

Global Standards and Traceability Glossary of Terms

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Term	Definition
automatic identification and data capture (AIDC)*	A technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics, and RFID. ¹
barcode*	A symbol that encodes data into a machine-readable pattern of adjacent, varying width, parallel, rectangular or square dark and light spaces.
barcode verification*	The assessment of the printed quality of a barcode based on International Organization for Standardisation (ISO)/International Electrotechnical Commission (IEC) standards using ISO/IEC-compliant barcode verifiers.
batch/lot*	Associates an item with information the manufacturer considers relevant for traceability of the trade item.
brand owner*	The Organization that owns the specifications of a trade item, regardless of where and by whom it is manufactured. The brand owner is normally responsible for the management of the Global Trade Item Number (GTIN).
classification	A form of cataloguing, or identifying, products that can be defined as a process for grouping products into categories based on an understanding of the essential properties and relationships between them. A classification system is used to group like products such as medical devices versus pharmaceutical drugs. Example classification systems are UNSPSC, GPC, eClass, and ATC.
check digit*	Numeric character calculated from data and appended as part of the data string to ensure that the data is correctly composed and transmitted.
concatenation*	The representation of several element strings in one barcode.
data architecture	Models, policies, rules, or standards that govern how data is stored, managed, and utilized in an information system.
Data carrier	Any medium that can record and convey data; a medium that holds machine-readable data.
data governance	The development, execution, and supervision of policies, programs, and practices that standardize, collect, control, protect, deliver, and enhance the value of data and information assets.
data synchronization	The process of maintaining the consistency and uniformity of data instances across all consuming applications and storing devices.
Data Matrix	A standalone, two-dimensional (2D) matrix symbology that is made up of square modules arranged within a perimeter finder pattern.
EAN-13 barcode	The barcode of the EAN/UPC symbology that encodes a Global Trade Item Number (GTIN) for retail purposes
EAN-8 barcode*	A barcode of the EAN/UPC symbology that encodes GTIN-8 or RCN-8.
Electronic Product Code Information Services (EPCIS)	An open standard which allows businesses to capture and share supply chain information about the movement and status of goods, both within their enterprise and with their business partners.
event data	The information generated by an item as it moves through the supply chain. It includes the what, where, when, and status of an object each time the item's RFID tag is read.
Expiration date	The date up until which the drug manufacturer can guarantee that the medicine is fully potent and safe to take based on scientifically-sound product testing.
Global Data Synchronization Network (GDSN)	Connects interoperable data pools so pharmaceutical manufacturers, logistics providers, regulatory authorities, supply chain managers, and healthcare workers can share and use the same accurate information about health commodity orders.
Global Location Number (GLN)*	The GSI identification key used to identify physical locations or parties. The key comprises a GSI Company Prefix, location reference, and check digit.
Global Trade Item Number (GTIN)*	The GSI identification key used to identify trade items. The key comprises a GSI Company Prefix, an item reference and check digit.
GSI	A neutral, not-for-profit, global organization that develops and maintains the most widely used supply chain data standards in the world.
GSI-128 linear barcode	A barcode symbology using bars and spaces in one dimension that leverages a subset of Code 128 that is used exclusively for GSI system data structures.
GSI Application Identifier*	The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.

¹ Definition taken from GSI General Specifications 2021

GSI Company Prefix*	A globally unique string of four to twelve digits assigned to an entity and used to issue GSI identification keys. The first digits are a valid GSI Prefix and the length must be at least one longer than the length of the GSI Prefix. The GSI Company Prefix is issued by a GSI Member Organization. As the GSI Company Prefix varies in length, the issuance of a GSI Company Prefix excludes all longer strings that start with the same digits from being issued as GSI Company Prefixes.
GSI DataMatrix*	A subset of Data Matrix which uses the function that allows the encoding of element strings
GSI Healthcare	A global, voluntary user group that develops standards to advance global harmonization. GSI Healthcare consists of manufacturers, wholesalers, distributors, hospitals, and pharmacy retailers and maintains close contacts with regulatory agencies and trade Organizations worldwide. It drives the development of GSI standards and solutions to meet the needs of the global healthcare industry and promotes the effective use and implementation of global standards for the industry.
GSI identification key*	A unique identifier for a class of objects (e.g., a trade item) or an instance of an object (e.g., a logistic unit).
GSI Member Organization*	A member of GSI that is responsible for administering the GSI system in its country (or assigned area). This task includes, but is not restricted to, ensuring user companies make correct use of the GSI system, have access to education, training, promotion, and implementation support and have access to play an active role in the Global Standards Management Process (GSMP).
GTIN-12*	The 12-digit GSI identification key composed of a U.P.C. Company Prefix, item reference, and check digit used to identify trade items.
GTIN-13*	The 13-digit GSI identification key composed of a GSI Company Prefix, item reference, and check digit used to identify trade items.
GTIN-14*	The 14-digit GSI identification key composed of an indicator digit (1-9), GSI Company Prefix, item reference, and check digit used to identify trade items.
GTIN-8*	The 8-digit GSI identification key composed of a GSI-8 Prefix, item reference, and check digit used to identify trade items.
healthcare primary packaging*	The first level of packaging for the product marked with an AIDC data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system and may consist of a single item or group of items for a single therapy such as a kit. For packaging configurations that include a retail consumer trade item, primary packaging is a packaging level below the retail consumer trade item.
healthcare secondary packaging*	A level of packaging marked with an AIDC carrier that may contain one or more primary packages or a group of primary packages containing a single item.
human readable interpretation (HRI)*	Characters, such as letters and numbers, which can be read by persons and are encoded in GSI AIDC data carriers confined to a GSI standard structure and format. The human readable interpretation is a one-to-one illustration of the encoded data. However, start, stop, shift, and function characters, as well as the symbol check character, are not shown in the human readable interpretation.
kit*	A collection of different regulated healthcare items assembled for use in a single therapy.
label	And tag, brand, mark, pictorial, or other descriptive matter, written, printed stenciled, marked, embossed, or impressed on or attached to a container of any medicinal product.
logistic unit*	An item of any composition established for transport and/or storage that needs to be managed through the supply chain. It is identified with an SSCC.
manufacturer	An entity that makes or produces drugs, pharmaceuticals, or medical devices through a process involving raw materials, components, or assemblies, usually on a large scale.
marketing authorization holder (MAH)	Any legal entity that holds are marketing authorization issues by the country-designated body or organization to distribute and sell its pharmaceutical products in a given country.
master data	The identification number and descriptive attributes of an object that are static or nearly so that provide more information or characteristics of the object identified.
medical device	Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for any medical purpose.
mono-carton	Cartons used for compact packaging of medicinal products.
point-of-care (POC)*	Location where dispensing or use of a non-retail, regulated healthcare pharmaceutical or medical device to or for a patient occurs.

point-of-sale (POS)*	Refers to the retail checkout where omnidirectional linear barcodes must be used to support high-volume laser-based scanning or low volume checkout where linear barcodes (or for regulated healthcare trade items, GSI DataMatrix) are used with image-based scanners.
Product	An object with a defined set of attributes or characteristics.
Pharmaceutical	Any substance or mixture of substance: <ul style="list-style-type: none"> a) used in the diagnosis, treatment, mitigation or prevention of human disease, disorder, abnormal physical or mental state, or the symptoms thereof; b) used in restoring, correcting or beneficial modification of organic or mental functions in humans; c) which are articles other than food, intended to affect the structure or any function of the body of humans; and d) which includes articles intended for use as a component of any articles specified in clause (a), (b) or (c).
pharmaceutical supply chain	The flow from the origin to the consumption of pharmaceuticals covering the manufacturing, import, distribution, transportation, storage, and dispensing stages, as well as other types of flows.
primary packaging	The first level of packaging for the product marked with a data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system and may consist of a single item or group of items for a single therapy such as a kit.
QR Code	A machine-readable code consisting of an array of black and white squares, typically used for storing URLs or other information for reading by the camera on a smartphone.
Radio frequency identification (RFID)*	A data carrier technology that transmits information via signals in the radio frequency portion of the electromagnetic spectrum. A radio frequency identification system consists of an antenna and a transceiver, which read the radio frequency and transfer the information to a processing device, and a transponder, or tag, which is an integrated circuit containing the radio frequency circuitry and information to be transmitted.
secondary packaging	The level of packaging marked with a data carrier that may contain one or more primary packages or a group of primary packages containing a single item.
serial number*	A code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime. Example: a unique individual item may be identified with the combined Global Trade Item Number (GTIN) and serial number.
Serial Shipping Container Code (SSCC)*	The GSI identification key used to identify logistic units. The key comprises an extension digit, GSI Company Prefix, serial reference, and check digit.
solution provider	A vendor that provides products and/or technical or service support to a company. It offers companies hardware, software, guidance, resources, and tools in a variety of areas. Examples are barcode services, including labels, printing, designing, and verifying; barcode hardware, including printers, readers, and scanners; and barcode software.
supplier	An entity with which a procurement agent has a contractual relationship for providing one or more trade items. The supplier is involved or plays a role in the buying, selling, or production of the pharmaceutical or medical device and can be a manufacturer, brand owner, wholesaler, or distributor.
supply chain entity	Any person in the supply chain who manufactures, imports, distributes, transports, stores, or dispenses pharmaceuticals or is involved in related activities.
tertiary homogenous pack	A tertiary pack that consists entirely of the same trade item with the same batch number and expiration date.
tertiary mixed pack	A tertiary pack that contains either more than one unique trade item or entirely the same trade item with different batch numbers or expiration dates.
tertiary packaging	The highest level of packaging that may include a pallet that contains (one or usually) several cases or a case that contains (one or usually) several items in its primary or secondary packaging. Tertiary packaging may refer to either a logistic unit or a trade item.
tertiary partial pack	A homogenous pack of products that is not to be considered a trade item because it is less than full.
traceability	the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application, or location of a pharmaceutical product.
track and trace	The business process of tracking forward and tracing back a uniquely identifiable "traceable item" at any point along the entire supply chain from creation to the point of sale, use, or

	destruction. Track and trace requires trading partners to exchange data for defined events and provide the what, when, where, and why about trade items as they move through the supply chain.
trade item*	Any item (product or service) upon which there is a need to retrieve predefined information and that may be priced, or ordered, or invoiced at any point in any supply chain.
transactional data	The information exchanged between two organizations about the products and services they are selling, ordering, delivering, receiving, invoicing and paying for.
unique identifier	A numeric or alphanumeric string captured in a machine-readable data carrier and human-readable form on the label of the pharmaceutical package that is associated with a single product or product group.
verification	Determining whether the unique identifier affixed to, or imprinted upon, a pharmaceutical package corresponds to the unique identifier assigned to the product by the manufacturer or the repackager.