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DSCSA Requirements: Serialized Products

November 27, 2018* manufacturer and repackager requirements

Manufacturers are required to place a 2D barcode, containing the product identifier, on the smallest saleable unit and homogenous case.



What is passed in a 2D barcode

Enhanced product identifiers

- NDC
- Lot number
- Expiration Date
- Serial Number

Manufacturer

Distributor

Dispenser/
Practice

DSCSA provider impact checklist



GLNs

Ensure you have a Global Location Number (GLN) as it is required to identify all unique locations in the supply chain, meeting the FDA tracing requirements. They also provide critical data in the EPCIS messaging standard that are used in DSCSA transactions. **We will provide you a GLN by November 2023 if you do not have one already.**



EPCIS

Ability to access and receive serialized data through an **Electronic Product Code Information Services (EPCIS)** file using a third-party vendor solution or by accessing the DSCSA report in ABC Order.



Returns

Be prepared for **an** added step in the returns process as distributors will only be able to accept returns purchased through that distributor originally. Returns will require a Standardized Numerical Identifier (SNI). ABC Order will allow you to type in the SNI number or use a 2D scanner to quickly scan. **We recommend obtaining a 2D barcode scanner, but it is not required.**



DSCSA SOPs

Establish processes and procedures to ensure you are buying product from an authorized trading partner, and how to investigate and properly handle suspect and illegitimate drugs.

Q & A

The background of the slide is an abstract, fluid design. It features broad, sweeping waves of color that transition from deep purple at the top to bright pink and magenta towards the bottom. The colors are layered and blended, creating a sense of movement and depth. The overall effect is modern and artistic.





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