

ORACLE PEDIGREE AND SERIALIZATION MANAGER

KEY FEATURES

- Operations Dashboard
- Serial Generation
- Serial Data Import and Export
- Electronic Pedigree
- Inference Management through Pack Hierarchy
- Returns Repudiation
- Web Services to create shipment, return and import transactions, merge lots, and manage serial data.
- Serial Import capabilities

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. When paired with the Serialization and Tracking Integration Pack for Oracle Pedigree and Serialization Manager and Oracle E-Business Suite (Serialization and Tracking Integration Pack), OPSM seamlessly combines its serialization and pedigree management capabilities with Oracle E-Business Suite's (EBS) robust inventory, manufacturing and order management applications.

The Need for Better Product Tracking

Drug counterfeiting is a worldwide problem and threat to public health and safety. Often thought of as mainly a problem in the developing world, where it's estimated that anywhere from 10-30% of the drugs purchased may be counterfeit, it is also a significant problem in the developed world, with some estimates putting counterfeits at 1% of the US market. This may seem low, but it's significant when you consider that over 3.5 billion doses of prescription pharmaceuticals are administered in the US annually, so over 35 million could be counterfeits made with substandard ingredients and processes, active ingredients that are in the wrong potency, absent, or substituted with other unknown ingredients with potentially harmful effects. Counterfeiters are estimated to take in about \$75 billion annually in this illegal business, so they have incentive and the resources to carry out their crimes. Industry and regulators are looking to minimize their opportunity to do so.

Industry recognizes that more detailed tracking and tracing of their products across the supply chain with unique, serialized codes on each salable unit is 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. A pre-built integration for Oracle E-Business Suite Releases 11.5.10 and 12.1.2 is available with the Serialization and Tracking Integration Pack.

Compliance with Business Benefits

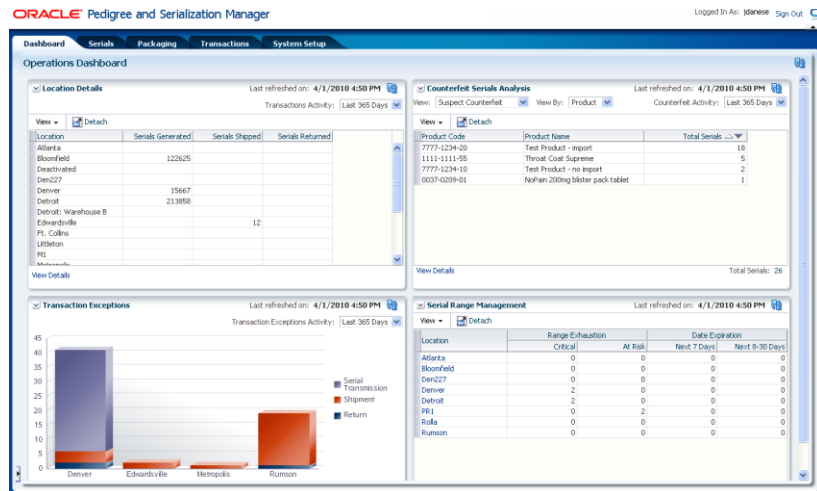
Regulatory bodies around the world, including those in the United States, Europe, Turkey, Brazil and India are pushing industry toward unit level serialization of drug products. In 2015, the state of California will begin requiring drugs distributed within its borders to have an electronic pedigree tracking each serialized unit back to the manufacturer. The FDA may also take action with a similar, nationwide mandate, which may preempt the California rules. In Europe, several countries, along with Turkey, already require serialization and Brazil is likely to be next to follow suit with their own serialization variant.

For the pharmaceutical industry, serialization is a huge change from lot level control. Fortunately there are significant business benefits to be realized. Tracking product transactions at the serial unit level will enable manufacturers to realize improvements to their top and bottom line. Better returns reconciliation is one area of significant potential savings. The pharmaceutical industry writes off an estimated \$2 billion in returned product annually and has no way to verify the legitimacy of the returned product in an efficient manner, if at all. Some companies estimate that 50% of the returned product should not be accepted because it's expired, never shipped in the first place, may be counterfeit, or is returned at a different invoice price than it was sold. Automated reconciliation of returns at the serial level will add the scrutiny required to cut down on illegitimate returns.

Other areas where serialization could yield business benefits are in the reduction of diversion and parallel trade, "gray market" sales, reconciliation of chargeback requests and protection of brand integrity.

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.



Operations Dashboard

Enable Serialization Without Impacting Existing Systems

Putting unique IDs on product packages will make it more difficult for counterfeiters to pass their products off as legitimate and will help cut down on the counterfeit problem, but the conversion from lot management to serialization is, without a doubt, the most challenging change for industry to uptake. 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 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. The available integration with EBS via the Serialization and Tracking Integration Pack generates serials based on manufacturing order quantity and, if volumes increase, will request additional serials to cover the difference.

OPSM has the ability to generate, import, manage and view serial numbers in GS1 SGTIN standard format as well as sequential or random product neutral formats and can accommodate bespoke serialization algorithms. It can be deployed to work with multiple, heterogeneous transaction systems 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.

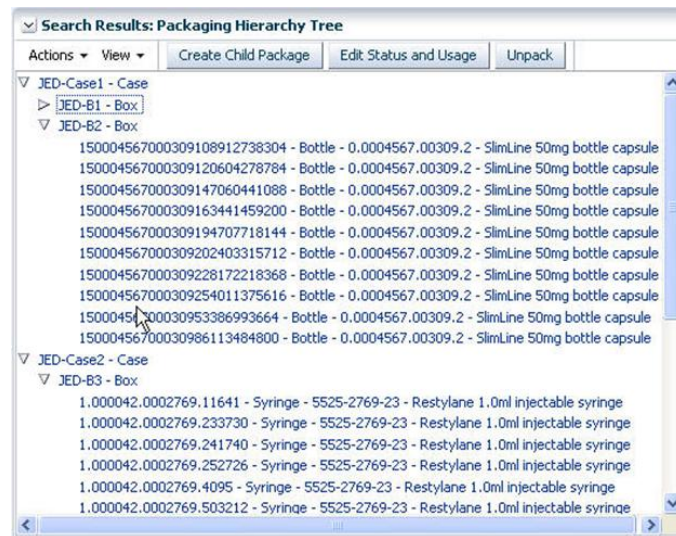
Support Inference by Modeling the Packaging Hierarchy

The adoption trend of RFID technology in the pharmaceutical industry has declined,

with 2D barcodes having emerged as the data capture format of choice. Reading these codes, however requires line of sight, so inference is a critical to knowing what is being shipped or received when the lowest level salable units are within one or more levels of packaging.

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. The packaging hierarchy can be built manually in OPSM through a drag and drop user interface, but in most implementations it will likely be built automatically through web service calls from a back end ERP, packaging execution system or warehouse management system.



Modeling the Packaging Hierarchy Supports Inference

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. The Serialization and Tracking Integration Pack includes integration points that track these returns from EBS.

Bottom Line

Oracle Pedigree and Serialization Manager is purpose-built for and with the pharmaceutical industry, combining serialization and pedigree management in a

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. However, it will also benefit high tech consumer product and luxury goods manufacturers who are also concerned with counterfeiting and product piracy.

A pre-built integration with Oracle E-Business Suite provides faster implementation with decrease risk.

**RELATED PRODUCTS
AND SERVICES:**

- Oracle Serialization and Tracking Integration Pack for Oracle Pedigree and Serialization Manager and Oracle E-Business Suite
- Oracle E-Business Suite
- Oracle Applications Integration Architecture
- Oracle Fusion Middleware

single, integrated application delivering regulatory compliance and business value.

Productized integration between OPSM and Oracle E-Business Suite maximizes return on your investment by reducing initial and ongoing total cost of ownership and reducing complexity and risk associated with your implementation.

Additionally, if you need to integrate OPSM with other transaction processing systems, the common business object and web services provided with this integration pack may be reused to give you a starting point for building those additional integrations, thereby reducing their cost and complexity.

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

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