporting functionality required under EU FMD.



Working with TraceLink

TraceLink is the only Level 5 serialisation solution provider with an established network of more than 260,000 pharmaceutical and other supply chain companies. TraceLink enables you to:

- **Reduce the time, cost and risk of integrations.**
  With just one integration to TraceLink, you can interoperate with all of the pharmaceutical companies that are already on our network and leverage the information maps, format interoperability, messaging choreography, and configurable workflows that are already developed. By being part of the world's largest track and trace network, you benefit from the likelihood that your customers and potential future customers are already part of it.

  This eliminates the need to develop a connection to each customer, significantly speeding up on-boarding times. Configuring for serialisation is a complex process, and if you are using on-premise software or single tenant solutions, integration costs can be astronomical, and implementation timelines take far longer than anticipated: it can take up to 45 days or longer to integrate with each customer, often costing more than $65,000 per integration. With the EU FMD deadline fast approaching, any delay during integration risks you not being ready in time.

- **Work with customers' varying file formats, sequencing, and workflows.**
  In practice, two-thirds of the top 50 MAHs require custom interfaces. TraceLink handles those custom interfaces to MAHs without requiring custom development work on your side. You upload data in your standard format, and TraceLink's configurable workflows pass it to the MAH in the required fashion.

- **Be in a position to win new business.**
  There is a real danger that many CMOs won't be compliant in time for EU FMD coming into force in 2019. Being on the TraceLink Network puts you in prime position to win new business from MAHs who are looking for serialisation-ready CMOs.

> "TraceLink offers a cloud-based solution with flexibility for CMOs. The team is flexible and customer focused and we couldn't name one area for improvement since working with them. They're working closely with our team to help as much as possible when it comes to complying with global serialisation requirements and I'd recommend them for any CMO looking for a cloud-based solution."
>
> **STAFFAN WIDENGREN**
> **Director of Corporate Projects and Program Manager for Global Serialisation, Recipharm**

TraceLink provides a comprehensive solution for serialised product management, including the ability to generate and manage serial numbers, exchange serial numbers and events across packaging sites and line management systems, track serialised inventory operations across plant and warehouse operations, and automatically trigger reports and other compliance activities.

Onboarding

TraceLink assigns a dedicated integration expert to guide every step of your project, tests your configuration to ensure that you're ready for successful data exchange, and provides templates for Standard Operating Procedures (SOPs) to make it easy for you to communicate with your customers on project timelines and deliverables.

European Hub Certification

TraceLink is one of a very small number of certified connection providers to the European Hub, meaning that MAHs are ensured a valid, tested connection. This reduces the risk of any delays in you and your customers being ready to continue trading once the new regulation comes into force.

Leveraging the Value of Intelligent Data

The connectivity of the TraceLink Network puts CMOs in a better position to offer value-added services to their customers, such as decommissioning products and managing recalls. Organisations are already looking beyond February 2019, to see how they can use the network to further protect the supply chain, and how they could potentially extract value from the data being captured.

Getting ready for EU FMD compliance should not be seen as a one-off activity, but the start of a new mode of operation using a connected network as a platform for future initiatives. Becoming part of that network will set you up for success, putting you at the forefront of serialisation and the future opportunities it brings.

Contact us to learn how TraceLink is helping CMOs meet their customers' EU FMD requirements.

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