

The aim of this questionnaire is to assist you in evaluating whether your existing systems and processes adhere to DSCSA regulations and compliance standards. Should you answer "no" to any of the questions below, it may be advisable to explore alternative Compliance Software solutions promptly.

**Inbound Shipments**

Yes No

Do your current systems have the ability to:

- Receive the electronic transmission of drug serial numbers from your supplier?  Yes  No
- Scan the 2D datamatrix barcodes on the physical product received?  Yes  No
- Compare the serial numbers scanned to the serial numbers listed in the electronic file sent to you from your suppliers?  Yes  No

**Outbound Shipments**

Do your current systems have the ability to:

- Scan the 2D datamatrix barcodes on the physical product being shipped?  Yes  No
- Generate an outbound electronic file of serial numbers and aggregate data?  Yes  No
- Transmit that file electronically to your customers?  Yes  No
- Make that file available via a web portal?  Yes  No

**Returns**

Do your current systems have the ability to scan and verify inbound returns?

Yes  No

**Single vs. Multi-Systems**

- If multiple systems are required, does information flow automatically between those systems?  Yes  No
  - Do you have to manually duplicate data between different systems?  Yes  No
- Do employees have to spend time keeping the systems in sync?  Yes  No
  - For example, do you have to enter customers/vendors/orders/returns etc. into two different systems?  Yes  No
- Is the management of conflicting data cumbersome?  Yes  No

Does your current solution automatically receive/transmit serial data electronically?

Yes  No

Do you know what data you require from suppliers or customers to be able to transmit serial data electronically?

Yes  No

- For example, do you know the difference between a GLN, sGLN or GS1 company prefix?  Yes  No

**DSCSA - Drug Supply Chain Security Act**

This act, signed by President Barack Obama in 2013, combats illegitimate drugs in the pharma supply chain through a 10-year phased implementation plan for electronic tracing at the package level.

**EPCIS**

Electronic Product Code Information Services.

A global GS1 standard file format that has been approved by the FDA to manage the movement of information across the US Pharma supply chain.

**TS + TH + TI = T3**

Transaction Statement, Transaction History, Transaction Information

Is the “pedigree” of each product. Who owns the product from MFG to dispenser (across the supply chain)

**DTR – Drug Transaction Record**

Is a readable document that contains the information in the EPCIS file.

**SOM - Suspicious Order Monitoring**

This functionality monitors the purchasing habits of companies AND is a reporting system to the DEA of sales orders containing addictive drugs deemed suspicious. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

**GCP/GLN/sGLN**

Company Prefix / Global Location Number / Serialized Global Location Number.

Used in the EPCIS File to identify the company and physical location of each ship to location.

**GTIN - Global Trade Item Number**

Unique number for a product. Contains the “NDC” and package information of the product.

**NDC - National Drug Code**

Unique product identifier for drugs in the US. Normally NDC is for human consumption but sometimes used in Veterinarian medicine.

**SSCC – Serial Shipping Container Code**

This is the shipping label outside of a shipping unit that compiles all of the info inside of that shipment.