ORACLE PEDIGREE AND SERIALIZATION MANAGER

KEY FEATURES

- Operations Dashboard
- Serial Generation
- Serial Data Import and Export
- Electronic Pedigree with Digital Signature
- Inference Management through Pack Hierarchy
- Returns Reconciliation
- Web services to:
  - Import, commission and decommission serials
  - Create shipment and return transactions
  - Web services to import / update lots and products
  - Serial Import capabilities
  - EPCIS Capture and Query services
  - EPCIS Repository for data exchange with supply chain partners
- Digital signature and audit trail support for 21 CFR Part 11 compliance
- Secure transaction data based on user's location

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 to implement changes, including mass-serialization, intended to enable better tracking, tracing and authentication 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

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 (OPSM) is an application 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 is available with the Serialization and Tracking
Integration Pack.

OPSM also includes an Electronic Product Code Information Services (EPCIS) repository built using the GS1® standard for capturing and communicating business events for tracking and tracing products within an enterprise and across the supply chain. EPCIS defines a standard interface for representation and exchange of data and provides the following capabilities:

- Aids customers in obtaining and sharing business information with their trading partners.
- Allows capture of the events in the life cycle of an Electronic Product Code (EPC)
- Provides a query interface for trading partners to track and validate EPC information

**Compliance with Business Benefits**

Regulatory bodies around the world, including those in the United States, Europe, Brazil and South Korea are enacting regulations, which are pushing industry toward unit level serialization of drug products. Several countries, including Turkey, India, Italy and China already require serialization on various levels of pharmaceutical packaging. 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 serialized drug product tracking and tracing could yield business benefits include 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.
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 Oracle Pedigree and Serialization Manager (OPSM) is separate from 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 those systems to be burdened with the massive additional data volume. The available integration with Oracle E-Business Suite 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 transmission 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, Share and Digitally Sign Electronic Pedigrees

Oracle Pedigree and Serialization Manager (OPSM) 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, global regulatory requirements and company-specific formats and graphics such as logos.

OPSM also supports digital signatures for electronic pedigrees. Applying a digital signature to the electronic pedigree helps ensure that the data within the document has not been altered and that the content is valid. It also validates the sender’s identity.
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.

Oracle Pedigree and Serialization Manager (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 Reconciliation

Oracle Pedigree and Serialization Manager (OPSM) 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 Oracle E-Business Suite.

Audit Trail Capabilities

Equally important to tracking product in the supply chain is the need to track data internally. Auditing capability also aids in complying with 21 CFR Part 11 electronic recordkeeping requirements. Oracle Pedigree and Serialization Manager’s
(OPSM) Audit Trail feature provides information on all changes made to selected business objects. The Audit Trail Setup application is included as part of the application and allows flexibility in determining which business objects are audited and which attributes within those business objects are audited. This functionality is available out of the box. Once setup is complete, the Audit Trail feature captures changes to the specified business object. Captured changes include those made via the user interfaces, the integrations with online transaction processing systems and web service processes (add, update, and delete).

Using the Audit Trail History interface, an administrative user can inquire on changes made to the system using query criteria such as: the user who made the changes; the business object changed; changes made during a specific date range; or a combination of all of the above. The query results can then be exported for further analysis.

Secure Data by Location

The Location Security feature allows you to restrict access based on the user's location assignment. Securing the data allows you to maintain a central data repository for all processing without exposing site-related data and prevents accidental data tampering. Access can be further restricted by giving users Read, Update and/or Delete privileges as required for their task requirements.

Bottom Line

Oracle Pedigree and Serialization Manager (OPSM) 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. 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.