

SAP Solution in Detail
SAP Solutions for RFID



SAP® SOLUTIONS FOR RFID FOR THE HEALTHCARE SUPPLY CHAIN

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CONTENTS

- Executive Summary 4

- Introduction 5

- Strategic Approach to Serialization 6**
 - SAP Auto-ID Infrastructure 6
 - Core SAP Auto-ID Infrastructure Elements 7
 - Preconfigured Business Process: Outbound Shipment 7
 - Preconfigured Business Process: Inbound Receiving 7
 - Preconfigured Business Process: Returnable Transport Item (RTI) Tracking 7
 - Other Core Elements 7
 - Partner Network 8
 - Pedigree Generation Support 8

- New Functionality 9**
 - SAP Object Event Repository and Product Tracking and Authentication 9
 - Object Event Repository 9
 - Product Tracking and Authentication 10

- SAP RFID Ecosystem 10**
 - Device Management 10
 - Independent Software Vendors 11

- Summary and Closing 11**

EXECUTIVE SUMMARY

Drug counterfeiting and diversions are large and growing problems in the life sciences supply chain, not only representing a threat to patient safety and to the brands and reputations of drug manufacturers and wholesalers, but also costing the industry billions of dollars.

Governments all over the world – including U.S. state and federal agencies – are passing legislation and instituting regulations to protect the public from these threats. Two key requirements being promulgated are electronic pedigrees (ePedigrees) and serialization. Electronic pedigrees are electronically signed documents that certify the origin and chain of custody of a drug. Serialization is the method by which individual drugs are labeled with electronically readable unique serial numbers that can be used to verify the authenticity of the product. Radio frequency identification (RFID) tags are a leading technology supporting serialization. The EPCglobal organization, a nonprofit worldwide standards organization made up of vendors and users, is drafting specifications based on a serialization standard called the Electronic Product Code (EPC) and spearheading the development of standards for RFID, serialization, and pedigree.

SAP® solutions for RFID offer end-to-end support for the creation, capture, storage, and use of serialized data throughout the life sciences supply chain – from the manufacturer's packaging and warehousing operations to wholesale distributors and pharmacies.

The SAP Auto-ID Infrastructure offering is the core component of the current release. Two new components are available as of Q2 2007:

- SAP object event repository is the enterprise-level system of record repository for all serialized information, based on the EPCglobal standard for an EPC Information Services (EPCIS) repository.
- SAP product tracking and authentication accesses information in the repository to support product tracking and product authentication processes.

SAP views the object event repository as a strategic component that is positioned to leverage serialized information in support of supply chain, compliance, financial, and customer relationship management applications. Companies now undertaking or considering serialization projects can regard the repository as a strategic asset.

SAP has also created an ecosystem that includes numerous device management, independent software vendor, and systems integration partners to further increase the value proposition of SAP solutions for RFID.

INTRODUCTION

For pharmaceutical and biotechnology companies in the life sciences supply chain, counterfeit drugs and diversions jeopardize patient safety and represent a growing threat to growth and profitability. Counterfeits are “fake” or adulterated drugs that may be diluted, contaminated, or contain no active ingredients. Such drugs can find their way into the drug supply and impact manufacturers’ brand names as well as the confidence level of patients. Diversions are drugs sold into unauthorized markets due to differential pricing or drug shortages. Diversions significantly increase the possibility that counterfeit drugs will be introduced to market.

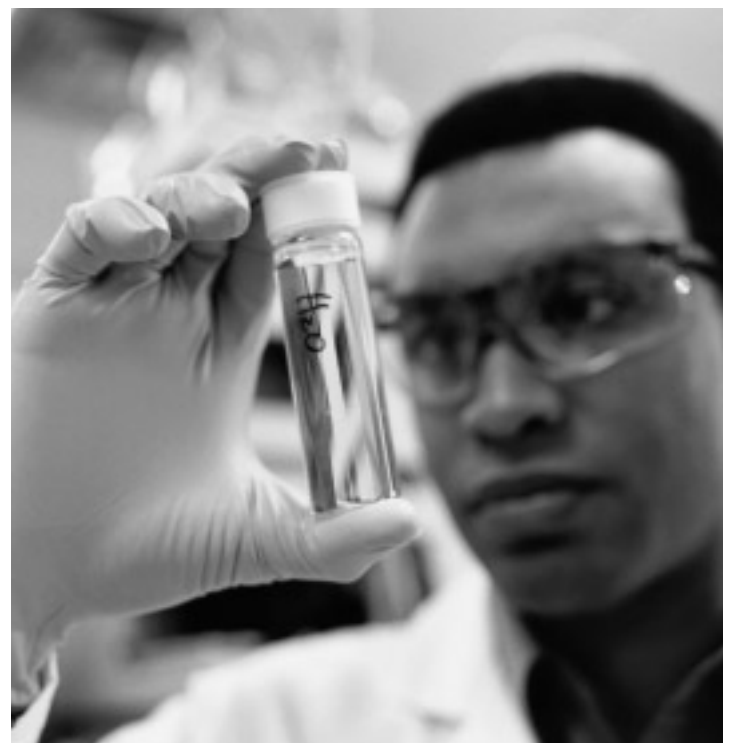
These problems are acute in the pharmaceuticals industry, where 7% to 8% of drugs worldwide are counterfeit. (In some countries this figure can reach 50%.) Shrinkage and counterfeits account for 0.22% to 0.73% of revenues for manufacturers. With the counterfeit rate growing at 6% to 8% annually, this is estimated to be a US\$30 billion problem for U.S. retailers and US\$50 billion worldwide.¹

In Europe, some countries have adopted serialization programs, and the European Union is looking at establishing a European standard. In the United States, existing and emerging FDA and state laws and regulations require wholesalers to document the entire chain of custody for the drugs they distribute to dispensing pharmacies. California legislation that takes effect in 2009 requires organizations to label prescription drugs with unique serial numbers and to transmit electronic pedigrees with products as they move from manufacturers to wholesale distributors and then to dispensing pharmacies and hospitals. The pedigree documents must refer to the serial numbers so that these unique numbers will serve as a basis for validating the authenticity of products. Manufacturers, distributors, retailers, and regulatory bodies will be able to track product movements in real time at the lowest level of dispensing (bottles, for example) and at each level of overpacking (cases and pallets).

1. Projections by Center for Medicine in the Public Interest, based on 2006 estimates by the World Health Organization.

While none of these requirements specifies the method for serial identification, RFID has emerged as a leading supporting technology. RFID allows organizations to capture a large number of tag reads simultaneously without line of sight or individual scanning of tags. EPCglobal is coordinating the development of a series of standards to facilitate the tagging, capture, and exchange of serialized product information.

In addition to the use of serialized information to support pedigree and authentication, the unique tracking of objects (with RFID or bar code) is also useful for supply chain management (SCM) applications, asset-tracking applications, and a host of other business processes. RFID is being deployed not only in life sciences, but many other industries to support these applications and processes.



STRATEGIC APPROACH TO SERIALIZATION

With more than 200 licensed customers in more than 16 industries, SAP is a recognized leader in the development and deployment of productive RFID applications. Within the life sciences industry in particular, SAP has worked with a wide range of manufacturers and wholesalers to support their pedigree, serialization, and authentication projects.

To help life sciences companies extract the most value from the technology, SAP views serialization as a strategic enabler of a new family of applications that will enhance not only patient safety, but also supply chain management, reverse logistics, clinical trial management, contract management, and other business processes.

The core of this strategy involves the following:

- The creation of a software foundation to facilitate serialization, not as a point solution, but as part of the application infrastructure
- The integration of serialization activities into a wide variety of business processes, and the association of business information from a variety of business applications with serialized data

Leveraging data and functionality residing in both SAP and non-SAP business applications, SAP solutions for RFID integrate the serialization activities originating from core packaging, shipping, and receiving processes within the production facilities and distribution centers of manufacturers, wholesalers, and retail pharmacies. Serialized data is created, captured, and associated with relevant business objects such as batches, advanced shipping notices (ASNs), deliveries, and orders. This data is then stored in a centralized repository (based on the EPCIS standard) and is accessed and exchanged with trading partners in support of tracking and authentication requests.

SAP Auto-ID Infrastructure

The SAP Auto-ID Infrastructure offering is the component of SAP solutions for RFID that directly supports site-level serialized processes. We use the term “auto-ID” to refer to any technology, including RFID and bar coding, that holds serialized information. The SAP Auto-ID Infrastructure landscape is shown in Figure 1.

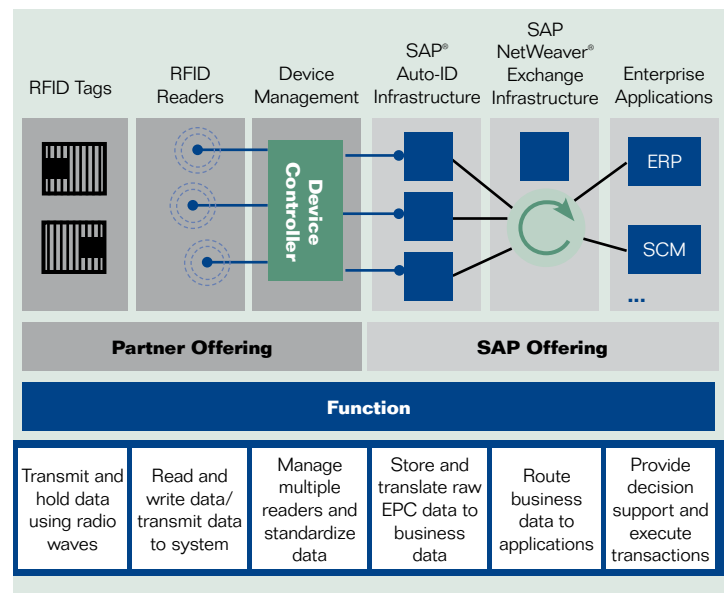


Figure 1: The SAP Auto-ID Infrastructure Offering Landscape

Core SAP Auto-ID Infrastructure Elements

Core elements of SAP Auto-ID Infrastructure include the following:

- **RFID device management** – Enables synchronous and asynchronous communication with the devices used to capture auto-ID data.
- **Mapping engine** – Enables contextualization and rapid analysis of raw data captured during supply chain operations. The interpreted data in SAP Auto-ID Infrastructure is mapped to the relevant business objects inside SAP Business Suite applications, including the SAP ERP application, to facilitate automation of business processes. Using the mapping functionality of the SAP NetWeaver® Exchange Infrastructure (SAP NetWeaver XI) component, it is also possible to map to processes and data in non-SAP applications.
- **Prepackaged, configurable business processes** – Many business processes are available as preconfigured content, including inbound receiving, outbound shipments, and returnable transport item (RTI) tracking. These processes can be deployed out of the box or can be flexibly configured to meet specific organizational requirements.

Preconfigured Business Process: Outbound Shipment

With robust support for outbound shipments, SAP solutions for RFID enable you to do the following:

- Generate serial numbers
- Commission tags
- Associate tags and items
- Generate flexible multilevel hierarchies for cases, inner packs, and pallets
- Scan and track outbound items associated with loading
- Associate EPCs with delivery documents
- Verify delivery requirements at the data capture source
- Process goods issue in the back-end enterprise resource planning (ERP) application
- Automatically trigger ASN based on predefined conditions

Preconfigured Business Process: Inbound Receiving

With powerful inbound receiving functionality, you can do the following:

- Scan and validate receipts with respect to ASN
- Process goods receipt in the back-end ERP application
- Automatically generate proof-of-delivery documentation based on predefined conditions

Preconfigured Business Process: Returnable Transport Item (RTI) Tracking

RTI tracking functionality supports:

- Tracking of returnable containers from supplier to customer and back again through various operations such as packing, loading, unpacking, unloading, and moving
- Commissioning and maintenance of RFID tags placed on returnable assets using the standard Global Returnable Asset Identifier (GRAI) format
- Automatic monitoring of events, such as empty and full status, using event management tools that alert relevant parties of unintended or unexpected events or changes in status

Other Core Elements

Other core functions include the following:

- **Serialized number and format management** – Supports encoding and writing RFID tags, including Gen 2 RFID tags
- **Serial number and event repository** – Stores site-level EPC serialization data and associated observation and event data, multilevel data aggregation, and associated business data. This repository integrates with the object event repository (see next section) and can be used to facilitate local reporting.
- **Integration with business planning and execution applications via SAP NetWeaver XI** – Supports preconfigured integration with SAP ERP, as well as the ability to integrate to non-SAP back-end ERP applications

- Integration with the SAP Event Management application**
 - Facilitates the tracking and tracing of business objects and processes within and beyond enterprise boundaries
 - Through SAP Event Management, it is possible to set up alerts and exception management scenarios to track events such as early, late, or missed deliveries. Each EPC number is automatically modeled as an event handler that can be tracked through the full life cycle of the EPC.
- Analytical reports** – Predefined content for the SAP NetWeaver Business Intelligence (SAP NetWeaver BI) component allows for the tracking of a range of critical key performance indicators (KPIs) such as tag read/write statistics or supply chain metrics including cycle times and dwell times.

Partner Network

To facilitate integration of SAP Auto-ID Infrastructure with customer-selected devices, SAP has built an extensive partner ecosystem to provide a comprehensive end-to-end solution. The certification program ensures that certified device management partners are able to integrate hardware of the customer's choice with SAP Auto-ID Infrastructure, based on SAP published protocols for device integration. Information about SAP partners is covered in more detail below.

Pedigree Generation Support

SAP has released a service pack for its previous release of SAP Auto-ID Infrastructure to further facilitate the generation of ePedigree documents. This functionality, shown in Figure 2, assembles the relevant data from business processes supported by the ERP system and provides a standard XML interface to transfer to pedigree partners most of the necessary data to comply with U.S. state regulations. This includes sales and distribution data such as customer name, address, shipment dates, and delivery number. Also included is manufacturing or product data such as drug information and batch and expiration information, which are married to the EPC data from SAP Auto-ID Infrastructure.

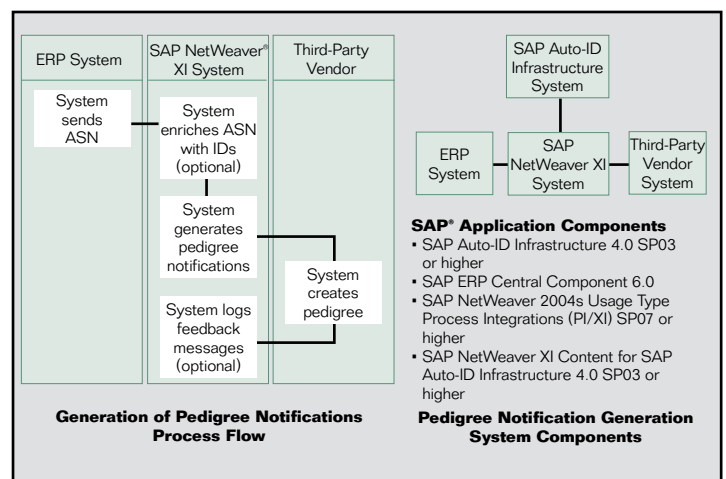


Figure 2: Generation of Pedigree Notifications

This interface is designed to be used by third-party pedigree management software to generate pedigrees that conform to legal requirements. SAP Auto-ID Infrastructure also provides a message interface for pedigree management software to return feedback messages and status reports. See below for an updated list of SAP pedigree partners and their certification status.

NEW FUNCTIONALITY

SAP Auto-ID Infrastructure features a number of important new enhancements, as follows:

- Service enablement of numerous SAP Auto-ID Infrastructure services to facilitate the development of customized processes that leverage serialization
- Support and integration for SAP object event repository, SAP enterprise EPCIS technology (see below)
- RFID integration with the SAP Extended Warehouse Management application (a component of the SAP Supply Chain Management application), including RFID support for inbound shipments, outbound shipments, and the use of resources

SAP Object Event Repository and Product Tracking and Authentication

Two new modules have been included in the latest SAP Auto-ID Infrastructure release.

Object Event Repository

The first new module, the SAP object event repository, is an enterprise-level EPC repository intended to be the system of record for all enterprise serialized information. The object event

repository is based on the core requirements specified by EPCglobal, including the EPCIS Capture Interface and the EPCIS Query Interface.

The object event repository, shown in Figure 3, consists of an enterprise-level repository for uniquely identified objects such as EPCs. It also features a rich services layer to provide business context, discovery, event capture, and data exchange for these objects, supporting EPCglobal requirements. It consists of a repository, capture interfaces, query interfaces, and core services, including central number range management.

The SAP object event repository can support any number of SAP auto-ID infrastructure instances, which are responsible for managing serialized (EPC or other) data, events, and business processes at a local level, such as a warehouse or manufacturing plant. As shown in Figure 3, each of the instances of the SAP auto-ID infrastructure is integrated with the object event repository at the enterprise level. The object event repository supports enterprise-level applications as well as data exchange with trading partners.

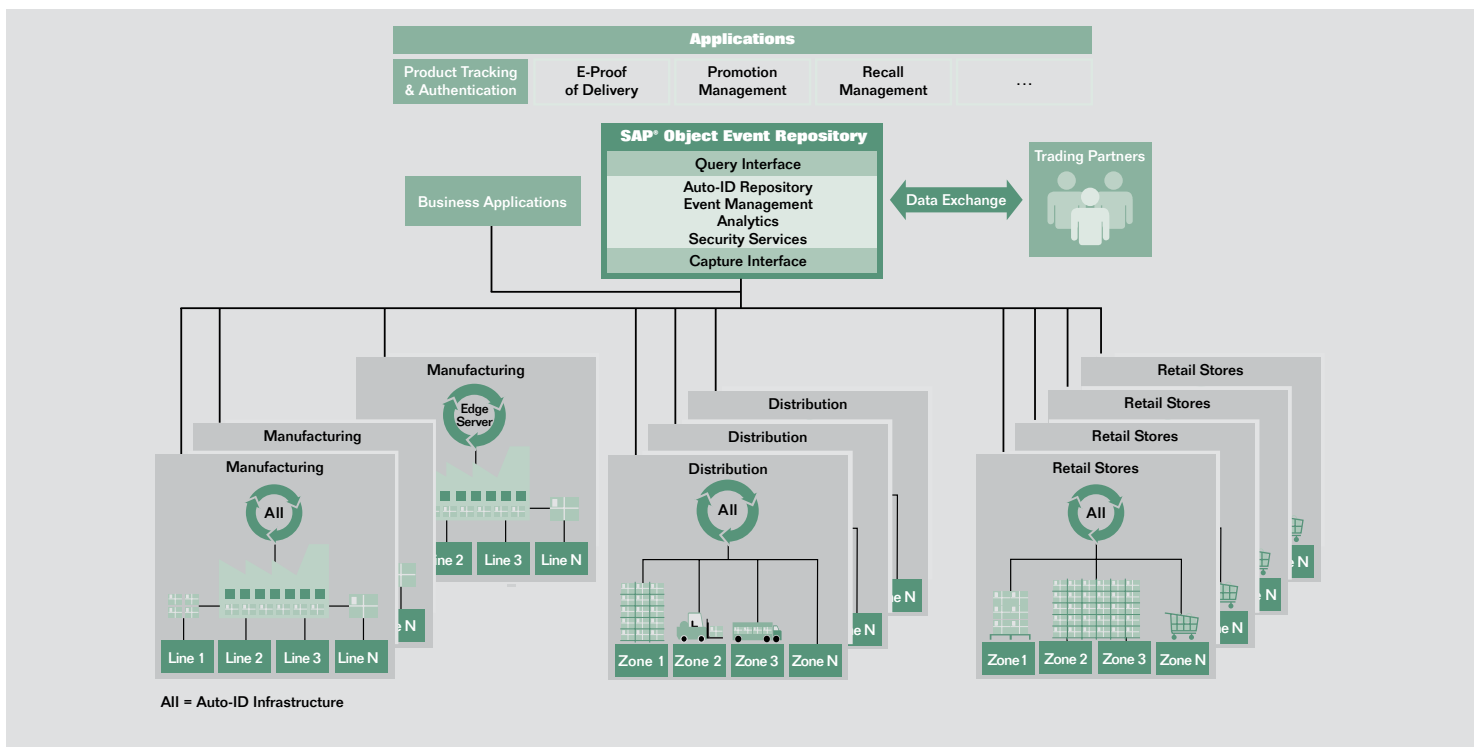


Figure 3: SAP Object Event Repository

SAP RFID ECOSYSTEM

Product Tracking and Authentication

The product tracking and authentication module provides functionality to support business processes to track serialized information through the supply chain. It also provides services to authenticate that the serialized product originated from a trusted source and arrived at the intended destination. This functionality is based on the serialized content stored in the SAP object event repository in conjunction with business information from back-end business systems. The key functionality of the SAP object event repository and the product tracking and authentication module includes the following:

- Capture
 - EPCs, hierarchies, locations, and events from local SAP auto-ID infrastructure instances and third-party systems
 - Business object data from back-end ERP and other business applications
 - Association of EPC information with business objects such as batches and lots, orders and deliveries, and other characteristics
 - Data exchange from trading partners
- Product tracking (via query interface or user interface)
 - By EPC – status, location, or events
 - By order or other business characteristics (batch)
 - Alerts via event management (for example, a shipment did not arrive at the intended destination)
- Authentication
 - EPC authentication
 - Extended authentication against secondary characteristic such as tag-ID, holospot, or other unique identifier, and location
 - Logging of authentication attempts and responses

As part of its RFID go-to-market program, SAP has an active partner ecosystem. SAP's RFID partners fall into two categories: device management and independent software vendors (including ePedigree providers).

Device Management

In establishing the SAP device management partner program, SAP has done the following:

- Published integration protocols for fixed and mobile devices
 - SAP Auto-ID Infrastructure–DC 1.0 for fixed devices
 - SAP Auto-ID Infrastructure–Mobile for mobile devices
- Established a standard certification program for our device management partners through SAP Integration and Certification Center locations
 - SAP Auto ID Infrastructure–Device Controller Interface (SAP Auto-ID Infrastructure-DC-RFID) for fixed devices
 - SAP Auto ID Infrastructure–RFID Mobile Device Integration (SAP Auto-ID Infrastructure-MBL-RFID) for mobile devices

Companies certified as device management partners include the following:

- Acsis Inc. (Data-Link Enterprise)
- GlobeRanger Corp. (iMotion)
- Infosys Technologies Ltd. (RFID Integration Platform)
- InSync Software Inc. (Edgeware)
- MARKEM Corp. (CoLOS Exchange)
- PEAK Technologies Inc. (Automation Controller)
- Printronix Inc. (XML Forms)
- Psion Teklogix Inc. (TEKAID)
- Reva Systems Corp. (Tag Acquisition Processor)
- RF Code Inc. (TAVIS)
- SATO International Pte. Ltd. (XML-enabled 3.0)
- Sun Microsystems Inc. (Sun Java System RFID)
- Sybase Inc. (RFID Anywhere)
- Systech International (Serialized Product Tracking)
- Zebra Technologies Corp. (XML Schema)

SUMMARY AND CLOSING

Independent Software Vendors

A number of independent software vendors (ISVs) are certified SAP partners. In general, ISV certification is a two-level process. The first level is to become “Powered by SAP NetWeaver.” Partners work with SAP to move to the next level, which is to develop and deliver an application (an SAP-certified composite application) on top of the SAP NetWeaver platform.

“Powered by SAP NetWeaver” partners supporting electronic pedigrees include:

- SupplyScape
- Cognizant

These lists continue to grow as other companies apply for and receive certification. The latest partner status information can be found on our corporate Web site at

www.sap.com/partners/directories/searchpartner.epx.

The life sciences industry is in the initial stages of a major deployment of new technology and processes in support of improved patient safety and brand protection. While the initial focus is on meeting regulatory requirements, companies are making these investments with an eye towards laying the foundation for leveraging serialized data in various business processes to drive significant business value, such as supply chain management, reverse logistics, clinical trial management, contract management, and other business applications. Serialized data captured and stored in the object event repository is an asset of strategic value to our customers.



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