

# Origin: A Starting Point for DSCSA Data Compliance

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According to Merriam-Webster, “origin” means, “rise, beginning, or derivation from a source,” an appropriate name for the industry tool — available from the Healthcare Distribution Alliance (HDA) and ValueCentric, LLC — intended to enable the starting point for item-level data to support Drug Supply Chain Security Act (DSCSA) compliance.

HDA's Origin creates a standardized method to identify and share each packaging level of a National Drug Code (NDC) for pharmaceutical supply chain participants. The Global Trade Item Number (GTIN-14) is the GS1 data standard widely accepted by the pharmaceutical industry and will be used to comply with DSCSA electronic data transmission requirements through operational business processes.

## Why Origin?

It is important to understand the driver behind Origin's development. As the 2015 DSCSA operational milestones approached, wholesale distributors recognized that their master data did not contain the critical information necessary for compliance. That essential information, the source of products being purchased and whether the drug was exempt, had to be collected by every wholesale distributor, for each of the nearly 24,0001 NDCs purchased from drug suppliers.

How was this activity being conducted? Through spreadsheets, emails and other manual processes. The collection method was unique for each wholesale distributor; it was an extremely tedious process that did not provide equal access to information for all supply chain participants. Despite the efforts of wholesalers and manufacturers, this data collection was not complete by the 2015 compliance date. It was clear, in hindsight, that a better approach was necessary for future DSCSA requirements that rely on trading partner data.

With product identifier obligations on the horizon, HDA staff and members discussed potential methods to level the playing field for all stakeholders and to offer equal, easy and efficient access to critical DSCSA-related data to the entire supply chain. With the help of a trusted technology partner, ValueCentric, the data management solution became Origin.

## How Does It Work?

Origin provides an accessible, single source of GTIN data for anyone in the supply chain who chooses to participate. As “contributors” (manufacturers and repackagers) populate GTIN data into Origin, downstream trading partners — “consumers” (wholesale distributors and dispensers) — will be able to download that information into their master data systems. On a schedule that meets the needs of each subscribing company, that information can be available to enable both data and product flows without disrupting the supply chain. (For distributor and manufacturers that contract with third-party service providers to exchange data on their behalf, HDA recently announced the introduction of a new certification program for solution providers to link their clients' data into Origin using an Application Programming Interface.)

If a consumer does not have the GTIN from a product's label in its master data, the product is likely to become “trapped” either at a receiving or shipping process until the data issue can be resolved.

## Why Now?

DSCSA required manufacturers to apply the product identifier for each package and homogeneous case, and perform verification, in certain situations, in 2017 (though FDA granted enforcement discretion in a draft guidance, stating that it will not begin to enforce manufacturers' product identifier requirements until November 27, 2018). In 2019, wholesale distributors must verify the product identifier prior to reselling returned product. To enable verification, a minimum of 48,000 GTINs (at least two GTINs for each NDC) will be added to wholesale distributor master data, supporting various operational processes.

IT system modifications generally involve long lead times, especially those that hit the core of a wholesale distributor — the identification of units received and shipped. Therefore, it is important for participating manufacturers and repackagers to populate Origin as product identifiers are applied to packages. This, in turn, will allow participating wholesale distributors to plan and make changes necessary to leverage the GTIN as soon as practical, but certainly no later than 2019.

Experience with DSCSA to date indicates that this is going to be a journey that does not end with the exchange and use of the GTIN among trading partners. There will be unintended data errors and omissions, requiring trading partners to work together to solve these problems. The time to discover those challenges and put corrective actions in place is now — before the regulatory requirement is in effect.

Origin is now fully functional. Many manufacturers and distributors are engaging with the system and high growth is expected in 2018 and beyond. For further information on subscribing to the service, visit the Origin product website at [www.hdaorigin.com](http://www.hdaorigin.com).

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For more information:

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