



Compliance and DSCSA



[Read our White Paper about DSCSA Compliance and WDSrx Serialization Services](#)

3PL Pharmaceutical Quality Assurance, Regulatory DSCSA Compliance and Industry Participation

WDSrx is entrusted to safely receive, store and distribute prescription and over-the-counter pharmaceutical drug products within the healthcare supply chain.

The vital importance of this responsibility requires quality assurance to ensure shipments efficiently reach their final destinations.

LICENSES AND VERIFICATIONS

In addition to being state licensed nationally, the Federal government through regulatory authorities including the U.S. Food and Drug Administration (FDA), Drug Enforcement Agency (DEA), the Environmental Protection Agency (EPA) and the Department of Transportation (DOT) set requirements that must be met and practiced to continue business operations. WDSrx maintains DEA licenses for Over-The-Counter, Prescription and Controlled Substance (CII-CV) pharmaceutical drug products. WDSrx is also licensed by

the DEA as a Distributor, Reverse Distributor, Importer and Re-Packager. Our facilities meet current Good Manufacturing Practices (cGMP) guidelines established by the FDA to ensure proper design, monitoring and control of operations.

WDSrx maintains VAWD accreditation at facilities in Boca Raton, FL; Pompano Beach, FL; Dayton, NJ and in Sugar Land, TX. VAWD is an intense examination and certification program scrutinizing warehouse facilities and procedures administered by the National Association of Boards of Pharmacy to protect the public from the threat of counterfeit drugs.

Click [here to view details about licenses and accreditations](#) with State and Federal regulatory authorities for our facilities in Boca Raton, FL; Pompano Beach, FL; Dayton, NJ and in Sugar Land, TX

WAREHOUSE MANAGEMENT SYSTEM

Our Datex Warehouse Management System (WMS) fully supports WDSrx warehouse and distribution center operations. The system is Validated to meet the Code Of Federal Regulations (CFR) 21 Part 11 concerning electronic records with accompanying Standard Operating Procedures (SOPs) addressing data backup, data security and other regulatory requirements.

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA)

The Drug Supply Chain Security Act (DSCSA) is a set of Federal regulations administered by the FDA to identify and trace certain prescription drugs distributed in the United States. WDSrx is in compliance with current DSCSA requirements with plans for early completion of future requirements prior to published deadlines.

The initial process selected to achieve the high level of transparency outlined in the DSCSA within the pharmaceutical supply chain is known as serialization. By 2017, manufacturers must utilize a standardized method to individually identify the Smallest Salable Unit (SSU) available for purchase by authorized pharmacies or other dispensers.

As a Third Party Logistics (3PL) provider that also has active packaging lines, WDSrx is making a considerable investment in its packaging operations, distribution centers, IT infrastructure, training and quality assurance to meet current and future DQSA/DSCSA requirements.

Serialization programs are completed, underway or planned in the WDSrx Warehouse and Distribution facilities and also in the Pharmaceutical Packaging and Labeling operations located in Boca Raton, FL and

in Sugar Land, TX.

For more information on the WDSrx Action Plan for DSCSA compliance, read our White Paper in the Resources section of this website.

INDUSTRY PARTICIPATION

WDSrx is a proud member of the Healthcare Distribution Alliance (HDA), the Specialty Pharma Association (SPA), the Generic Pharmaceutical Association (GPhA), BioFlorida, BioHouston, the Warehousing Education Resource Council (WERC) and the National Association of Chain Drug Stores (NACDS).

RELATED MATERIAL

White Paper: [Serialization Implementation And Operations For DSCSA Compliance](#)

Blog: [Serialization Solutions For DSCSA – Challenged Manufacturers](#)

Blog: [Manufacturers, Take These Four Steps Now With Your 3PL For DSCSA Compliance](#)

Case Study: [WDSrx Keeps Client Cool With Pharmaceutical Cold Chain Logistics](#)

Case Study: [WDSrx Vaults Into Action For Manufacturer Of Controlled Substance \(CII\) Pharmaceutical Drug Products](#)

White Paper: [DSCSA Implementation For Pharmaceutical 3PL Providers](#)

News Release: [WDSrx Implements DSCSA Pharmaceutical 3PL Compliance Prior To FDA Deadline](#)

News Release: [WDSrx Sugar Land, TX Facility Approved For VAWD Accreditation](#)

Please allow us to [contact](#) you to discuss your pharmaceutical 3PL compliance requirements.