Traceability Solutions

gerresheimer
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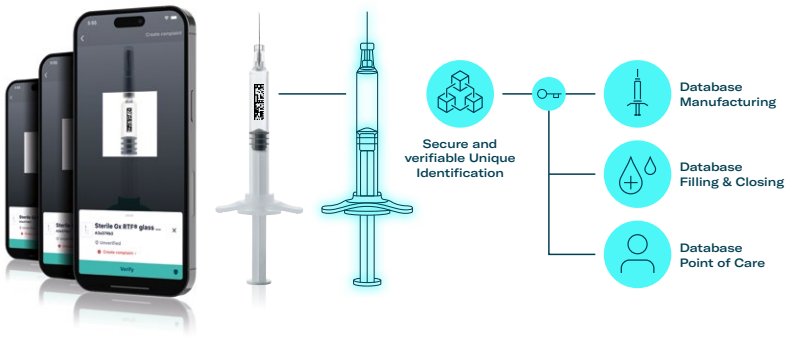


Traceability Solutions for Parenteral Drug Delivery Systems:

State-of-the-art digital twin technology enabling a new level of efficiency in the pharmaceutical supply chain and contributing to patient safety.

How it works

Unique Identification: At the start of the manufacturing process, each primary package is marked with a unique, randomized identifier (UID). The UID is recorded in a blockchain-based eco-system which is secure, immutable and decentralized, ensuring its identity during its entire lifecycle.

Digital Twin Creation: A Digital Twin of a unique primary package is created by linking its UID with data from the first manufacturing step in a tamper-evident manner. During subsequent steps of production up to the moment of drug administration, the digital twin is enriched with new data sets linked to the UID. This digital twin represents the identity and characteristics of each container during its entire lifecycle.

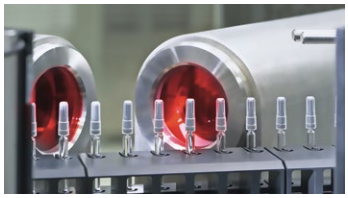
Verification and Access: Applications, whether mobile or M2M, validate the UID via the traceability eco-system. They then display the digital twin data from a retrieved link to a relevant database, subject to authorized rights for use or service.

Physical unique identification methods

Showcasing a range of 2D Matrix codes of varying sizes, compliant with ISO/IEC 16022 standards for error correction. These are expertly applied to pharmaceutical containers such as glass or COP syringes, vials, ampoules, and cartridges. The codes are imprinted using durable ink or laser printing techniques to ensure legibility and resilience throughout pharmaceutical processing and testing.

RFID Tag Integration for Pharmaceutical Syringes: Ensuring seamless and accurate reading of unique identifiers with specialized RFID tags affixed to syringe closures.

Enhancing quality control with data-driven traceability across Pharma Manufacturing Sites



Traceability enhances manufacturing quality assurance by enabling swift and secure scanning of a primary package's Unique Identification throughout production – from material formation to labeling commencement.

Data Integration: No manual measurement is required as comprehensive quality data can be acquired at each step, which reduces errors and streamlines quality control processes.

Operational Efficiency: Not only is adherence to regulatory standards optimized, but also when a defect is identified, traceability helps expedite root cause analysis by correlating data across processes and sites.

Defect Inventory Management: Simple, fast identification of batches with defects avoids the need to retain inventory during manual investigation, contributing to sustainability and cost efficiency.

Reduced risk of mix-ups: Primary packaging contents can be immediately verified by manual scanning or automated machine-reading, which significantly reduces risk of errors, even on lines handling multiple formulations.

Improving patient safety and trust in the healthcare eco-system

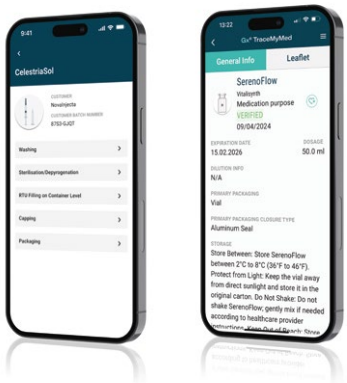
Ensuring patient safety, particularly during the administration of medications via parenteral drug delivery systems, is a collaborative effort within the healthcare ecosystem, involving pharmacists, nurses, and doctors.

Secure Verification of Medication: At the point-of-care, the medication's authenticity, data such as expiry date and IFU can be immediately verified via the primary package's unique identification.

Electronic Integration: The information about the medication can be seamlessly integrated into the patient's electronic medical records, reducing the risk of manual errors. Proactive Safety Measures: Before administration of the drug, inspection of the primary packaging, such as a multi-dose vial, will immediately flag up any potential recall, which adds another layer of patient protection.

Counterfeit Prevention: Public health safeguards are augmented, as counterfeit, falsified, or diverted medications can be quickly identified by law enforcement or pharmaceutical inspectors.

Key benefits



Comprehensive Traceability in Parenteral Drug Delivery: Enhancing Supply Chain Quality and Patient Safety.

End-to-end traceability in parenteral drug delivery ensures quality and increases patient safety by maintaining a secure data flow from primary packaging production to medication administration.

A singular, immutable, and tamper-evident Unique Identification serves as the cornerstone for accessing diverse information sources in a decentralized system, from the inception of the drug delivery container to its disposal.

Machine-to-machine interfaces can supplant mobile applications, ensuring that data usage is always under the control of the data's owner.