

How Can Your Wholesale Distributor Help Prepare for DSCSA 2023?¹

 <p>Support that CAN be expected</p>	 <p>Support that SHOULD NOT be expected</p>
<p>They can store Transaction Information, Transaction History and Transaction Statement (TI/TH/TS) for product they sold to you for six years (under a written agreement).</p> <ul style="list-style-type: none"> Note: wholesale distributors will only store TI/TH/TS for product they sold to you, not your full inventory. You must make sure to understand the system capabilities for each wholesale distributor or trading partner you are doing business with. TH will no longer be required after November 27, 2023. 	<p>They will not maintain your company's Global Location Number (GLN).</p> <ul style="list-style-type: none"> A Global Location Number (GLN) is a business' unique identifier used by trading partners to gather location information and master data. Many companies were provided a GLN through special programs made available by wholesale distributors. You may contact GS1 directly to help you obtain your new business GLN or determine if you already have a GLN assigned.
<p>They can provide training or support on how to use their systems for ordering, transferring and storing product data.</p>	<p>They will not conduct verification of the product identifier.</p> <p>They cannot conduct product trace requests/inspections/investigations or quarantine product on your behalf.</p>
<p>To receive the TI with the product identifier using Electronic Product Code Information Services (EPCIS), they can help you with testing the data transmission.</p> <ul style="list-style-type: none"> As of July 2023, EPCIS v1.3 should be used by all trading partners as the standard for sharing product and transaction data across the supply chain. 	<p>They are not able to create or advise you on the drafting and execution of your own standard operating procedures.</p> <p>They are not permitted to assume your responsibility and respond on your behalf or provide data in response to requests from FDA or other appropriate governmental authorities for the transaction data (TI/TH/TS) you received.</p>
<p>They will collaborate on suspect and illegitimate product investigations.</p>	<p>In accordance with DSCSA requirements, they cannot respond on your behalf to requests from Authorized Trading Partners for information necessary to facilitate gathering of TI you may have received for a transaction.</p>
<p>In summary, wholesale distributors should be expected to comply with their DSCSA obligations when distributing product to dispensers.</p>	

¹–This checklist is not intended to provide legal advice. The reader is cautioned that it cannot cover all elements of the DSCSA and we refer you to FDA, the DSCSA (and implementing guidance) and/or to their own legal counsel for more information.