

ORACLE PEDIGREE AND SERIALIZATION MANAGER

KEY FEATURES

- Analytic Dashboard
- Serial Generation
- Serial Data Import and Export
- Electronic Pedigree
- Inference Management through Pack Hierarchy
- Returns Repudiation
- Web Services

As a result of counterfeit and diverted drugs entering the drug distribution supply chain and endangering patient safety, many healthcare and life sciences organizations are facing increased supply chain integrity and brand integrity risks. In response, regulations are evolving, which are driving the pharmaceutical industry toward better tracking of their products in the supply chain. Oracle Pedigree and Serialization Manager (OPSM) is an integrated mass-serialization and pedigree application that enables companies to implement mass-serialization of drug products and share serialized product data across the supply chain.

The Need for Better Product Tracking

Industry recognizes that more detailed tracking and tracing of their products across the supply chain with unique, serialized codes on each salable unit is a key to making the counterfeiter's job more difficult and providing the means to authenticate or verify the validity of their products prior to dispensation to the patient. Regulators around the world are also driving this push toward drug product serialization.

Oracle Pedigree and Serialization Manager is a new application Oracle has developed from the ground up for the pharmaceutical industry to enable serialization and electronic pedigree management in a single solution which is designed to work alongside your existing manufacturing, shipping and receiving systems, be they Oracle or third-party applications.

Analyze Product Risk and Usage

The Operations Dashboard is the entry point into Oracle Pedigree and Serialization Manager (OPSM). Information about potential counterfeit threats, serial shipping, receipt volumes and exceptions and more is available at a user's fingertips upon logging into the application via charts and detailed data drilldown capability.

Enable Serialization Without Impacting Existing Systems

Because OPSM is separate from your existing online transaction processing systems, it can be installed with minimal impact on the existing systems, which is especially important in validated environments and it will keep the massive additional data burden from impacting the ongoing performance of those systems. OPSM enables GS1 SGTIN standard format serialization in environments where the existing systems do not support it, are not configured for it and where companies do not want them to be burdened with the data volume. It is designed to work alongside

KEY BENEFITS

OPSM enables compliance with evolving drug product track and trace and authentication mandates by combining serialization and electronic pedigree management in a single, integrated application.

It is built on a service oriented architecture (SOA) to integrate with and impart minimal impact on existing transaction systems.

OPSM has been designed with input from pharmaceutical industry companies to address compliance needs and deliver top and bottom line benefits.

your existing manufacturing, shipping and receiving systems, be they Oracle or third-party applications and supports export of the serial data in various formats, including electronic pedigree, at the time of shipment, to downstream supply chain partners and government regulatory databases.

Generate, Print and Share Electronic Pedigrees

Oracle Pedigree and Serialization Manager generates electronic pedigrees in xml format suitable for export and in human-readable and printable document format. Multiple pedigree formats are supported and the layout is easily tailorable to support evolving regulatory requirements and company-specific formats and graphics such as logos.

Support Inference by Modeling the Packaging Hierarchy

Inference enables the results of transactions conducted at the parent (case) packaging level to be automatically cascaded to all of the contents of that level automatically, without having to scan each individual unit packed within the parent. OPSM has powerful query capabilities that enable searching for serials based on their individual codes, or on the identifier of their parent level packs.

Improve Returns Repudiation

Oracle Pedigree and Serialization Manager supports the import of serial data from product return receipt transactions entered in your ERP, WMS or other transaction processing system. This data is automatically cross-referenced against previously shipped serial transactions and checked for exceptions, such as counterfeit serials, serials that do not exist and serials that were not previously shipped. This data can also be used to cross check against other systems that manage invoicing and chargebacks to enable additional validations of return receipts.

Bottom Line

Oracle Pedigree and Serialization Manager is purpose-built for and with the pharmaceutical industry, combining serialization and pedigree management in a single, integrated application delivering regulatory compliance and business value.

With Oracle's Supply Chain Integrity approach, it's not only regulatory compliant, it's business efficient.

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