How to comply with FMD

What

What is the FMD?

The EU Falsified Medicines Directive (FMD) was enacted in 2011 as an anti-counterfeiting measure and demands the introduction of two safety features on every individual pharmaceutical drug package.

By 9 February 2019, most countries in the European Union are required to enforce the FMD.

FMD Requirements

Anti-Tamper device
Safety feature allowing the verification of whether the packaging of a medicinal product has been tampered with.

Unique Identifier
The EU FMD requires that every prescription drug have its own unique identifier in machine- and human-readable forms. The machine-readable form must be a 2D barcode that contains the following:

- Product Code: varies between member states between GS1 GTIN, NTIN or a combination
- Random serial number
- Batch number
- Expiration date
- National reimbursement number (where required)

Why

Prevent illegal medications from:

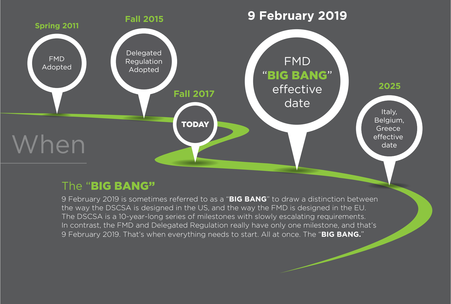
Entering Supply Chain

Poisoning Patients

Harming Trusted Brands, etc.

Systech is a proven global leader in serialisation with **95% of the top pharma companies** calling us their solution provider.

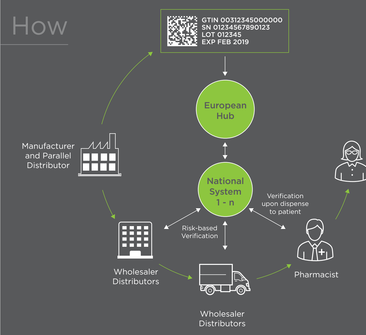
When



The "BIG BANG"

9 February 2019 is sometimes referred to as a "**BIG BANG**" to draw a distinction between the way the DSCSA is designed in the US, and the way the FMD is designed in the EU. The DSCSA is a 10-year-long series of milestones with slowly escalating requirements. In contrast, the FMD and Delegated Regulation really have only one milestone, and that's 9 February 2019. That's when everything needs to start. All at once. The "**BIG BANG.**"

How



With over **30 years of experience** and a tested methodology grounded on **GAMP guidelines**, we can get you to compliance faster than our competitors.

Where do I begin?

1.

What drugs need to be serialised?

- Prescription
- Some OTC drugs prone to falsification

2.

Get your team onboard

- Packaging management
- Legal
- Marketing
- Package design
- IT

3.

Evaluate your vendors

- What is their serialisation experience
- Integration and certification with packaging equipment
  - with new machines
  - retrofitting existing machines
- How is their formal project management

Systech can have you up and running in **under 90 days**.

Systech enables **faster time to compliance**

Systech is a **proven world leader** in serialisation

Systech has **flexible solutions** designed to fit your line

Systech's software-based solution is **future proof**

SYSTECH ONLY ONE