Pedigree, RFID, and Business Value: The SAP Comprehensive Roadmap for Serialization in the Life Sciences

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RFID / Serialization
Life Sciences
Key issues and pain points in pharmaceuticals

- Drug track and trace overview
- SAP solution overview and roadmap
- Customer examples
- Benefit areas, KPIs, and benchmarking
Patient Safety
Increasing Operating Costs
Downward Margin Pressure
Reduced Operating Efficiency

- Cost Pressure (esp. Generics)
- Supply Chain and Reverse Logistics Opportunity
- Complex Multi-step Supply Chain

Government Regulations

Pharmaceutical Industry Overview

Standards Activities

Safe and Secure Supply Chain

Inventory
Recalls

* Calculated from data in each company's 2003 & 2004 Annual Reports
Drug track and trace overview

Key issues and pain points in pharmaceuticals

SAP solution overview and roadmap

Customer examples

Benefit areas, KPIs, and benchmarking
Base Reference Model

Safe & Secure Supply Chain

Is the product genuine?

Authentication

Product Identity

Is the EPC associated with the unit of sale valid?

Pedigree

Physical Features

Does the unit of sale have the expected covert and/or overt features?

Is the chain of custody intact?

Track

Where is the product and where is it headed?

Trace

Where was the product? (Locations & Custodians)
Serialized Track/Trace

<table>
<thead>
<tr>
<th>Bottle</th>
<th>Folding box</th>
<th>Shipping carton</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="RFID and/or barcode" /></td>
<td><img src="image" alt="Sequential numbers (like license plate)" /></td>
<td><img src="image" alt="EPC/EAN coding scheme" /></td>
</tr>
</tbody>
</table>

- Sequential numbers (like license plate)
- EPC/EAN coding scheme
- Purpose: authentication & logistics use

* Places where trace data gets recorded
Is Chain of Custody Intact? Pedigree
Product Authentication Techniques

EPC

EPC with Tag ID

EPC with Security Marking

Pallet Hierarchy
Key issues and pain points in pharmaceuticals

Drug track and trace overview

SAP solution overview and roadmap

Customer examples

Benefit areas, KPIs, and benchmarking

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Integration and scalability in compliance with international standards of EPCglobal are the key success factors of the SAP RFID solution landscape.
Enterprise-Wide Deployments

SAP Object Event Repository (OER)

Applications
- Product Tracking & Authentication
- e-Proof Of Delivery
- Promotion Management
- Recall Management
- ...
SAP Auto-ID Solutions Mapped to EPCglobal

EPCglobal Core Services
- Subscriber Authentication (TBD)
- EPCIS Discovery (TBD)
- ONS Root
- Manager Number Assignment (offline service)

ONS Interface
- Local ONS
- EPCIS Accessing Application

Partner EPCglobal Subscriber
- EPCIS Query Interface
- EPCIS Accessing Application
- "Pull" or "Push" mode

SAP OER:
- Object Event Repository

Device Controller
- RFID Reader
- Reader Management
- Reader Management Interface
- Tag Protocol (UHF Gen 2, Class 0, Class 1)
- RFID Tag

Optional bypass for real-time "push" mode

ERP
- PTA
- ...
## SAP Auto-ID Infrastructure Product Profile

<table>
<thead>
<tr>
<th>Device Interface</th>
<th>Communication directly with RFID devices</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Communication with major device controllers</td>
</tr>
<tr>
<td></td>
<td>Certified interface and extensive partner eco-system</td>
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<tr>
<td>EPC Number Ranges</td>
<td>Maintain EPC number ranges locally in SAP Auto-ID Infrastructure (AII)</td>
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<tr>
<td></td>
<td>Configure EPC encoding according to current and emerging standards</td>
</tr>
<tr>
<td>Tag Commissioning</td>
<td>Write an Electronic Product Code (EPC) on each individual tag</td>
</tr>
<tr>
<td></td>
<td>Write EPCs in batch mode using an RFID label printer</td>
</tr>
<tr>
<td></td>
<td>Support multiple-tag commissioning modes, multiple hierarchies</td>
</tr>
<tr>
<td>User Interface (UI)</td>
<td>Has mobile/desktop UI</td>
</tr>
<tr>
<td></td>
<td>Offers enhanced execution guidance in both mobile and desktop UI</td>
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<tr>
<td>Master Data</td>
<td>Import master data for integrated scenario</td>
</tr>
<tr>
<td></td>
<td>Maintain product, location, and business master data locally for standalone deployment</td>
</tr>
<tr>
<td>Deployment</td>
<td>Integrate deployment on SAP application system</td>
</tr>
<tr>
<td></td>
<td>Deployable with integration to non-SAP back-end</td>
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<tr>
<td></td>
<td>Deployable standalone</td>
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<tr>
<td>Reporting</td>
<td>Business Monitoring and Reporting</td>
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<tr>
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<td>Stock situation at different locations</td>
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<td>Movements across/within locations</td>
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<tr>
<td></td>
<td>Dwell time/cycle time</td>
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<tr>
<td></td>
<td>Current status of tracked objects</td>
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<tr>
<td></td>
<td>Technical Monitoring and Reporting</td>
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<tr>
<td></td>
<td>Read/write rate quality reports</td>
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<tr>
<td></td>
<td>BW extractors from SAP All</td>
</tr>
</tbody>
</table>
SAP Event Management (EM)

Monitor

- Supply chain object
- actual events
- expected events
- event 1
- event 2
- event 3
- event 4

Notify

Alerts

Event Management

Control

- Learn
- Partner Performance

Simulate

- Plan/Schedule

Collaborate

- Adjust

Measure
Pre-Configured Business Processes

SAP RFID

- Platform to provide business context
- Rules, activities, event handlers, data management, integration, and so on
- Gateway to SAP applications
RFID-Enabled Outbound Processing

Vendor

Pick or Produce

Pack

Issue Goods (Loading)

Scan IDs

Associate Items / Pallet / Tags

Create Delivery

SAP ERP

Delivery

Goods Issue

Create HU

Adv. Ship Notification

Purchase Order

Buyer

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Enterprise-Wide Deployments

Applications

Platform

SAP Object Event Repository (OER)

- Query Interface
- Auto-ID Repository
- Event Management Analytics
- Security Services

Product Tracking & Authentication
- e-Proof Of Delivery
- Promotion Management
- Recall Management

Captured Interface

Platform Applications

TRADING PARTNERS

DATA EXCHANGE

Manufacturing

DISTRIBUTION

Retail Stores
PTA Concept

1. Capture

- ERP
- RFID Devices
- External Systems

2. Tracking

3. Authentication

EPC | Product/ Material (Tracking/ Authentication) | Lot/ Batch | Delivery # (Tracking) | Customer Ship-to (Tracking) | Pkg. Hierarchy (Authentication Level Number) | ... | Reports
---|--------------------------------------------|------------|----------------------|-----------------------------|---------------------------------------------|---|---
1 |                                           |            |                      |                             |                                             | ... | Reports
... n |                                          |            |                      |                             |                                             | ... | Reports

Event Management
Tracking Services

**EPC Tracking**
- Current status/location of EPC
- List of statuses/locations of EPC within Enterprise

**Delivery Tracking**
- List of statuses/locations of EPCs associated with a delivery

**Attribute Tracking**
- Selection of deliveries and associated EPCs by:
  - Order Number
  - Date
  - Customer
  - Status
  - Location
  - Batch (Lot)
  - Others

**Event Management**
- Trigger alerts based on exceptions associated with under/over delivery, or supply chain movements that are early/late/not expected/missing
Authentication

**Basic Authentication (Tiered/Level)**
- [EPC Numbers]

**Extended Authentication**
- Authentication of one or more EPCs based on EPC, location of item
- Authentication based on EPC, Alternative ID (Tag ID, Holospot®, and so on)

**Logging**
- All queries logged

**Alerting**
- Alert if repeated queries for same item, and so on

**EPC Authentication**
- Authentication of one or more EPCs, based on EPC number
Enterprise-Wide Deployments

Applications

Product Tracking & Authentication

e-Proof Of Delivery

Promotion Management

Recall Management

SAP Object Event Repository (OER)

QUERY INTERFACE

AUTO-ID Repository
Event Management Analytics
Security Services

CAPTURE INTERFACE

Platform

DATA EXCHANGE

TRADING PARTNERS

Product Tracking & Authentication

Product Tracking & Authentication

e-Proof Of Delivery

Promotion Management

Recall Management

SAP Object Event Repository (OER)

QUERY INTERFACE

AUTO-ID Repository
Event Management Analytics
Security Services

CAPTURE INTERFACE

Product Tracking & Authentication

PRODUCT TRACKING & AUTHENTICATION
RFID-Enabled Electronic Proof of Delivery

Order 64007010 - Payment is Less Than Invoice Value

eMail to customer

Resolution Actions

Shipping Details

You Can

Launch Best Practices
Create Collaboration Task
Complete
Decline
Forward
Replace

In reference to the above order, it appears that you took an unauthorized deduction for $249.10 related to 10 cases of CA-0125. After reviewing the supporting RFID read data, it appears that in fact you did receive these cases at your Philadelphia DC on 7/3/2005. We will be issuing a debit memo against your account for this month. All supporting information can be accessed below. Thank you.
Future Serialization Opportunities

Recall Management

Identify and communicate
- Visibility into magnitude and scope

Problem containment
- Red-flag and contain affected product at various nodes of the supply network in real-time
- Automatically halt all affected business transactions

Reclaim
- Targeted reclaiming only affected product – based on EPC serial number traceability, delivery history, and e-Pedigree

Receive/Authenticate

Disposal/Destruction

Assess
- Cost analysis, credit/debit management

Chargeback Management

Identify and Trace
- Association of every product instance (EPC) to shipments, invoices, and chargebacks ensures traceability between payments and physical goods
- Improved transaction history will significantly improve chargeback/rebate accuracy, reducing errors and manual validations

Validate
- Check against contract data
- Double chargeback and rebate payments due to illegal diversions can be detected automatically by validating sales history

Analyze
- Customer/contract profitability analysis
SAP RFID Release Schedule

SAP Product Innovation Lifecycle

Develop

Deploy

Optimize

Release to customer: SAP All 2.0
Release to customer: SAP All 2.1
Release to customer: SAP All Feature Pack
Release to customer: SAP All 4.0
SAP All Feature Pack for 4.0
Release to Customer SAP All 5.1
Release to Customer SAP All X.X


SAP RFID Solution Focus

Standalone RFID Preconfigured toolkit Reporting
Returnables (RTI) BI Reporting Event Mgmt Bar Codes
RFID Outbound
RFID Inbound
e-Pedigree Interface ESA Subset

Object Event Repository (OER)
EPC Global Data Exchange
Product Tracking and Authentication (PTA)
UID Enablement, Kanban, RFID-enabled EWM
ESA Enablement of All

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THE BEST-RUN BUSINESSES RUN SAP
# SAP RFID Partner Strategy for Life Sciences

## PRODUCTS/SOLUTION

<table>
<thead>
<tr>
<th>Category</th>
<th>Strategic Partners</th>
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</thead>
<tbody>
<tr>
<td>e-Pedigree (Powered by SAP NetWeaver®)</td>
<td>■ SupplyScape</td>
</tr>
<tr>
<td></td>
<td>■ Cognizant</td>
</tr>
<tr>
<td>Mobile</td>
<td>■ Nokia – under All certification process</td>
</tr>
<tr>
<td>Device Mgmt. (All Certified)</td>
<td>■ Acsis</td>
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<tr>
<td></td>
<td>■ Systech</td>
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<td>■ Globeranger</td>
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<td>■ Infineon</td>
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<tr>
<td>Hardware</td>
<td>■ Symbol</td>
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<td>■ Matrix</td>
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<td>Printers</td>
<td>■ Zebra</td>
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<td>■ HP</td>
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<td>■ Printronix</td>
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<td>■ Alien</td>
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<td>■ LXE</td>
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</tbody>
</table>
Key issues and pain points in pharmaceuticals
Drug track and trace overview
SAP solution overview and roadmap
Customer examples
Benefit areas, KPIs, and benchmarking
Wrap-up
200+ RFID Companies; 17+ Industries

Number of RFID Customers by Industry [150]

- CPG 23%
- Chemicals 11%
- Lifesciences 10%
- Transportation 7%
- Retail 3%
- Auto 5%
- Hi-Tech 6%
- A&D 5%
- Utilities 5%
- O&G 5%
- Industrial 4%
- PS 5%
- Other 3%
- Mining 1%
- Media 1%
- Mill Products 1%
- Services 3%
Abbott Labs: Case/Pallet Tagging

- **ERP system - R/3**
  - Delivery
  - Update

- **Device Mgmt Partner - ACSIS Device Controller**
  - Associate pre-encoded Tags (Case/Pallet) with Delivery

- **Warehouse Management System**
  - Pick/Pack
  - Delivery

- **Update pallet hierarchy and delivery**
  - ASN

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THE BEST-RUN BUSINESSES RUN SAP
Company and project overview:

- Manufactures class two narcotics; is a key Wal-Mart pharmaceutical supplier
- Is world’s first company to tag at item level
- Has improved tracking of goods within the facility for controlled substances
- Complies with Wal-Mart while achieving internal process improvements
- Uses SAP RFID technology to meet these requirements

Business benefits

- Tactical: Complies with Wal-Mart mandate:
  - Unit-level tagging by mid-year 2004
  - Case-level tagging by the end of 2006
- Strategic: Generates business benefits:
  - Lead the pedigree tracking requirements
  - Drive cost out of the supply chain
  - Increase supply chain responsiveness
  - Ensure legislative compliance to the FDA, DEA, and so on

“We selected SAP’s RFID solution not only to achieve this compliance but also to help us generate value for our business in the future. By being able to track our products automatically, we not only fulfill Wal-Mart’s mandate, we also position ourselves to meet future requirements from the FDA & DEA.”

Chuck Nardi, Vice President
Purdue Pharmaceuticals: Item-Level Tagging

- Pack
  - EPC #
  - Batch #

- InVault
  - EPC #
  - Delivery #

- OutVault
  - EPC #
  - Delivery #

- SAP Repository
  - EPC #
  - Batch #
  - Del. #
  - Etc.

- XI
  - Delivery #
  - Batch #
  - Sales Info.
  - Esp. Date
  - NDC Info.
  - Cust., P.O. #
  - Etc.

- E-Peddige Data Flow
- RFID Tag Data Flow

- Internet
  - Retrieve
  - HTTPS
  - ePedigree Partner XML API

- e-Pedigree Partner System - Supply Scape
Novartis Pharmaceuticals: Item-Level Tagging

Global Data repository, Reporting & Alerts (mid '07)

Managing serialized information, local data repository

Serialized information

Device control/
Data Acquisition System

PLC  ...  PLC
Reader  ...  Camera

Packaging Line

Device control

Reader  ...  Printer

Warehouse Distribution Process
(PharmOps Warehouse/ Turn-Table / CPO)

Source: Novartis Pharma AG – SAP Life Sciences Council, 21 April 2006 - Marc Bechet
Company and Project Overview:
The Jena University Hospital consists of 26 different facilities. It has 4,000 employees and treats 250,000 patients annually. The hospital selected SAP R/3 and All as part of an innovative comprehensive solution to prescribing, dispensing, transporting, and administering medications to its patients.

Business Challenge
Every 20\textsuperscript{th} patient in a hospital suffers from an Adverse Drug Event (ADE). More than 55\% of these ADEs are avoidable.

The average cost of an ADE is 3000 \(€\). In Germany, with 16.7 million patients treated every year, the potential savings from avoiding ADEs is 1.4 billion \(€/\text{year}\).

RFID Business Process
- Electronic order entry of prescriptions
- Tagging of medications in pharmacy and dispensed in unidose quantities
- Tracking of medications transported from pharmacy to intensive care and individual patients
- RFID bracelets worn by patients
- Instant access to detailed patient information
- Real-time matching of medications to patients
- Recording of medication in patient files
Commissioning: Pick and verify medication and pack into patient boxes

Load Container: Exit pharmacy to ICU * via automated vehicle

@ ICU: Register container arrival

Empty content of patient box at clinic bed

- Scan tags of health personnel
- Scan patient’s wristband
- Scan and record medication
- Real-time validation of match

* ICU = Intensive Care Unit

Prescription

Verify observations

Jena University Hospital: Benefits
Company Overview:  
Headquartered in Warsaw, Ind., Biomet Inc. designs, manufactures, and markets implants for musculoskeletal medical specialists. With net sales of more than US$1.9B in 2005, Biomet is the world’s fourth-largest company in its industry. Netherlands-based Biomet Europe has 1,800 employees and revenues of 500 million euros.

Business Challenge  
Biomet’s inventory consists of a large variety of high-value items  
• Items are assembled into loaner sets (kits)  
• Only a few items are used during an operation  
• Partial kits are returned and visually inspected  
• Missing items are invoiced and replenished  
Biomet was looking to improve accuracy and reduce the manual effort involved in this process.

Business Process for Loaner Kits  
• Goods Issue: Kit scanned by the RFID Tunnel, all items counted  
• Goods Receipt: Kit scanned by RFID Tunnel, remaining items counted  
• Difference: Invoiced to customer and replenished  
• Mismatches: Items from other kits used during surgery are resolved quickly
RFID-Enabled Business Processes at Biomet

Create Serialized Loaner Sets ⇒ Tagged Serialized Implant Parts

Goods Issue Records Specific Serial IDs

Records Specific Serial IDs

Consumption of Implants

Returned Loaner Sets ⇒ Including Unused Implants

Register Consumed Implant Parts

Invoice Based on Consumed Implants

Refill Loaner Sets
RFID-Enabled Applications are Evolving Quickly from Compliance to Innovative Value Add!

Value-Driven Business Scenarios
- Contracts and Chargebacks

Extended Healthcare Applications
- Medical Instrument Track/Trace/Invoice
- Hospital Medication Administration
- Clinical Trial Management

Supply Chain Management
- Product Recall management
- Product Authentication
- End-to-end Track/Trace
  - Electronic Proof of Delivery
  - Supply Chain Analytics

Retail and Regulatory Compliance
- Regulatory Case-Level Track/Trace: e-Pedigree; RxASN
- Retail CII Item-Level Track/Trace
- Retail Shrinkage and Track/Trace

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RFID-Enablement Value Ladder

Scope of Business Process and Information

- Material/inventory/batch
- Order/delivery/ASN
- Customer information
- Plans and forecasts
- Event models

Business Capability

- Alerts or required actions
- Alerts for upset avoidance
- Generate billable events
- Proof of delivery/deductions management
- Simplify process/manpower reduction
- Inventory move (GR/GI)
- e-Pedigree
- Serialized ASN
- Supply chain visibility
- Proof of activity
- Packing hierarchies
- Analytics: average move and dwell times

Increasing value
Questions?

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