

Drug Manufacturer Challenges in Complying with DSCSA Addressed by Origin

The traceability system the DSCSA mandates will require a massive amount of frequent and accurate data exchange based on standards. Many in the pharmaceutical industry are supporting standards developed by GS1. EPCIS, used for data exchange, requires assignment of GTINs to each level of product packaging. The GTIN also is the identifier that links a scan of a product barcode to the master data associated with that product. The GTIN is a critical foundational element for communicating with downstream trading partners.

Challenge	What Happens Without Origin?	What Happens With Origin?
1. Distribution of new GTINs and master data to distributors and dispensers	Email or fax distribution of GTIN catalog to any wholesaler and dispenser handling your products.	Distribution is automatic. Provides a uniform method to share product master data rather than sharing same data multiple times with multiple trading partners. Once GTINs are entered into Origin, subscribing distributors and dispensers can download the entire catalog of GTINs in several data formats.
2. Communicating; packaging changes, acquisitions or divestitures	Manufacturers must communicate any changes in pack size or packaging hierarchy (bottle, carton, case and pallet) or changes in product ownership to all downstream trading partners.	Distribution is automatic. Once a change is entered into Origin, it is immediately available to every Origin subscriber.
3. In the field: Day-to-day shipping/receiving problem resolution	Errors identified in the supply chain, such as a product GTIN with no corresponding data, an error in the data or a numbering error on the label, may be duplicated across trading partners and trigger a large volume of calls and emergency correspondence from many customers. Because the new law requires a match between product and data before an exchange of ownership can occur, these errors could result in product quarantine or rejected product being returned to the manufacturer.	Problems downstream are reported to Origin's support team. Origin support contacts you, serving as a single point of contact to correct errors as quickly as possible, communicating your corrections to the universe of subscribers and preventing repeat problems.
<i>Bonus/Added benefit: Validation of GTINs and labeler codes prior to communicating GTINs to the channel</i>		When entered into Origin, all GTIN prefixes are re-verified, and numerical sequences are double-checked using GS1 template standards.

Wholesaler and Dispenser Challenges in Complying with DSCSA Addressed by Origin

Challenge	What Happens Without Origin?	What Happens With Origin?
1. Ensuring you have the master data to meet requirements of the law to identify product for receipt	Collecting GTINs and associated master data is up to you — one manufacturer at a time.	Origin gives you full access to the product master data from all Origin-subscribed manufacturers.
2. Problem resolution when data do not match or is not present	You need to communicate individually with every manufacturer to reconcile issues, which means finding the right contact, even if you do not have a direct relationship with the manufacturer.	You communicate the problem to the Origin support team who works with contributing manufacturers to address the problem.
3. Timely knowledge of product or packaging changes	You depend on each manufacturer to send information on changes that you must then manually update into your systems.	The Origin master data catalog is continually updated. Your systems can communicate directly with Origin via Origin's API to automatically update your master data.
4. How to establish a viable communications channel with indirect trading partners	Especially for smaller distributors, it can be a challenge to ensure that you are receiving data from manufacturers with whom you do not have a direct relationship.	The playing field is leveled. All members of the supply chain have access to the same timely and accurate data.