Partnership for DSCSA Governance

PDG *Blueprint*: Glossary

***Statutory Term**

Accreditation	an agreed upon process through which to evaluate various credentialing, verification, and tracing solutions and confirm they meet the PDG-established minimum expectations
Accreditor(s)	organization(s) that accredit credential issuers and systems and processes that meet the PDG-established requirements
Accredited Credential Issuers	organizations that issue credentials in accordance with PDG-established requirements
Authorized*	(A) in the case of a manufacturer or repackager having a valid registration in accordance with section 510; (B) in the case of a wholesale distributor, having a valid license under State law or section 583, in accordance with section 582(a)(6), and complying with the licensure reporting requirements under section 503(e), as amended by the Drug Supply Chain Security Act. (C) in the case of a third-party logistics provider, having a valid license under State law or section 584(a)(1), in accordance with section 582(a)(7), and complying with the licensure reporting requirements under section 584(b); and (D) in the case of a dispenser, having a valid license under State law.
Business Requirements	technical characteristics of a proposed system that are operationally necessary to meet compliance requirements
Compliance Requirements	characteristics of a proposed system that are necessary to meet statutory obligations under the DSCSA
Credential	a tool by which, as an authorized trading partner, each organization can demonstrate that it meets a set of additional requirements as defined by PDG to ensure they are a valid trading partner who is both uniquely identified and authorized, as required by the DSCSA
Credentialed	for a trading partner, having demonstrated both authorized status and identity according to PDG-defined credentialing process
Co-Licensed Partner (CLP)	any entity, including a private label distributor, that receives product from the new drug application (NDA)/abbreviated new drug application (ANDA)/biologics license application (BLA) holder pursuant to a license or similar contractual agreement that confers a right on the entity to sell the product through its distribution channels is a co-licensed partner of the NDA/ANDA/BLA holder and therefore meets the DSCSA definition of “manufacturer.”

Contract Manufacturing Organization (CMO)	an entity that performs manufacturing operations for the NDA/ANDA/BLA holder or a co-licensed partner of the NDA/ANDA/BLA holder, to fulfill a contractual obligation with such manufacturer, but is not responsible for the introduction of the product into interstate commerce (See FDA's May 2016 guidance on Contract Manufacturing Arrangements for Drugs: Quality Agreements).
DSCSA 2023 Requirements	the requirements in Section 582(g)(1) of the FDCA, which go into effect Nov. 27, 2023 and include interoperable exchange, interoperable verification, and interoperable tracing
EPCIS	Electronic Product Code Information Service, a GS1 standard that enables trading partners to share event-based information about the physical movement and status of serialized products as they travel throughout the supply chain (see https://www.gs1.org/standards/epcis)
Exclusive Distributor*	the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser
Foundational Blueprint for 2023 Interoperability	a set of functional requirements and an overall functional framework defined by PDG that can be adopted to achieve interoperability consistent with the DSCSA 2023 requirements
Governance Model	the method by which a governance body ensures that the governance body's business and technology requirements are being met
GTIN	Global Trade Item Number, the globally unique GS1 Identification Number used to identify "trade items" (i.e., products and services that may be priced, ordered or invoiced at any point in the supply chain).
Homogenous Case*	a sealed case containing only product that has a single National Drug Code number belonging to a single lot
Human Readable Presentation	the presentation of machine readable data in a user interface or written report
Illegitimate Product*	a product for which credible evidence shows that the product— (A) Is counterfeit, diverted, or stolen; (B) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) is the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans

Individual Saleable Unit*	the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser
Interoperable Exchange	the DSCSA 2023 requirement that trading partners exchange required transaction information (TI) and transaction statements (TS) in a secure, electronic, interoperable manner, and the TI must include the product identifier at the package level
Interoperable Verification	the DSCSA 2023 requirement that trading partners be able to verify a product identifier on a package or sealed homogenous case in a secure, electronic, interoperable manner
Interoperable Tracing	the DSCSA 2023 requirement that trading partners maintain secure, electronic, interoperable systems and processes to provide TI and TS in response to a request for it and promptly facilitate gathering the information necessary to produce the TI for each transaction going back to the manufacturer
Interoperability	the ability of systems and processes to exchange and use information accurately, efficiently, and consistently among trading partners
lGTIN	the combination of a GTIN plus batch/lot number
Licensed*	(A) in the case of a wholesale distributor, having a valid license in accordance with section 503(e) or section 582(a)(6); (B) in the case of a third-party logistics provider, having a valid license in accordance with section 584(a) or section 582(a)(7), as applicable; and (C) in the case of a dispenser, having a valid license under State law.
Machine-Readable Data	data in a format that can be processed by a computer; machine-readable data must be structured data
Misalignment Exceptions	when there is a misalignment between the physical supply chain and virtual supply chain
Model	the systems, processes, connectivity, and governance across the supply chain to achieve interoperable data exchange, verification, and traceability
Operational Exceptions	situations that do not directly cause a misalignment of the physical supply chain and virtual supply chain, but do disrupt the normal systems and processes implemented
Partnership for DSCSA Governance (PDG)	an independent, balanced, sector-neutral nonprofit industry governance body that supports the secure, electronic, interoperable tracing, and verification of prescription drugs in the U.S. supply chain, as required by the DSCSA
PDG “Ecosystem”	a space in which participating authorized trading partners (ATPs) have the requisite trust and confidence in the governed environment, and the other

	trading partners within that environment, to be able to efficiently and easily share and exchange data as necessary to meet their DSCSA obligations
Physical Supply Chain	the path a physical package of product follows as defined by each change of ownership associated with the package
Private Label Distributor	with respect to a particular drug, a person who did not manufacture, repack, relabel, or salvage the drug but under whose label or trade name the drug is commercially distributed (See 21 CFR 207.1).
Product Identifier*	a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product
sGTIN	the combination of a GTIN and serial number
Standard	an open, technology-independent established norm or requirement to permit interoperability that was developed by a recognized standards-development body
Status	metadata associated with a product identifier that reflects events associated with that product identifier that have occurred since the product identifier was commissioned by the manufacturer or repackager
Suspect Product*	a product for which there is reason to believe that such product – (A) is potentially counterfeit, diverted, or stolen; (B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) is potentially the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans
System	a technological infrastructure and mechanism used to store, exchange, and/or discover information
Trading Partner*	(A) a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or (B) a third-party logistics provider from whom a manufacturer, repackager, wholesaler distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product
Transaction*	the transfer of product between persons in which a change of ownership occurs

Transaction History (TH)*	a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product
Transaction Information (TI)*	(A) the proprietary or established name or names of the product; (B) the strength and dosage form of the product; (C) the National Drug Code number of the product; (D) the container size; (E) the number of containers; (F) the lot number of the product (G) the date of the transaction; (H) the date of the shipment, if more than 24 hours after the date of the transaction (I) the business name and address of the person from whom ownership is being transferred; and (J) the business name and address of the person to whom ownership is being transferred Beginning on November 27, 2023, transaction information "shall include the product identifier at the package level for each package included in the transaction"
Transaction Statement (TS)*	a statement, in paper or electronic form, that the entity transferring ownership in a transaction— (A) is authorized as required under the Drug Supply Chain Security Act; (B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act; (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582; (D) did not knowingly ship a suspect or illegitimate product; (E) had systems and processes in place to comply with verification requirements under section 582; (F) did not knowingly provide false transaction information; (G) did not knowingly alter the transaction history
Quarantine*	the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures
Verification*	determining whether the product identifier affixed to, or imprinted upon, a package or homogenous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with section 582
Virtual Manufacturer	an NDA-, BLA-, or ANDA-holder or co-licensed partner of a manufacturer that does not engage in the manufacturing, preparation, propagation, compounding, or processing of a drug and is therefore not registered under section 510 of the FD&C Act, but still meets the definition of a manufacturer in

	section 581(10) of the FD&C Act and is therefore able to acquire an ATP credential
Virtual Supply Chain	the digital or electronic reflection of the physical supply chain, generally represented in the form of transaction information