



Workflow Solutions

Videojet IMprints AI21™
Pharmaceutical serialization platform



A right-sized option for DSCSA compliance

The Drug Supply Chain Security Act (DSCSA) deadline for serialization is fast approaching and the challenges to comply can seem complex. You need to not only determine how to implement serialization on your packaging lines, but also how to manage the downstream and upstream flow of the associated data. The challenges can be even more daunting if you are a contract manufacturer (CMO) or small/virtual pharmaceutical company that has to coordinate a variety of partners with their own unique implementation needs.

Videojet IMprints AI21™*, a pharmaceutical serialization platform, can get you on the fast track to compliance with a solution that can standalone or integrate with components and systems you may already have in place.

Cost-effective

As a set of standard modules focused strictly on the basics of DSCSA compliance, IMprints AI21 provides a right-sized option, particularly for small pharma and CMOs.

Expandable

Modules can be added on as regulations evolve, business needs change or new trading partners are added.

Flexible

IMprints DataShare Connector Modules offer multiple straightforward options to exchange data with internal or external enterprise systems or directly manage and report serialization events.

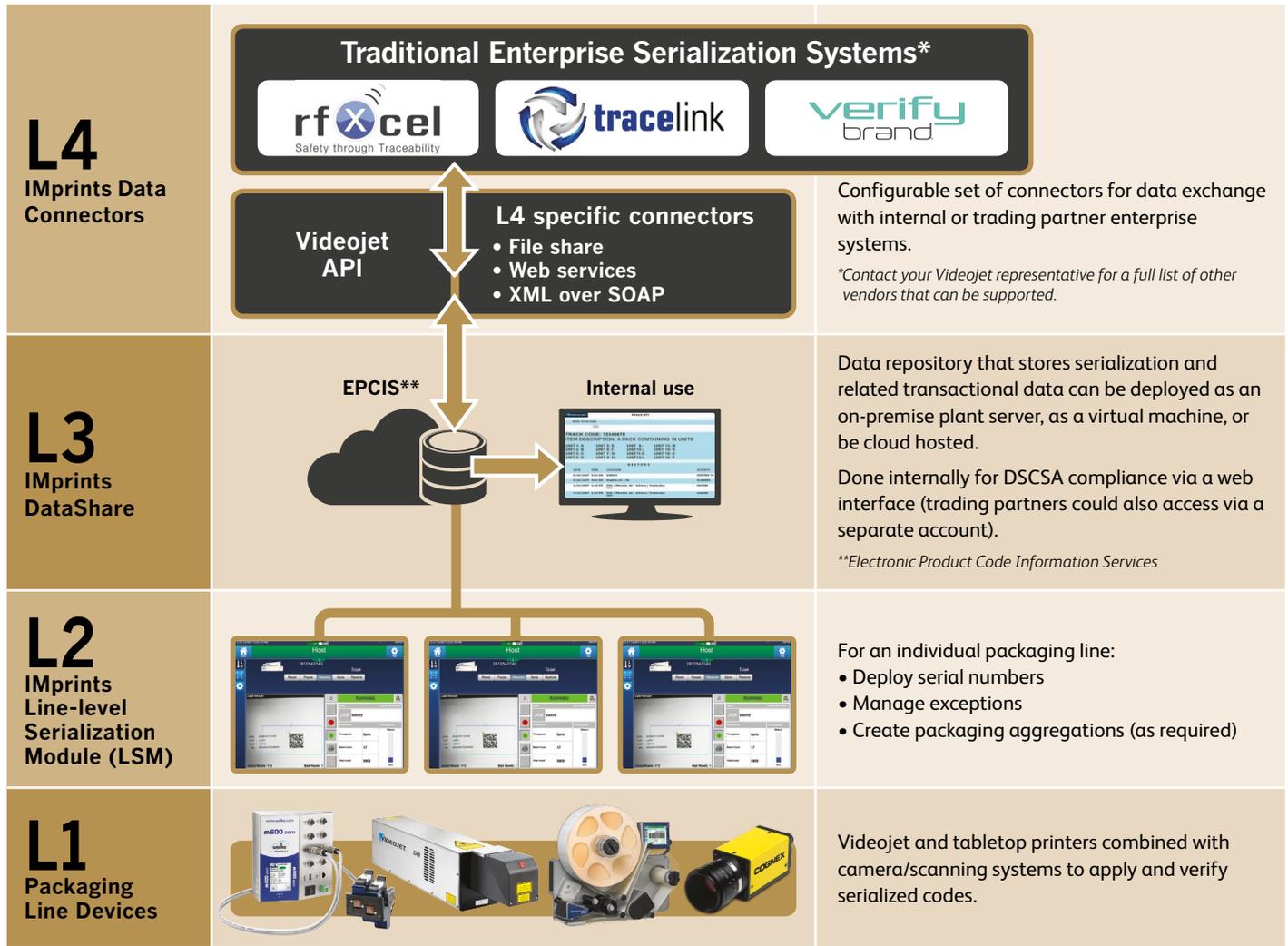
Expertise

Provided by a global leader in marking and coding and installed and supported by an expert team that specializes in traceability applications.

**Videojet IMprints AI21™ is available only in North America.*



Videojet IMprints AI21™



DSCSA timeline and requirements

Deadline	Requirement	Description
November 27* 2017	Unique IDs for each drug package and sealed homogeneous case	<ul style="list-style-type: none"> • Mark unit of sale packages with a code that contains a unique IDs, GTIN number, lot code and expiration date • Data to be encoded in 2D bar code format - adherence to GS1 standards recommended • Keep a record of the unique IDs that are put into circulation for 6 years
	Respond to verification requests	<ul style="list-style-type: none"> • A manufacturer must respond within 24 hours to requests from trading partners or the FDA that the code in question represents a legitimate item shipped by that manufacturer and supply any related transactional history
	Verify the Unique ID of returned products intended for resale	<ul style="list-style-type: none"> • Manufacturers must check a returned product's code against their own database to ensure that the returned product received is legitimate before sending it back into the distribution chain
	Transactional information in electronic format	<ul style="list-style-type: none"> • Typical transmitted as an Advance Ship Notice per EDI 856 guidelines
November 27 2023	Interoperable package level traceability system	<ul style="list-style-type: none"> • Electronic exchange of package-level transactional information, including the unique ID, in a manner that enables regulators to view a drug's full distribution history • FDA to further define requirements by 2021 • Parent-child aggregation of packaging levels to support inference throughout the distribution chain expected to be a requirement

*June 2017 FDA guidance indicates that enforcement will begin in November 26, 2018.

Why partner with Videojet

A serialization system is only as good as the code applied to the product or package. A world leader in marking and coding, Videojet is the ideal partner to help ensure that your essential serialization process goes smoothly. With multiple technology options for each level of packaging, Videojet can help you find the ideal coding solution for your particular application.

Options include the Wolke thermal inkjet line of printers, the gold standard for applying unique IDs in pharmaceutical applications. These printers, available in various configurations, are extremely adept at applying high-resolution 2D bar codes on packaging lines. They also offer powerful data handling features specifically designed for high-speed serialization.

IMprints AI21™ is compatible with most makes and models of Videojet printers as well as popular desktop label printers.



Thermal Inkjet (TIJ)



Continuous Inkjet (CIJ)



Laser Marking



Labelers



Thermal Transfer Overprinting (TTO)



Large Character Marking (LCM)

IMprints™ Line-level Serialization Module

The IMprints™ Line-level Serialization Module (LSM) is a dedicated automation system that interfaces with packaging line devices such as printers, cameras and material handling systems that are part of the serialization process.

Users can configure the basic metadata and business rules around their product, including associated print templates and minimum code levels. The LSM uses the serialization data that is allocated to it to create fully-formed codes and to drive the printers at the item, case and pallet levels. Optional camera systems can be used to verify code presence and accuracy, and I/O is available for automated exception handling.

Once a batch is closed, the transactional data from the line can be sent upstream for transmission back to an Electronic Product Code Information Services (EPCIS) repository. All codes are reported back as either commissioned, retained or destroyed.

Typical DataMatrix pharmaceutical code



(01) 40987654321012	←	Product code (GTIN) – (01)
(21) 19000000000000008201	←	Unique serial number – (21)
(17) 100428	←	Expiry date – (17)
(10) 12345678	←	Lot or batch number – (10)

The unique identifiers, which are obtained from an upstream system are combined with data that has either been preconfigured for that product or entered at the start of a batch, to create fully-formed product codes.

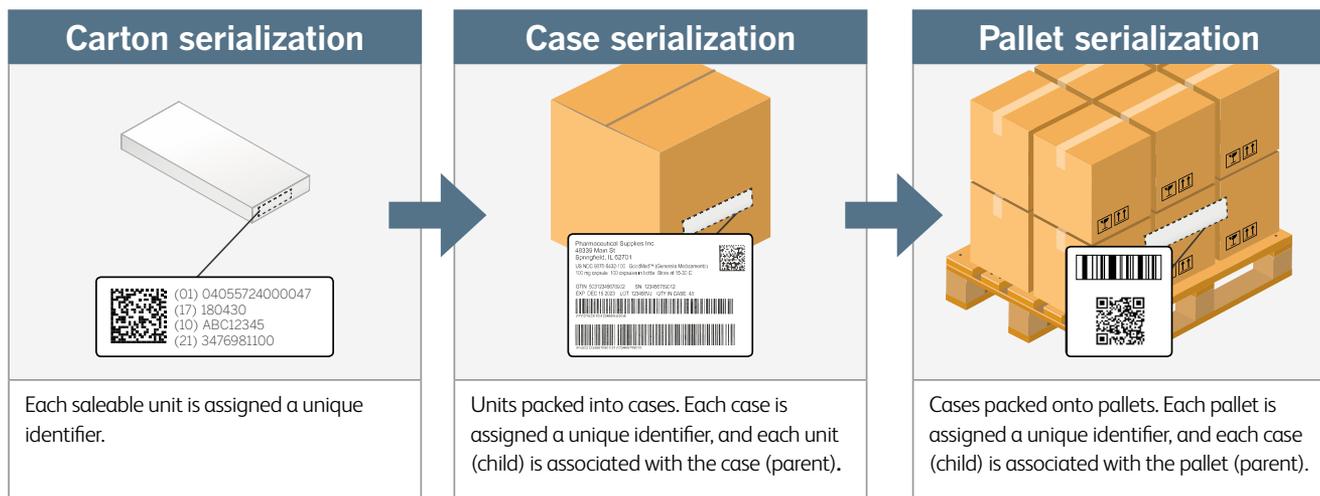
A line-side or remote user interface helps enable operators to input necessary data, see batch run information, and query the status of individual codes.



IMprints™ Aggregation Module

The optional IMprints Aggregation module can address multiple levels of aggregation (inner pack, master pack, case, pallet) and can be added at any time. The module is compatible with programmable hand-held scanners for manual pack operations, and can also be configured for more automated approaches.

While the DSCSA does not specifically require creating parent-child relationships between packaging levels at this time, doing so provides additional efficiency and is often requested by large wholesalers.



Aggregation and inference work together to make traceability practical

Aggregation: The process of creating “parent/child” relationships between the codes used in the packaging hierarchies (e.g. package to inter-pack, inter-pack to case, case to pallet). In this manner, a pallet code can be used to track all of the codes for the individual products that are shipped on that pallet.

Inference: The result of using aggregation is that a supply chain partner may “infer” what codes are contained in a shipment, based on the information passed on from the packager. This helps enable traceability to occur without having to open up every shipment and scan the individual contents – a process which would add significant handling costs and add the potential for additional error.

IMprints™ DataShare Module

The IMprints DataShare Module serves as the plant level EPCIS repository. The module interfaces with upstream enterprise systems to obtain unique IDs and then deploys those to the LSM when a batch is to be run. Once a batch is closed, the related transactions are passed back to the IMprints DataShare Module and formatted for further transmission.

The EPCIS repository can be deployed locally on a plant server or even on one of the packaging line PCs, or in the cloud. The repository can be utilized in several ways:

- Internal DSCSA compliance via a web portal that facilitates quick look up of serial number history and creates reports in electronic format*
- Access to serial number history for your trading partners through the same portal
- Data exchange with your trading partners via:
 - Configurable connectors specific to enterprise serialization systems from vendors such as Tracelink, Verify Brand, and rfXcel
 - A published Videojet application programming (API) interface that enables the trading partner to access the repository*

Data integrity is safeguarded via secure folders, individual/role-based passwords and temporal database design that keeps a full history of changes in order to facilitate 21 CFR part 11 compliance.

** Available second half of 2017*



Videojet IMprints AI21™ is more than just data management software and packaging line hardware and includes:

- Full project management
- Installation from an experienced team of Videojet field engineers dedicated to deploying traceability solutions
- IQ/OQ documentation and audit trail to facilitate your validation efforts
- Site audits
- Factory acceptance testing
- Operator training

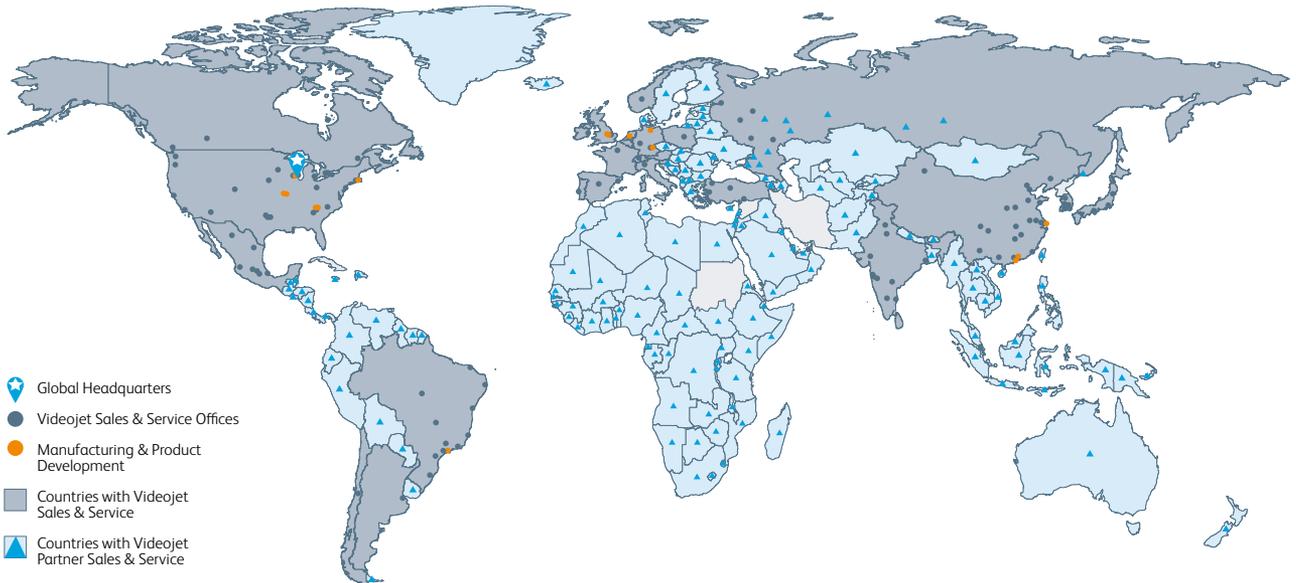
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Peace of mind comes as standard

Videojet Technologies is a world-leader in the product identification market, providing in-line printing, coding, and marking products, application specific fluids, and product life cycle services.

Our goal is to partner with our customers in the consumer packaged goods, pharmaceutical, and industrial goods industries to improve their productivity, to protect and grow their brands, and to stay ahead of industry trends and regulations. With our customer application experts and technology leadership in Continuous Ink Jet (CIJ), Thermal Ink Jet (TIJ), Laser Marking, Thermal Transfer Overprinting (TTO), case coding and labeling, and wide array printing, Videojet has more than 345,000 printers installed worldwide.

Our customers rely on Videojet products to print on over ten billion products daily. Customer sales, application, service and training support is provided by direct operations with over 4,000 team members in 26 countries worldwide. In addition, Videojet's distribution network includes more than 400 distributors and OEMs, serving 135 countries.



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