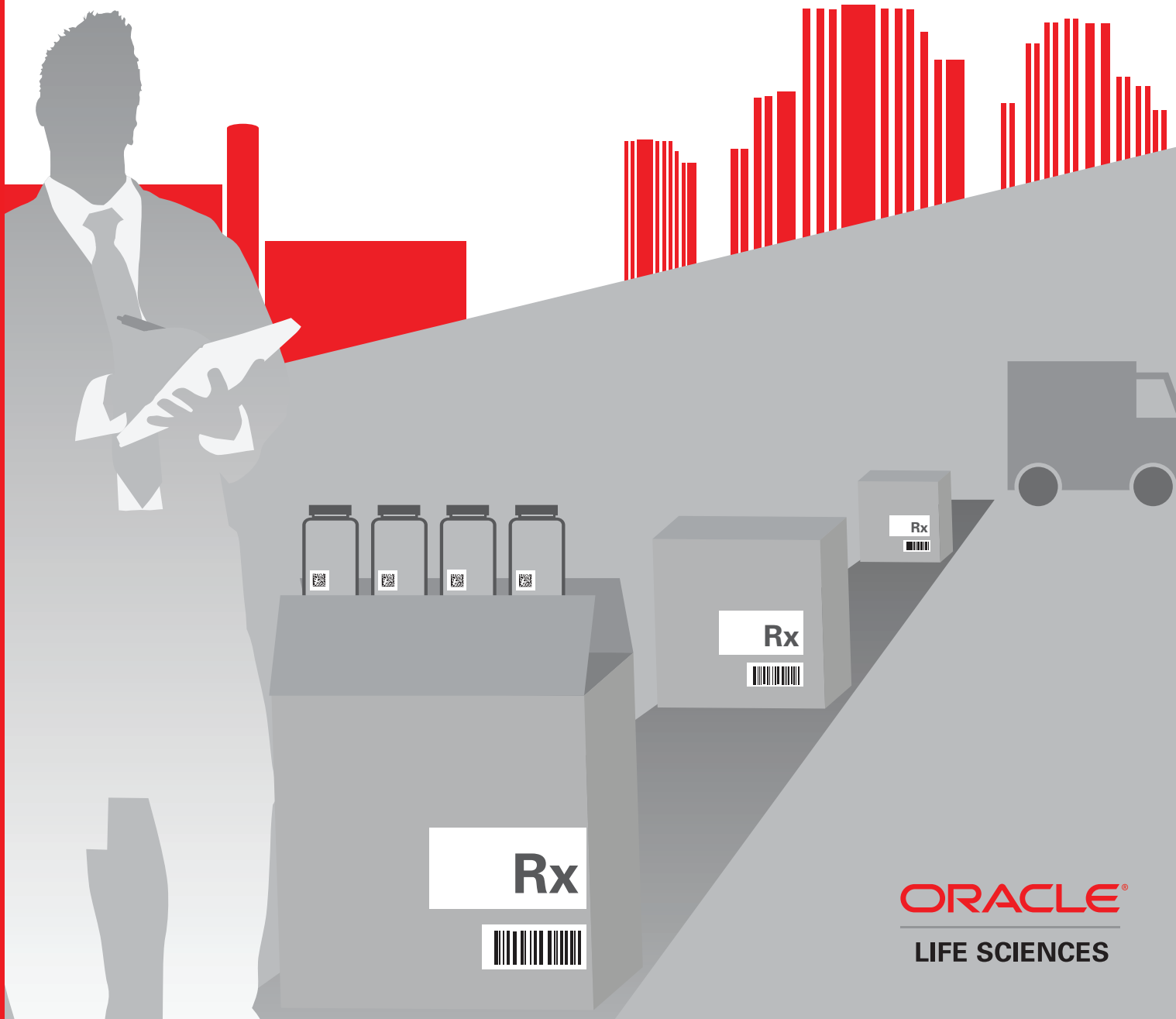


Combating Counterfeit Medicine:

Enabling Mass Serialization And Pedigree Management
In The Pharmaceutical Industry



CONTENTS

EXECUTIVE SUMMARY	3
Introduction	4
SUPPLY CHAIN SECURITY	5
Patchy Regulatory Response	5
Mass Serialisation holds the Key	6
INTRODUCING ORACLE PEDIGREE AND SERIALIZATION MANAGER	7
OPSM: How it Works	7
Pre-Built Integration to Leading ERP Packages	8
Data Management and Security	9
World-Class Data Management	9
Unparalleled Data Security	10
Why Oracle?	11
Conclusion	11

EXECUTIVE SUMMARY



International trade in counterfeit medicines is rapidly increasing, presenting serious risks to public health around the world. To ensure patient safety, pharmaceutical manufacturers urgently need to find ways to protect the integrity of their own products and keep counterfeit medicines out of the legitimate supply chain.

While individual countries and US states have started to build local legislative frameworks to address the problem, there is currently no standardised regional or global approach to preventing trade in illegitimate drugs. Pharmaceutical manufacturers must therefore move to protect their supply chains in the absence of a single set of regulatory standards.

What is clear, however, is that serialisation – applying a unique and inviolable identifier at the level of the individual product unit – is emerging as a core requirement for any supply chain security initiative. Additionally, the ability to track, trace and audit individual units throughout the supply chain, whether they are being shipped or returned, will be key to establishing a product's pedigree at every stage in its journey.

Both initiatives have the potential to deliver many positive business benefits to pharmaceutical companies, protecting revenues, reputations and profits while delivering unprecedented levels of useful insight into supply chain operations.

To enable pharmaceutical manufacturers to implement serialisation and pedigree management initiatives quickly, easily and at low overall cost, Oracle has developed a new software application: Oracle Pedigree and Serialization Manager (OPSM). This paper describes the core capabilities of OPSM, showing how it can help pharmaceutical companies to combat the threat posed by counterfeit medicines today while creating a solid technological infrastructure for compliance with the likely regulatory requirements of tomorrow.

INTRODUCTION



The pharmaceutical industry today is dealing with one of the most serious challenges affecting the integrity of the supply chain; that of counterfeit medicine. As awareness of this issue grows among healthcare providers and patients, there is increasing pressure on the industry to put measures in place to protect patients from unscrupulous criminals who are responsible for this menace to public health.

This is not merely a problem concerning the purchase of fake medicines over the internet; this is about fake products entering the legitimate supply chain and being prescribed to a patient by a health professional in good faith. Neither is it confined to “lifestyle” drugs. Today a wide range of illegitimate medicinal products are being uncovered, from drugs that help patients manage high blood pressure through to treatments for breast cancer. To give an indication of the scale of the problem, in 2008 the European Healthcare Fraud and Corruption Network reported that the number of counterfeit medicines discovered at EU borders increased from 560,598 articles in 2005 to 4,081,056 in 2007¹.

Fake products range from placebo starch pills to products containing anything from cement powder to more harmful substances, or even the wrong quantity of an active ingredient. Whatever the nature of the counterfeit, there is a clear risk of serious and even fatal harm being caused to individuals. The World Health Organization cites two cases of women in Argentina who died after receiving injections of an iron supplement for anaemia which were later discovered to be ‘highly toxic counterfeits’ that had entered the legitimate supply chain undetected².

The potential rewards for the counterfeiters are huge. A study conducted by Pfizer in 2008 estimated that the market for counterfeit medicines is worth €10.5bn in Europe alone, with one in five Europeans admitting to buying prescription drugs over the internet³. That’s a remarkable incentive for illegal trade to continue, particularly while the penalties handed out to those convicted of these crimes remain relatively light.

SUPPLY CHAIN SECURITY

Given the obvious threat to public health, patient safety remains the number one driver for increasing vigilance against counterfeit medicines. However, there are also significant business benefits to be gained from securing the supply chain against counterfeit products, including reducing reimbursement fraud against healthcare payers, protecting brand integrity, and gaining better insight into parallel trade activity. Pharmaceutical companies can also benefit from the resulting improvements to supply chain processes, including increased visibility into supply chain operations, improved recall and returns management processes, more accurate shipping and fulfillment and, potentially, access to more precise sales data⁴.

¹ Source: <http://www.ehfcn.org/eu-corner/eu-policy/counterfeit-medicines/>

² Source: World Health Organization, International Medical Products Anti-Counterfeiting Taskforce (IMPACT) brochure

³ Source: Pfizer UK, Cracking Counterfeit Europe press release, November 2008

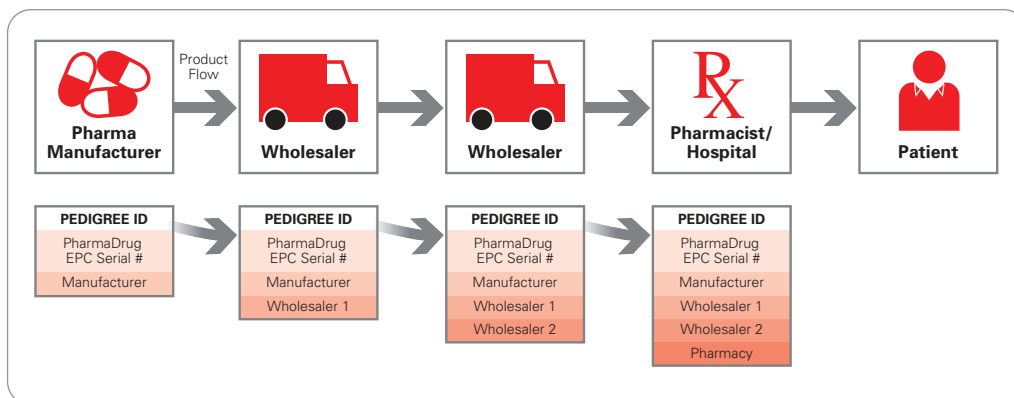
⁴ Source: AMR Research, “The Track and Trace Paradox: Will the Healthcare Value Chain be Ready to Comply Globally?”, Wayne McDonnell, William McNeill, and Hussain Mooraj, April 2009

Patchy Regulatory Response

To date, the legislative and regulatory response to the threat of counterfeit medicines has been patchy and local in nature. In the US, individual states such as California and Florida have focused on recording the chain of custody of a drug shipment, but no common approach has been agreed upon, let alone implemented. ePedigree legislation was due to be implemented in California in January 2009, now but has been delayed until 2015. In March 2010 the Food and Drug Administration (FDA) published some guidance for the industry, however this was restricted to coding standards, rather than a Federal directive on the steps each party in the supply chain should take to protect the products as they make their way to the patient.

The California ePedigree Approach

Tracks Movement Through Each Node in the Supply Chain



In Europe, nationally-coordinated efforts in countries such as Belgium, Greece and Italy have tended to concentrate on authenticating a drug at the point of dispensing, rather than addressing the changes of ownership in the supply chain. In 2010 the Turkish Ministry of Health also introduced a system to store and authenticate serial numbers on prescription drugs. In addition to these initiatives, the European pharmaceutical industry body EFPIA successfully completed its authentication pilot in January 2010⁵ and proved that this model could work.

This patchwork approach means that the principal challenge facing the industry is the lack of harmonised legislation and coding standards in place across the European Union and beyond. This could change soon as, at the time of writing, the European Commission is due to make recommendations on securing the pharmaceutical supply chain – recommendations that could mandate monitoring the chain of custody, similar to legislation currently being considered in the US. But in the meantime, the absence of an overarching regulatory framework dramatically increases operational complexity for pharmaceutical manufacturers and supply chain partners, since any solution has to be able to address the different requirements in each market.

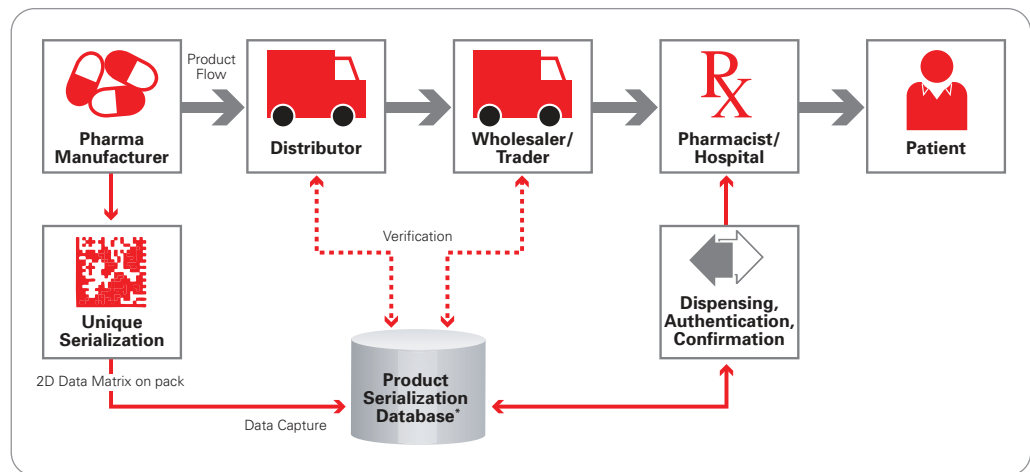
⁵Source: EFPIA Press Release, "Results demonstrate EFPIA anti-counterfeit product verification pilot project successful", <http://www.efpia.eu/content/default.asp?PageID=559&DocID=8771>

Mass Serialisation holds the Key

There is, however, one common building block to all of the initiatives currently being piloted or considered, and that is mass serialisation. The ability to identify a product at the saleable unit level rather than the lot level has gained general acceptance as an imperative to securing the supply chain.

The Evolving European Approach

Focus on Serialization and Authentication



As a result, most pharmaceutical manufacturers are proceeding with plans to mark each saleable product pack with a unique identifier – both in order to reap the associated business benefits and in the expectation that such a capability will also assist compliance with any future regulatory or legislative framework.

INTRODUCING ORACLE PEDIGREE AND SERIALIZATION MANAGER

To support pharmaceutical companies in their efforts to introduce electronic pedigree and serialisation capabilities into their manufacturing and supply chain operations, Oracle has developed a dedicated software application: Oracle Pedigree and Serialization Manager (OPSM). OPSM is a standalone application that is designed to 'slot into' existing IT environments regardless of which enterprise resource planning (ERP) software the organisation is running. This presents pharmaceutical companies with a number of advantages:

- OPSM can be installed with minimal impact on existing transactional systems, especially important in validated environments
- As a standalone application, OPSM can provide serialisation and ePedigree management across multiple ERP systems from multiple vendors within the same organisation
- The large volumes of data resulting from mass serialisation or ePedigree management will not adversely affect the performance of the ERP system

In developing OPSM, Oracle has taken a different approach from other solutions available today. Most importantly, OPSM has been built to deliver both serialisation and pedigree management capabilities in a single application. This ensures that pharmaceutical companies do not waste time piecing together separate pedigree applications and serialisation technologies, or custom-building business logic and user interfaces. As a single application, OPSM is more cost-effective and easier to manage.

OPSM: How it Works

OPSM generates serial numbers in response to automatic requests from packaging and labelling systems. Once generated, the serial numbers are then sent to the packaging system which then prints the codes on labels and processes the packaging run. The packaging system then sends a notification to OPSM that the serial numbers have been commissioned or affixed to actual product packages, along with a record of the packaging hierarchy.

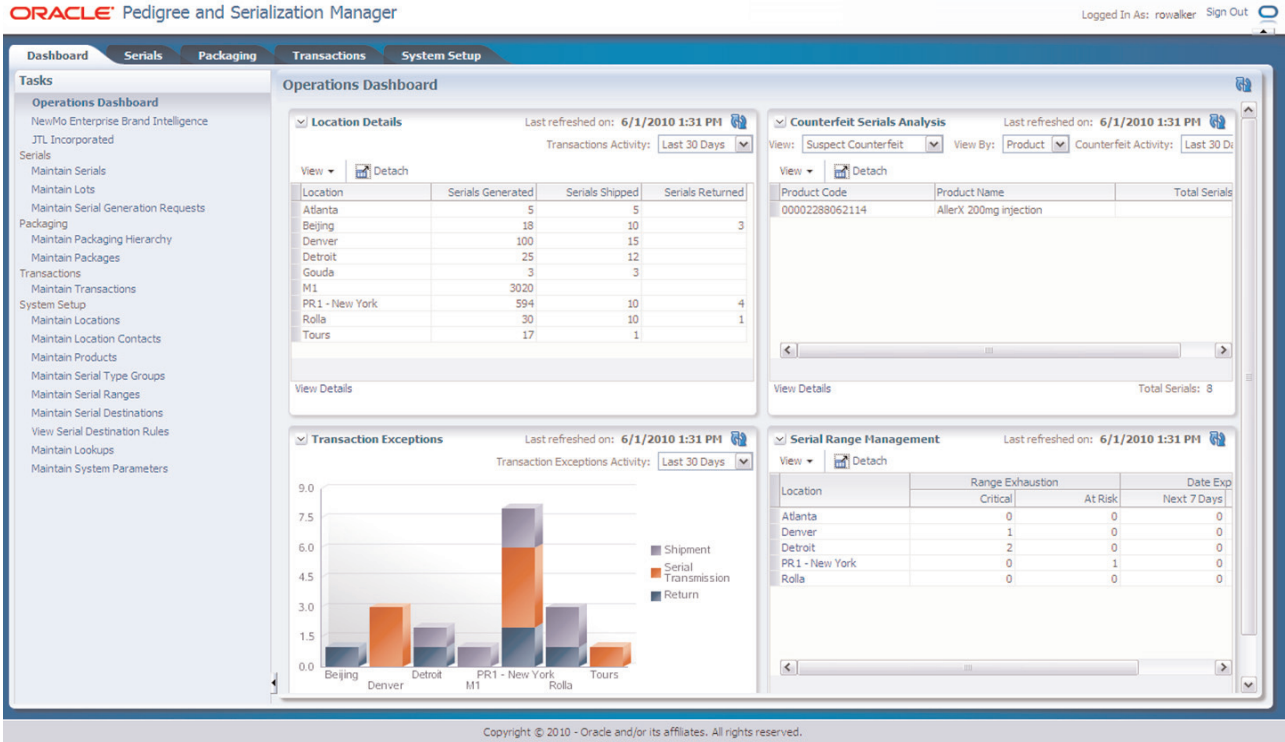
At the point of shipping, OPSM creates an electronic extract of the serial data that can be exported from OPSM to one or more receiving destinations. These destinations can be downstream trading partners who need pedigrees and/or other external government or industry databases set up to track and authenticate these products.

Product returns are also addressed in OPSM. Serial numbers on returned products can be reconciled against OPSM serial data to verify their authenticity. Checks performed for return transactions include verification that the serials exist in OPSM, that they are not flagged as counterfeit or suspected counterfeit, that they are not expired and that they previously shipped.

Lastly, OPSM comes with a sophisticated web-based user interface that allows for manual updates and interventions to all of the information managed by the application, as well as allowing the system to be configured to local needs. The user interface also offers a number of pre-built reports, enabling users to query the underlying data. For example, users can view serial numbers generated by manufacturing site, serial counterfeit status, and exception analysis.



Figure 1: OPSM Dashboard



In summary: functional areas addressed by OPSM v1.0:

- Serialization generation and management
- Packaging hierarchy recording and updating
- Serial export
- Serial shipment and return
- Electronic pedigree management
- Operational serial number analytics

Pre-Built Integration to Leading ERP Packages

Any serialisation and pedigree solution will need to exchange data with relevant ERP applications, and particularly the existing packaging and labelling infrastructure. To facilitate this process, Oracle is developing a pre-built integration pack to Oracle eBusiness Suite, and it is expected that this will be extended to other non-Oracle ERP systems. This approach will help to the time and cost of integration work, reduce complexity and help to maximise the customer’s return on their investment in OPSM.

Oracle’s Application Integration Architecture (AIA) is the service-oriented architecture (SOA)-based framework by which these integrations are built and executed. Best described as integration architecture in a box, it provides pre-built integrations between applications in the Oracle portfolio as well as between

Oracle and third-party applications where the need arises. It also provides a collection of shared components, known as the “Foundation Pack”, which enables users of AIA to extend the pre-built integrations and to create and govern new integrations.

What this means for users of OPSM is that the integration services needed to populate and synchronise reference data, such as Product, Lot, Work Order and Shipping information, will be available as installable products.

Data Management and Security

As well as the functionality provided by OPSM, there are two fundamental issues that must be considered for any repository containing pharmaceutical serial numbers: the management and security of the data itself. Oracle leads the field in both areas, offering both world-class data management features and unparalleled data security.

World-Class Data Management

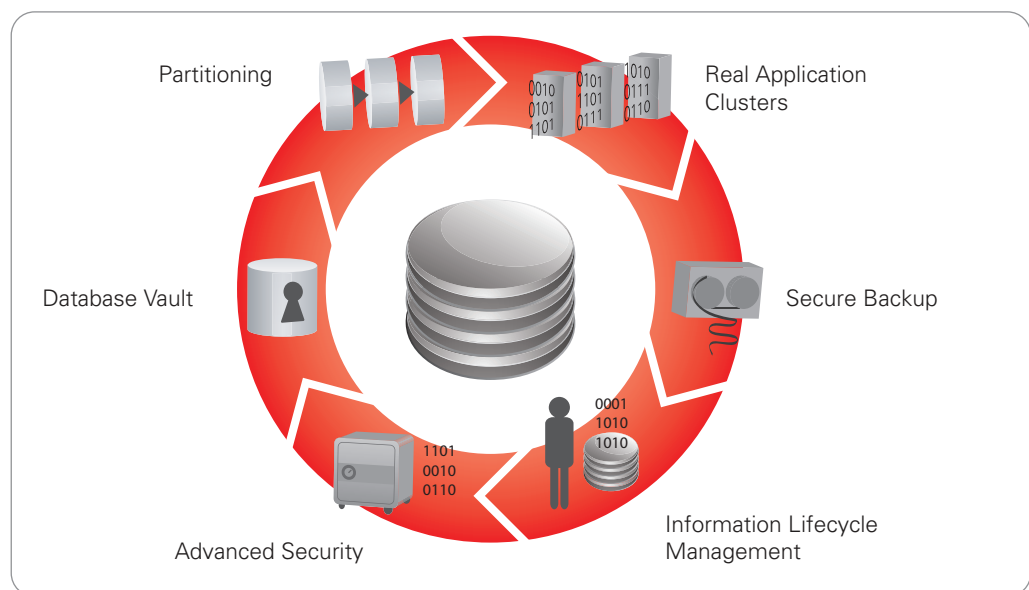
The ability to guarantee that serial data will be available when required is critical to the success of any pedigree and serialisation solution. If the serial number repository is unavailable and holds up a manufacturing run or delays the transmission of serial numbers to a regulatory database, the consequences could be significant. Meanwhile, the need to retain the data for anything up to 15 years for regulatory compliance purposes makes the management of the serial data throughout its entire lifecycle an important consideration.

As the industry’s leading database vendor, Oracle has unrivalled experience and expertise in this area, with capabilities in the Oracle database designed specifically for this purpose. Deploying OPSM with an in-built Oracle Database will deliver significant benefits, including:

- Fault tolerance, ensuring that the serialisation data store is always available to the users and applications that need it
- Ability to scale the database up using inexpensive commodity hardware servers. Capacity can grow or shrink as serialisation needs change by simply adding or removing servers. This capability is particularly useful to support additional capacity demands as new countries or regions go live with serialisation or pedigree requirements, or just to deal with increasing amounts of data as production volumes increase
- Automatically manage data in the most cost-effective manner throughout its lifecycle by moving older, infrequently accessed data to cheaper storage disks, leaving the higher performance disk to store the newer data

Unparalleled Data Security

Keeping the serial data secure will be of paramount importance. If a criminal obtains the means to print a valid serial number on a counterfeit pack, the fake product could pass verification checks and enter the legitimate supply chain entirely undetected.



It is therefore important to secure the serial data both while it is at rest within the application’s database and while it is in transit between systems or trading partners.

The fine-grained security features in Oracle Database enable pharmaceutical manufacturers to safeguard serial data against one of the most dangerous and challenging risks – that of “insider attack”. Counterfeiters are likely to try to break serial data security by targeting human links in the chain. The obvious target would be a Database Administrator (DBA) who typically has access to all the data.

Oracle Database Vault protects against this scenario by implementing the concept of database segregation of duties. It controls the databases (or domains) that DBAs have authority to manage and denies them the ability to access the actual business data itself. So, deploying this database feature with OPSSM shields the data from those who should not have access to it.

Importantly, these database features can be deployed with OPSSM without requiring any changes to be made to the application, allowing customers to easily benefit from Oracle’s industry leadership.

Why Oracle?

Single Vendor Solution: Most current solutions for serialisation and ePedigree involve a patchwork of niche solutions that must be manually built and/or integrated by internal IT departments or external Systems Integrators. This incurs high implementation costs and an associated long-term maintenance overhead. Oracle takes a different approach in providing a single solution for serialisation and ePedigree management, simplifying implementation and reducing total cost of ownership. Oracle is also developing out-of-the-box product integrations to Oracle and third-party ERP applications, further simplifying implementation and reducing TCO.

Leadership in Data Management: Oracle has built its business and reputation on its ability to manage large volumes of data efficiently at a low overall cost. Thirty years of continuous innovation have consolidated Oracle's leadership in data management and today, some of the largest databases around the globe rely on Oracle. By using Oracle Database for serialisation, pharmaceutical manufacturers benefit from superior performance, scalability and cost control.

Leadership in Data Security: Oracle has a 30-year track record of incorporating the highest security standards into its data management products. Recent additions to Oracle's security capabilities include Oracle Database Vault and Label Security, which build "segregation of duties" into the heart of the database management system, ensuring that only relevant individuals have access to serial numbers via the appropriate application. Oracle Audit Vault, encryption, authentication and authorisation features, meanwhile, provide a robust and secure data management platform.

Integration Platform: Oracle Pedigree and Serialization Manager is built on an industry-leading middleware integration platform. This provides state of the art capabilities to knit together other applications into an overall solution. This approach differs from using less flexible technology that is embedded in a packaged application to achieve the integration, thereby mitigating against further risks that may arise during implementation

Conclusion

As global trade in counterfeit medicines increases, pharmaceutical manufacturers must take urgent action to secure their supply chains, ensure the integrity of their products and protect vital revenue streams. Any action taken must deliver these benefits while complying with existing national regulations and paving the way for compliance with forthcoming international regulatory standards.

Two types of initiatives – serialisation and pedigree management – are emerging as key to achieving these objectives. To help pharmaceutical companies to implement these initiatives quickly, smoothly and at low overall cost, Oracle has introduced Oracle Pedigree and Serialization Manager 1.0, the only software application available today that supports both serialisation and pedigree management in a single application. Supported by Oracle's unrivalled capabilities in data management, availability, performance, scalability and security, OPSM v. 1.0 is the fastest and most cost-effective solution to combating the threat posed by counterfeit medicines – now and into the future,

To find out more about Oracle Pedigree and Serialization Manager, and other Oracle solutions for the Life Sciences industry, visit <http://www.oracle.com/us/industries/life-sciences/037879.htm>.



Oracle is committed to developing practices and products that help protect the environment

Copyright © 2010, Oracle and/or its affiliates. All rights reserved. This document is provided for information purposes only and the contents hereof are subject to change without notice. This document is not warranted to be error-free, nor subject to any other warranties or conditions, whether expressed orally or implied in law, including implied warranties and conditions of merchantability or fitness for a particular purpose. We specifically disclaim any liability with respect to this document and no contractual obligations are formed either directly or indirectly by this document. This document may not be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without our prior written permission.

Oracle and Java are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

AMD, Opteron, the AMD logo, and the AMD Opteron logo are trademarks or registered trademarks of Advanced Micro Devices. Intel and Intel Xeon are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. UNIX is a registered trademark licensed through X/Open Company, Ltd. 0410

**Combating Counterfeit
Medicine:** Enabling Mass
Serialization And Pedigree
Management In The
Pharmaceutical Industry

August 2010

Oracle Corporation
World Headquarters
500 Oracle Parkway
Redwood Shores, CA 94065
U.S.A.

Worldwide Inquiries:
Phone: +1.650.506.7000
Fax: +1.650.506.7200
oracle.com

ORACLE®

SOFTWARE. HARDWARE. COMPLETE.