SAP Advanced Track and Trace for Pharmaceuticals
Solution Overview

Peer Laslo, SAP Services
December 03rd 2015
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Market Requirements
International legislation fighting the counterfeiting/ falsification of medicinal drugs requiring serialization

1. In response to and with the aim to counter the large scale counterfeiting/ falsification of medicinal drugs, international governments have implemented, enacted or are planning to draft legislation calling for the serialization and reporting of medicinal drugs to improve patient safety.
Codification of drug trade items

The implementation of most of these legislations require serial numbers be encoded in 2-D barcodes.

- Serialized trade item information is contained in a 2-D barcode (GS1 Data Matrix) which is applied to medicinal sales unit packages, in some cases also to their aggregations to bundles, cases and then pallets - either for compliance or logistical reasons.

- The 2-D barcode typically contains the following elements:
  - Global Trade Identification Number
  - Expiration date
  - Batch/lot Number
  - Serial number

Source: 2-D Matrix barcode courtesy of GS1 Germany
Following production, codification is applied to the sales units of drugs at the packaging lines. Codification is typically also applied to case and pallet levels, building up serialized hierarchy levels. This is followed by shipping and compliant reporting, for example to governmental databases. Some legislation consider verification of point of dispense.
Three categories of approaches to the implementation of legislation fighting falsified medicines

Presently there are 3 types of compliance requirements

Serialization with reporting to a governmental database

Uploading serialized trade items into an institutional hub for verification

Initially lot traceability – then full supply chain track & trace of serialized trade items

in effect

enacted

enacted & partially in force

Expected

- Lot traceability in force
- Serialization required by 2017
- Full serialized track & trace by 2023
Requirements posited on Pharma Manufacturers and the Pharma Value Chain

1. Global serial number management
2. Serialization at packaging lines
3. Efficient process integration as this become part of “normal business”
4. Dealing with serial number volumes requiring a scalable serial number repository
5. Efficient reporting to different country reporting requirements regimes
Resulting key business challenges

1. How do I **efficiently comply with many country-specific compliance and reporting requirements** on drug trade item serialization?

2. How do I **efficiently manage my global serial number pool**?

3. How do I **efficiently integrate serialization with my business processes and systems**?

4. How do I **efficiently message serialization data to my business partners**?

5. How do I **scale with the expected data volume** arising from serialization?
Why SAP Advanced Track and Trace for Pharmaceuticals?
Goal: compliance to regulations that seek a safe and secure supply chain across the pharmaceutical value chain to ensure patient safety

CMO, 3PL
- Are often small companies with limited IT capabilities
- Need to manage externally generated serial numbers
- Ensure timely and correct communication to customers

MAH
- Are ultimately responsible for brand protection
- Need to manage external (for example, China) and internal serial numbers
- Often act as CMO also to Large Pharma Manufacturers

Wholesalers (US and elsewhere)
- Work with huge volumes (1 mio – 10b units/year)
- May require very limited functional scope
- WM-integration is a key aspect

Legend
MAH: market authorization holder (brand owner/OEM) | CMO: contract manufacturing organization | 3PL: third-party logistics provider
Why Customers asked us to invest into SAP Advanced Track and Trace for Pharmaceuticals?

During the period of 2012 – 2013, SAP received several requests from the Pharma Customer installed base of SAP Auto-ID Infrastructure/ SAP Object Event Repository to bring SAP Solutions for serialization in Pharmaceuticals to the next level.

Reasons

- Demand/ requirements for more focused Pharma specific functionality (e.g. master data, integration objects, process integration)
- Request for country reporting packages and associated functionality
- Scaling for the expected volume
- Severe concerns as to alternatives in the market place as to viable solutions on which one can place a bet for must do compliance to retain the right to sell into regulated markets
Why SAP Advanced Track and Trace for Pharmaceuticals?

Simplify regulatory reporting, to comply with international directives

Efficiently integrate serialization with business processes and your business network: master data, warehouse operations and supply chain partners

Effectively manage BIG DATA arising from the ever-growing number of countries that mandate serialization
How SAP Advanced Track and Trace for Pharmaceuticals delivers value

Simplify regulatory reporting
Readily available country reporting packages

Integrate serialization into your business processes
ERP Master data integration
Integration with ERP transactions & batches / lots
Integration to WMS operations

Manage expected steep increase in serialization data volume
A single scalable platform
Delivery of lean object/ event data model designed for performance and expected volumes

SAP Advanced Track and Trace for Pharmaceutical integrates with your supply chain network
Out of the box business partner integration (Contract Manufacturing Organizations ↔ Market Authorization Holders ↔ Wholesalers):
request/ response on serial number requests, supply chain partner notification with eASN or EPCIS XML
Benefits: SAP Advanced Track and Trace for Pharmaceuticals

**Comply**

Effectively comply with global serialization requirements, including different formats and country-specific reporting from a single corporate serialization repository.

**Cost**

Benefit from efficient integration of a corporate-level pharmaceutical serialization solution with your business processes and supply chain network, while reducing TCO and compliance cost.

**Scale**

Efficiently scale with a pharmaceutical solution capable of handling large serialization data volumes.

Reduce cost/ TCO of compliance

Reduce cost of business process integration

Reduce cost of platform operation – future proof investment

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Quick Overview
SAP Advanced Track and Trace for Pharmaceuticals provides a corporate serialization repository & serial number management solution with regulatory reporting interfaces and content supporting compliance to international legislation to fight falsified medicines.
SAP Advanced Track and Trace for Pharmaceuticals

**Compliant Reporting**
- Interfaces and predefined country version content for regulatory reporting
- Country versions available: Argentina, China, Turkey, USA
- Additional country versions planned

**Efficient SAP ERP Master Data Integration**
- ERP integration of trade items, locations and business partners

**Efficient Business Process Integration**
- Integrate with ERP transactions, warehouse management systems, and packaging lines
- Warehouse integration toolkit for integration to ERP Logistics Execution System WMS

**Global Serialization Repository**
- Capture serialized trade item events centrally
- View serialized trade item events with the repository browser
- Supports GS1 standards: core elements of EPCIS 1.1, EPCIS core business vocabulary, Tag Data Standard 1.9

**Manage Global Number Pools**
- Number ranges
- Randomized and sequential serial number lists
- Features an in-built randomizer

**Track & Trace**
- Serialized trade items, lot events
- Trade item up to pallet hierarchies (aggregations)
- Related business transactions
- Government and business partner reporting messages
High level process scope delivered by the solution

SAP Advanced Track and Trace for Pharmaceuticals delivers compliant reporting and integrates with your internal business operations and with your supply chain network.

Legend
MAH: market authorization holder (brand owner/ OEM) | CMO: contract manufacturing organization | 3PL: third-party logistics provider | PML: Product Markup language
Product details
Regulatory reporting: availability of country version content

Available for country reporting compliance

Regulatory reporting to MoH databases
Country version packages are available for SAP Advanced Track and Trace for Pharmaceuticals, version 1.0:
- China
- Turkey
- Argentina

Supply chain partner notification for US DQSA lot traceability
SAP Advanced Track and Trace for Pharmaceuticals, version 1.0 further supports notification messages from supply chain partners to support U.S. DQSA lot traceability compliance requirements

Outlook / road map*

Further country version content is planned subject to the availability to reliable and sufficient quality specifications.

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Main characteristics of SAP Advanced Track and Trace for Pharmaceuticals

**Designed as one component**

**Used GS1 global standards for implementation***
- EPCIS 1.1
- CBV 1.1 (core business vocabulary)
- TDS 1.9 (tag data standard)
- GS1 general specification (version 14, Jan 2014)

**Built for the Pharmaceutical Industry**
- Designed to work for MAHs, CMOs and US wholesalers
- Co-Innovation with 10+ leading pharmaceutical customers

**Minimum Footprint**
- Lean data model
- Designed for volume and speed
- Optimized for SAP HANA while also deployable on classical data bases

**Minimum Footprint**
- Minimized footprint
- Deployment and commercial model that works for the entire industry: 1m items -> 10b items / year

**Capable to handle any upcoming legislation**
- Roadmap for future legal requirements

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* EPCIS 1.1 is a powerful, comprehensive, generic and global standard. Not everything defined in EPCIS 1.1 is relevant to support the business processes of the pharmaceutical industry.
SAP Advanced Track and Trace for Pharmaceuticals
Technical solutions components

**SAP ECC add-on**
- SAP ECC add-on for SAP Advanced Track and Trace for Pharmaceuticals 1.0
- SAP ECC, 6.0 (EhP 6)+
- SAP NetWeaver 7.31+

**SAP Advanced Track and Trace**
- SAP Advanced Track and Trace for Pharmaceuticals 1.0
- SAP Application Interface Framework 3.0
- SAP NetWeaver 7.40 SP7

**Database options**
- Any database as supported by SAP NetWeaver 7.40
  or
- SAP HANA

**Supported languages:**
- English, German, French, Spanish, Portuguese, Russian, Turkish, Danish, Chinese
SAP Product Maintenance for SAP Advanced Track and Trace for Pharmaceuticals

These are the respective maintenance periods for SAP Advanced Track and Trace for Pharmaceuticals:

- Release 1 maintained until 31.12.2020
- Product maintained until 31.12.2025

PAM: https://websmp108.sap-ag.de/~sapidb/012002523100014967272015E
Solution Overview

Business Process coverage
Relevant business processes
Coverage of the core serialization process

Setting up for serialization

Create master data for trade items
Assign serial number profile to trade item
Create/ maintain number range/ serial number list
Distribute serial numbers to packaging lines or CMOs

Running the core serialization process

Capture serial number events from packaging lines/ CMOs
Capture S/N events from warehouse operations
Report S/N events to authorities, industry hubs and business partners
Receive S/N events from business partners
Receiving serialized products
Master Data Integration – Trade Items
Master Data Integration – Business Partners

<table>
<thead>
<tr>
<th>Business Partner Roles</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP No</td>
</tr>
<tr>
<td>SAP Pharma</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Business Partner Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP Name</td>
</tr>
<tr>
<td>BP Status</td>
</tr>
<tr>
<td>BP Category</td>
</tr>
<tr>
<td>Global Location No.</td>
</tr>
<tr>
<td>Notification Format</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Business Partner Company Registration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company Reg. ID</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Business Partner Role Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP Role</td>
</tr>
<tr>
<td>S - Own Organization</td>
</tr>
</tbody>
</table>

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Master Data Integration – Locations
Master Data Integration – Systems
Serial Number Management

![Image of a computer interface for serial number management](image_url)

### Range Details
- **Range Key Data**
  - Range Definition: 1000000120
  - Range Definition Value: 1
  - Serial Number Format: 100000000000000
  - Serial Number to: 1
  - Range Type: List Managed
  - Origin Indicator: Internal
- **Sanitation Attributes**
  - SN Type: Alphanumeric (case sensitive) with exclusion list
  - Excluded Chars: 
  - SN Length: 16
  - SN Randomization: Randomized 1:10000
  - SN Scope: 1: by Product Category

### Statistics
- **Max. Numbers**: 8,415
- **Sent Numbers**: 213
- **Commissioned Numbers**: 212
- **Numbers Lost**: 0
- **Fill Level**: 0
- **Alert Fill Level**: 0
- **Alert Status**: 0 (no current alerts)
- **No. Assoc. Sys.**: 1

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Business Process Integration
Track & Trace
Regulatory Reporting
Example Argentina
Regulatory Reporting
Example Argentina
Repository and regulatory reporting
Market authorization holder view
Repository and regulatory reporting
U.S. wholesaler view
High level process scope coverage

SAP Advanced Track and Trace for Pharmaceuticals integrates with your internal business operations and with your supply chain network.

Market authorization holder (brand owner/ OEM) | Contract manufacturing organization | Third-party logistics provider | Wholesalers
Process overview
Packaging and warehouse operations

### Packaging I
- Primary packaging (for example, tablets in blister)
- Secondary packaging (for example, blister in folding box)
- Apply barcode to secondary packaging
- Scan and verify barcode (commissioning)

### Packaging II
- Bundling (=aggregation)
- aggregations: pack bundles into shippers (= aggregation)

### Palletizing
- Palletizing (=aggregation)

### Packaging line integration
- SN request
- SN provisioning
- Commissioned SNs

### Warehouse integration
- Lookup and posting of EPCIS events

### Advanced track and trace serial number management

### Advanced track and trace object and event repository

---

### Site or line manager
- Wholesale management solution

### Warehouse operations
- Goods receipt
- Sample
- Putaway
- Unpack (=aggregation)
- Pack (=Aggregation)
- Pick
- Goods issue
- ....
- Count

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Components overview
Market authorization holder view

Advanced track and trace serial number management

Request and receive serial numbers (lists and ranges)

Packaging line Integration → Warehouse integration

Packaging line

Warehouse operations

Supply chain activities

Packaging line Integration

Warehouse integration

ERP integration

EPCIS or PML

request and receive serial numbers (lists and ranges)

Commissioned serialized trade items (SGTIN) and aggregations

EPCIS

Inbound and outbound delivery production order

Event capturing and rules processing

SAP Advanced Track and Trace for Pharmaceuticals

Request and receive serial numbers (lists and ranges)

Contract manufacturers

3PL

Commissioned serialized trade items (SGTIN) and aggregations

Authorities

Wholesaler

Regulatory reporting

DSCSA reporting

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Components overview
Contract manufacturing organization (CMO) view

Advanced track and trade serial number management

Request and receive serial numbers (lists and ranges)

Packaging line integration
Warehouse integration

Packaging line

Warehouse operations

Supply chain activities

Packaging line integration
Warehouse integration
ERP Integration

Request and receive serial numbers (lists and ranges)

Advanced track and trace event capturing and rules processing

SAP Advanced Track and Trace for Pharmaceuticals

Commissioned serialized trade items (SGTIN) and aggregations

Inbound and outbound delivery production order

EPCIS or PML

EPCIS

EPCIS Reports

commissioned serialized trade items (SGTIN) & aggregations

Pharma MAH

Pharma MAH
Detailed Solution Overview

GS1 Standards covered
GS1 Standards accommodation

SAP Advanced Track and Trace for Pharmaceuticals

Encoding and decoding

According to Tag Data Standard (TDS) 1.9

Repository

The following versions of the GS1 EPC global standard were considered for the repository implementation:

- EPCIS 1.1*
  - SGTIN
  - LGTIN (Lot)
  - Business Transaction Types
  - EPCIS Events
  - GLN as location identifier

GS1 general specification (version 14, Jan 2014)

Business vocabulary

EPCIS Core Business Vocabulary 1.1 (CBV)

EPCIS interface

EPCIS capture notification

*EPCIS 1.1 is a powerful, comprehensive, generic and global standard. Not everything defined in EPCIS 1.1 is relevant to support the business processes of the pharmaceutical industry.
Solution Overview

Content of Country packages available for SAP Advanced Track and Trace for Pharmaceuticals 1.0
## Product details
### Regulatory Reporting: available country version content

<table>
<thead>
<tr>
<th>Country version packages available for reporting to authority databases</th>
<th>Supply Chain Partner notification for US DQSA Lot Traceability</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>Regulatory reporting to MoH database</td>
</tr>
<tr>
<td>Turkey</td>
<td>Country version packages are available for SAP Advanced Track and Trace for Pharmaceuticals, version 1.0:</td>
</tr>
<tr>
<td>Argentina</td>
<td>• China</td>
</tr>
<tr>
<td></td>
<td>• Turkey</td>
</tr>
<tr>
<td></td>
<td>• Argentina</td>
</tr>
<tr>
<td></td>
<td>Supply chain partner notification for US DQSA lot traceability</td>
</tr>
<tr>
<td></td>
<td>SAP Advanced Track and Trace for Pharmaceuticals, version 1.0 supports notification messages to supply chain partners for U.S. DQSA lot traceability compliance requirements.</td>
</tr>
</tbody>
</table>
Country package China

Regulatory Reporting – China Reporting
Supported regulatory reporting messages to China FDA

- Supported messages ↔ China FDA
  - China product master data handling
  - Importing China serial number files
  - China send relation create message
  - China send sales warehouse out message
  - China send purchase warehouse in message
  - China send code replace message
  - China send destroy warehouse out message
  - China send return warehouse in message
  - China send check warehouse out message

SAP Advanced Track and Trace for Pharmaceuticals

China FDA
Regulatory reporting messages to China FDA
Delivered functions

**China product master handling**
- Uploading of China product xml file to trade item

**China serial number handling**
- Uploading of CN serial number files to advanced track and trace serial number management

**Commissioning of China serial numbers**

**Creation of CN regulatory reporting file, as related to shipping (sales warehouse out), receiving (purchase warehouse in) and other messages (e.g. relation create)**

**Change handling: new production license**
- Add new res codes
- End of validity of expired res codes
- Upload new prod master files
- Upload new serial numbers
- Cleanup serial number management for old expired res codes

**General Remark: Regulatory reporting is configured within rules maintenance**
Country package Turkey

Regulatory Reporting – Turkish Ministry of Health
Regulatory reporting to Turkish MoH
Supported messages

**Supported messages ↔ Turkish MoH**

**TRITS**
- Send production notification to Turkey (ITS)
- Send product purchase notification to Turkey (ITS)
- Send deactivation notification to Turkey (ITS)
- Send dispatch notification to Turkey (ITS)
- Send dispatch cancel notification to Turkey (ITS)
- Send exportation notification to Turkey (ITS)
- Send product return notification to Turkey (ITS)
- Send product turnover notification to Turkey (ITS)
- Send prod. turnover cancellation notification to Turkey (ITS)

**TRPTS**
- Reg. representative: Send package information to Turkey (PTS)
- Report: request package information from Turkey (PTS)
Exemplary E2E message choreography for Turkey

- **CMO MAH Wholesaler**
  - Send package info to PTS
  - Request package info from PTS
  - Send package info to PTS
  - Request package info from PTS
  - Send ProdNotif to ITS
  - Send SalesWhOut to ITS

- **TR PTS**
  - Send package info to PTS
  - Request package info from PTS

- **TR ITS**
  - Send SalesWhOut to ITS
SAP Advanced Track and Trace for Pharmaceuticals supports data exchange with the Argentina ANMAT server. The following messages are supported:

- sendMedicamentos: send medications
- getEnviosPropiosAlertados: get alerted deliveries
- sendCancelacTransaccParcial: cancel partial transaction
- getTransaccionesNoConfirmadas: get non confirmed transactions
- sendConfirmaTransacc: confirm transaction
- sendAlertaTransacc: alert transaction

SAP Advanced Tack and Trace for Pharmaceuticals

National Administration of Drugs, Food and Technology (ANMAT)
Regulatory reporting to ANMAT Argentina
Message types for sender and receiver

Messages relevant for sender
- sendMedicamentos
- getEnviosPropiosAlertados
- sendCancelacTransaccParcial

Messages relevant for receiver
- sendMedicamentos
- getTransaccionesNoConfirmadas
- sendConfirmaTransacc
- sendAlertaTransacc

EPCIS message
(optional but recommended)
Country package USA – Lot Traceability

Regulatory Reporting – US DQSA Lot Traceability
U.S. DQSA lot traceability compliance
Supported reporting to next supply chain partner

SAP Advanced Track and Trace for Pharmaceuticals
Market authorization holder

Lot level EPCIS

U.S. Wholesaler
Solution Overview

UI 5 Repository Browser
## UI 5 Repository Browser

### ATT Cockpit: Serialized Trade Items

<table>
<thead>
<tr>
<th>GS1 Elem String</th>
<th>Short Descrip.</th>
<th>Logistic Status</th>
<th>Pack Status</th>
<th>Disposition</th>
<th>Lot Number</th>
<th>Global Location No.</th>
<th>Global Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>(01)19734550000088421</td>
<td>SAPoten direk 15mg - 12 EA - TR</td>
<td>4 - Shipped (Anywhere)</td>
<td>1 - Packed (Level 1)</td>
<td>001 - active</td>
<td>BT220301</td>
<td>9734550000104</td>
<td>99</td>
</tr>
<tr>
<td>(01)19734550000088421</td>
<td>SAPoten direk 15mg - 12 EA - TR</td>
<td>1 - Created (Commissioned)</td>
<td>0 - Unpacked</td>
<td>001 - active</td>
<td>BT220301</td>
<td>9734550000104</td>
<td>99</td>
</tr>
<tr>
<td>(01)19734550000088421</td>
<td>SAPoten direk 15mg - 12 EA - TR</td>
<td>1 - Created (Commissioned)</td>
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<td>9734550000104</td>
<td>99</td>
</tr>
</tbody>
</table>

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Solution Overview

Business and Technical Monitoring of Messages with the built-in SAP Application Interface Framework Component
Business & Technical Monitoring
using the SAP Application Interface Component delivered as part of SAP Advanced Track & Trace for Pharmaceuticals
Business & Technical Monitoring

using the SAP Application Interface Component delivered as part of SAP Advanced Track & Trace for Pharmaceuticals

![Error Handling - 2015-07-20 (200)](image)

### Log Messages

#### Type Message Text

<table>
<thead>
<tr>
<th>Message Text</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Message (0465682396571E0580D71E192060750) processing started.</td>
<td>2015-07-20</td>
<td>00:00</td>
</tr>
<tr>
<td>Object Event received from um:apm:msg:033978.000000.1 Action ADD</td>
<td>2015-07-20</td>
<td>14:20</td>
</tr>
<tr>
<td>Object Event successfully processed</td>
<td>2015-07-20</td>
<td>14:02</td>
</tr>
<tr>
<td>Event on 2014-12-17 12:20:47 successfully booked. (1)</td>
<td>2015-07-20</td>
<td>16:20</td>
</tr>
<tr>
<td>Aggregation Event received from um:apm:msg:033978.000000.1 Action ADD</td>
<td>2015-07-20</td>
<td>14:20</td>
</tr>
<tr>
<td>Aggregation Event successfully processed</td>
<td>2015-07-20</td>
<td>14:20</td>
</tr>
<tr>
<td>Event on 2014-12-17 12:20:47 successfully booked. (2)</td>
<td>2015-07-20</td>
<td>16:20</td>
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</tbody>
</table>

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Solution Overview

Architecture & data model principles
<table>
<thead>
<tr>
<th>Repository data model</th>
<th>Objects covered</th>
<th>Event capture logic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only store what is required</td>
<td>SGTINs (EPCs)</td>
<td>Auto-unpack</td>
</tr>
<tr>
<td>All affected objects inherit an event</td>
<td>SSCCs</td>
<td>Auto-create</td>
</tr>
<tr>
<td>EPCIS data model</td>
<td>LGTINS (lots)</td>
<td>…</td>
</tr>
<tr>
<td>Inclusion of EPCIS core business vocabulary</td>
<td>Encoding/decoding based on coded logic instead of customized rules</td>
<td>Transactions</td>
</tr>
<tr>
<td>Searchable attributes at header level of the respective business objects.</td>
<td>Database access optimized for fast prevalidation of event activity</td>
<td>Production / process order</td>
</tr>
<tr>
<td>Database access optimized for fast prevalidation of event activity</td>
<td>All attributes optimized regarding compression capabilities and database clustering</td>
<td>Deliveries</td>
</tr>
<tr>
<td>All attributes optimized regarding compression capabilities and database clustering</td>
<td>Processing logic uses buffers and supports mass data handling</td>
<td>Batches</td>
</tr>
</tbody>
</table>
Integration
SAP Advanced Track and Trace for Pharmaceuticals
Integration with external systems (simplified)

- SAP ECC
  - Master data
  - Transaction data
  - Warehouse toolbox functions

- SAP Advanced Track and Trace for Pharmaceuticals
  - Packline requests serial numbers or ranges
  - Packline sends EPCIS / PML Events

- Government systems
  - Notification to authorities
  - Request data from authorities (e.g., TR PTS)
  - File handling:
    - China product master
    - China serial numbers
    - China regulatory message

- Supply chain partner
  - SCP requests/sends serial numbers or ranges
  - SCP sends/receives EPCIS

- Packaging line

TR PTS = Turkey MoH PTS Server
SCP = Supply Chain Partner
EPCIS = Electronic Product Code Information Sharing
PML = Product Mark-up Language
Integration paradigm
- Integration with ERP system is available but still all master data required can be maintained in SAP Advanced Track and Trace for Pharmaceuticals.
- Master data structures can be enhanced in Advanced Track and Trace for Pharmaceuticals to accommodate customer-specific processes.
- Integration can be enhanced to accommodate customer-specific data and processes.

Master data covered
- Material master
  - Including mass maintenance
- Business partners
  - Vendors
  - Customers
- Locations
- Batches/lots

Transactional data
- Inbound and outbound deliveries
- Production/process orders

ERP material master enhancements
- Basic data 1
  - Serialization type
  - Synchronization timestamp
- Add data -> Units of measure
  - New GTIN field
  - New national code field
  - New registration code field
  - Serialization Indicator
- Work scheduling (plant level)
  - Validity date for serialization
Integration (landscape/ landscape options)
Integration and interfaces

- SAP ECC
- RFC
- Web service (ODATA)
  - Master data
  - Transactional data
  - Warehouse toolbox events
  - eASN via Warehouse toolbox

- SAP Advanced Track and Trace for Pharmaceuticals
  - Request/Send serial number range and list requests
  - Send/receive serial number status information
  - Send/receive PML or EPCIS (AIF)

- Government systems
  - RFC
  - Web Service (SOAP)
    - CN: product master / Serial Number import
    - CN: regulatory reporting message

- Supply chain partner
  - AIF = SAP Application Interface Framework
    which is a software component (under restricted usage license) of SAP Advanced Track and Trace for Pharmaceuticals

- RFC
- Web Service (SOAP)
  - Request/Send serial number range and list requests
  - Send serial number status info
  - Send PML or EPCIS (AIF)

Packaging line
Integration and interfaces
Additional features

- SAP ECC
- RFC
- Web service (ODATA)
- SAP Advanced Track and Trace for Pharmaceuticals
- Web service (SOAP)
- Repository distribution:
  - customizing
  - master data
  - serial number range data
  - transactional data
- Pack line
- Government systems
- Request and import PTS data (commission and aggregate)
- Web service
- Web service (SOAP)
- File
- Supply chain partner
- SAP ECC
- SAP Advanced Track and Trace for Pharmaceuticals
- Web service (SOAP)
- Local SAP Advanced Track and Trace for Pharmaceuticals
- Supply chain partner
- Government systems
Integration
SAP ERP, non-SAP ERP, and third party WMS

- Master data
- Transaction data

- Master data
- Transaction data
- WHS toolbox functions
- eASN
- Serial number request

- O-DATA services
- eASN
- Serial number request
Integration
Reporting to authorities and packaging lines

Government systems

- Notification to authorities
- Request data from authorities (TR PTS)
- File handling:
  - China product master
  - China serial numbers
  - China regulatory message

SAP Advanced Track and Trace for Pharmaceuticals

- Packaging line requests serial numbers
- Packaging line requests number ranges
- Packaging line sends serial number status Info
- Packaging line sends PML events
- Packaging line sends EPCIS events

Packaging line
Integration
Local instances, SAP Auto-ID Infrastructure, supply chain partners

- SCP requests/sends serial numbers or ranges
- SCP sends/receives serial number status info
- SCP sends/receives EPCIS
- SCP sends PML

- SAP Auto-ID Infrastructure requests number ranges
- SAP Auto-ID Infrastructure sends EPCIS

- Repository distribution (customizing, master data, range definitions) to local instances of SAP Advanced Track and Trace for Pharmaceuticals
- Repository replication for transaction data (both directions)
- Local ATT requests serial numbers or ranges
- Local ATT sends serial number status information

Supply chain partner
Local SAP Auto-ID Infrastructure
Local SAP Advanced Track and Trace for Pharmaceuticals
## SAP Advanced Track and Trace for Pharmaceuticals
### Overview of integration methods

<table>
<thead>
<tr>
<th>Master data</th>
<th>Business partners (vendors, customers), locations, trade items (materials with assigned GTINs)</th>
<th>In-bound</th>
<th>Out-bound</th>
<th>SOAP service</th>
<th>ODATA service</th>
<th>RFC</th>
<th>HTTP Post</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transaction Data</td>
<td>Inbound deliveries, outbound deliveries, production orders</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serial number Management</td>
<td>Inbound and outbound of range request, number request, serial number status information</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ATT functions</td>
<td>WHS toolbox functions (validation, get contents, get hierarchy, …), eASN handling, serial number request</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EPCIS events</td>
<td>Inbound and outbound of LGTIN (Batches), SGTIN, SSCC</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>Only inbound</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PML events</td>
<td>Inbound</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulatory reporting</td>
<td>Notification to authorities, request data from authorities if applicable</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td>File handling for China</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Replication</td>
<td>Customizing, master data, range definition replication from Central to local ATTs</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Repository object replication between central and local ATT</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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SAP Advanced Track and Trace for Pharmaceuticals
Software components and integration

**ERP add-on**
- Master data
  - Business partners (vendors, customers)
  - Locations (GLNs)
  - Trade items (materials with assigned GTINs)

**Transactional data**
- Inbound and outbound Deliveries
- Production orders

**WM toolkit**

**SAP ECC**

**Third-party ERP/ third-party WMS**

**Packaging line, or third-party system sending EPCIS capture notifications**

**SAP AIF 3.0**
- RFC
- O-Data

**Object event repository**
- User interface
  - Cockpit: master data
  - Cockpit: serial number mgmt.
  - Cockpit: repository browser
- Objects: SGTIN, SSCC, GTIN (Batch)
- Events: [selected EPCIS events]
- Business transactions: [EPCIS business transaction types]
- Services and content
  - Global S/N mgmt. and algorithms
  - EPCIS core business vocabulary
  - ID profiles and mapping

**SAP AIF 3.0**
- Optional: local repository
- RFC
- Replication

**Government**
- China reporting package
- Turkey reporting package
- Argentina reporting package
- Future country package versions

**3PLs, CMOs, wholesaler**
- SOAP Service or RFC
- S/N request/ response
- SOAP Service for inbound & outbound [O-Data inbound only]
- EPCIS capture notification – inbound and outbound for business partner notification
Options for supply chain reporting

1. eASN

Sender

- SAP ECC
  - Retreive data for eASN in ATT

SAP Advanced Track and Trace for Pharmaceuticals

Receiver

- SAP ECC
  - Create inbound delivery

- Event message via WM toolbox for eASN data

2. ASN + EPCIS

Sender

- SAP ECC
  - Shipping event, e.g. via WH toolbox

SAP Advanced Track and Trace for Pharmaceuticals

Receiver

- SAP ECC
  - Create inbound delivery

- EPCIS event message

- SAP Advanced Track and Trace for Pharmaceuticals or other
Transactional data and batch integration
Simplified view

SAP ECC
- Inbound delivery
- Outbound delivery
- Production order
- Batch

SAP Advanced Track and Trace for Pharmaceuticals
- Transaction

SCP

Object
- LGTIN
- SGTIN
- SSCC

Event

RFCC

Web Service (ODATA)

Web Service (SOAP)
Transactional data and batch integration
Simplified view

SAP ECC
- Inbound delivery
- Outbound delivery
- Production order
- Batch

SAP Advanced Track and Trace for Pharmaceuticals
- Transaction
- Create

Event
- Object
  - LGTIN
  - SGTIN
  - SSCC

SCP

Web Service (ODATA)
Web Service (SOAP)
RFC
Transactional data and batch integration
Simplified view

SAP ECC
- Inbound delivery
- Outbound delivery
- Production order
- Batch

SCP

SAP Advanced Track and Trace for Pharmaceuticals
- Transaction
- Object
  - LGTIN
  - SGTIN
  - SSCC

Web Service (ODATA)
Create Event
Update (status, quantities)
RFC
Transactional data and batch integration
Simplified view

SAP ECC
- Inbound delivery
- Outbound delivery
- Production order
- Batch

SCP
- EPCIS with transaction and batch

SAP Advanced Track and Trace for Pharmaceuticals
- Transaction
- Event
  - LGTIN
  - SGTIN
  - SSCC

Web Service (ODATA)
- update, goods receipt for Prod
Web Service (SOAP)
- update (status, quantities)

RFC
Solution Overview

Supply Chain Partner Integration
Integration with supply chain network partners

Examples

**CMO ↔ MAH Integration**

A contract manufacturing organization (CMO) requesting serial numbers from a market authorization holder and reporting back their usage

**MAH ↔ US Wholesaler Integration**

A market authorization holder sending a DQSA compliant notification message to a wholesaler
Integration with supply chain network partners

Example: CMO ↔ MAH Integration

A contract manufacturing organization (CMO) requesting serial numbers from a market authorization holder and reporting back their usage.
Integration with supply chain network partners
Example: MAH ↔ U.S. wholesaler Integration

A market authorization holder sending a DQSA compliant notification message to a wholesaler
Solution Overview

Integration of Warehouse Processes
Warehouse operations supported with the warehouse integration toolkit in SAP Advance Track and Trace for Pharmaceuticals

- Goods receipt
- Sample
- Put away
- Unpack (=aggregation)
- Pack (=aggregation)
- Pick
- Goods issue
- ....
- Count
Integration of SAP Advanced Track and Trace for Pharmaceuticals
SAP ERP WMS and third party WMS

Overview warehouse toolkit Integration

SAP ECC
SAP ERP WM

• Master data
• Transaction data
• WHS Toolbox functions
• eASN
• Serial number request

SAP Advanced Track and Trace for Pharmaceuticals

3third party
WHS

• WHS toolbox functions
• eASN
• Serial number request

Warehouse operations covered
sampling | goods receipt | putaway | unpack | pack | pick | goods issue | count

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Process overview for packaging and warehouse operations in SAP Advance Track and Trace for Pharmaceuticals

- **Primary packaging (e.g., tablets in blister)**
- **Secondary packaging (e.g., blister in folding box)**
- **Apply barcode to secondary packaging**
- **Scan and verify barcode (commissioning)**

**Packaging I**
- Bundling (=aggregation)
- Aggregations: pack bundles into shippers (= aggregation)

**Packaging II**
- Palletizing (=aggregation)

- **Palletizing**

- **Goods Receipt**
- **Sample**
- **Putaway**
- **Unpack (=Aggregation)**
- **Pack (=Aggregation)**
- **Pick**
- **Goods Issue**
- **....**
- **Count**
Warehouse management integration
Functions and services

SAP ECC – Warehouse management (WM) integration
• Toolbox (vs. out-of-the-box solution) to support highly configured WM implementations as well as non-SAP warehouse management solutions and customer-specific processes
• Quick Validation service for fast validation of WM activities
• EWM-Integration on the roadmap

Non-SAP software WM integration
• Native use of provided services including quick validation service for fast validation of WM activities

### Functions for SAP ECC WM

<table>
<thead>
<tr>
<th>Inbound processes</th>
<th>Internal processes</th>
<th>Outbound processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHS_RECEIVE_DOCUMENT</td>
<td>WHS_UNPACK</td>
<td>WHS_PICK2PALLETT</td>
</tr>
<tr>
<td>WHS_RECEIVE_CONTAINER</td>
<td>WHS_PACK</td>
<td>WHS_LOAD</td>
</tr>
<tr>
<td>WHS_PUTAWAY</td>
<td>WHS_PICK</td>
<td>WHS_SHIP_CONTAINER</td>
</tr>
<tr>
<td></td>
<td>WHS_SAMPLE (destructive sampling &amp; non-destructive sampling)</td>
<td>WHS_SHIP_DOCUMENT</td>
</tr>
<tr>
<td></td>
<td>WHS_INSPECT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>WHS_INSPECT_HIERARCHY</td>
<td></td>
</tr>
<tr>
<td></td>
<td>WHS_COUNTING</td>
<td></td>
</tr>
<tr>
<td></td>
<td>WHS_PICK2PALLET</td>
<td></td>
</tr>
<tr>
<td></td>
<td>WHS_CREATE</td>
<td></td>
</tr>
</tbody>
</table>

### Native services

Adv. T&T functions for repository access

- VALIDATE_ACTIVITY
- GET_HIERARCHY_COUNT
- GET_HIERARCHY_CONTENTS
- GET_HIERARCHY_STRUCTURE
- GET_LOCATION_CONTENTS
- GET_DOCUMENT_CONTENTS
- GET_SERIAL

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Warehouse activity test UI you can use in the ERP add-on to SAP Advanced Track and Trace for Pharmaceuticals to simulate warehouse operations
## Technical integration of warehouse management solutions from SAP and third-party WM systems

<table>
<thead>
<tr>
<th></th>
<th>In-bound</th>
<th>Out-bound</th>
<th>SOAP service</th>
<th>ODATA service</th>
<th>RFC</th>
<th>HTTP post</th>
<th>Remarks</th>
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<td><strong>ATT functions</strong></td>
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<td></td>
<td><em>WHS toolbox functions (validation, get contents, get hierarchy, …), eASN handling, serial number request</em></td>
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<tr>
<td><strong>EPCIS events</strong></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td><em>Inbound and outbound of LGTIN (Batches), SGTIN, SSCC</em></td>
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<tr>
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<td>X</td>
<td>X</td>
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<td></td>
<td></td>
<td></td>
<td>Only inbound</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Also used for supply chain partner notifications</td>
</tr>
<tr>
<td><strong>PML events</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><em>Inbound</em></td>
</tr>
<tr>
<td></td>
<td>X</td>
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<td></td>
</tr>
</tbody>
</table>
Solution Overview

Packaging Line Integration
Packaging line integration

- Serial number request
  - Request for number ranges and lists
  - Response containing number ranges or list
- Commissioned data
  - PML and EPCIS capture notification
- PML is transformed into the EPCIS capture notification format before rules are executed and data are posted into repository
- Integration monitored via AIF
Solution Overview

Approach When Considering Distributed Repository Instances
Distributed instances of SAP Advanced Track and Trace for Pharmaceuticals

**Today**

Option 1: central deployment only
- SAP OER
  - AII
  - EM
- SAP Advanced Track and Trace for Pharmaceuticals
- SAP Auto-ID Infrastructure

**Future**

Option 2: central & regional/local deployment
- SAP Advanced Track and Trace for Pharmaceuticals
- SAP Auto-ID Infrastructure
- Potential migration path
- SAP Advanced Track and Trace for Pharmaceuticals
Distributed instances of SAP Advanced Track and Trace for Pharmaceuticals: Overview

- Master data is replicated from central ATT to local ATT (one way). Trigger is the change within the central system or a batch report.

- Object data captured within a local ATT instance is replicated to the central instance if its location is moving beyond the responsibility of the respective local instance.

- Object data captured within a central ATT instance is replicated to a local instance if its location is moving to one assigned to a local system. Check must be made that it is not sent back to the same ATT system if it was replicated from another system in the same processing step.
Distributed instances of SAP Advanced Track and Trace for Pharmaceuticals
Customizing and master data

Replication of settings / customizing

- To ensure that directly connected systems within the same organization are aligned in their settings, we need to ensure that customizing is synchronized.
- Synchronization in this context means we need to replicate the data from a central ATT instance to a local instance.
- The defined configuration tables will be transferred at DB level from the central ATT instance to all connected local ATT instances. The replication will be started based on a report that is batch-enabled. The data in the local ATT system will be overwritten for the same keys. Additional entries in local ATT instances will remain untouched.

Replication of master data

- To ensure that directly connected systems within the same organization are using the same master data, we need to ensure that relevant master data is synchronized.
- Synchronization in this context means we need to replicate the data from a central ATT instance to a local instance. The replicated master shall not be changed in the local instance.
- The defined master data objects with all relevant entities will be transferred at DB level from the central ATT instance to all connected local ATT instances. The replication will be started based on a report that is batch-enabled. Additionally, the replication will be triggered upon all updates of relevant entities for the master data objects in scope for replication.
- The data in the local ATT system will be overwritten for the same keys. Additional entries in local ATT instances will remain untouched.
- Remark: Internal keys for master data objects are GUIDs, so we can directly replicate them without requiring different internal identifiers. The GUIDS cannot collide within a landscape of different connected systems.
Distributed instances of SAP Advanced Track and Trace for Pharmaceuticals
Serial number management and transactional data

Replication of serial number management
• To ensure that directly connected systems within the same organization can cascade serial number provisioning the advanced serial number management component includes features to distribute serial number pools, subranges, and lists from central instance to local instances and report the status back to the central instance.
• The local ATT in this area behaves like any external ATT system (request/notify mechanism).

Replication of transaction data
• Transaction data (meaning serialized or non-serialized objects, events, business transactions) will be replicated between central and local ATTs in both directions.
• Transaction data can be created or changed in any local ATT or central ATT system, but only one instance can accept such changes at any time.
• Initially the ATT system that first receives an object will be responsible until it leaves the scope of responsibility of that local instance (change of location). When the responsibility changes, it always changes to the central ATT instance first. The central instance acts a moderator/hub for all replicated transaction data.
• We differentiate between two kinds of replication:
  – Visibility replication will only replicate data required for visibility within the target system of that replication process. This could be the global visibility of the existence of an object or a subsequent disposition change for an object that has originally been created in a local system.
  – Responsibility replication will replicate all relevant data required for subsequent processing and all checks and feature including reconstruction of the pack hierarchy at any time. In addition, the control of the object is handed over to the replication target. The object status will be changed to indicate that no event must be accepted to that object in the current instance (object status = ‘visible (read only)’)
• The replication of events can be influenced based on a BADI. By default all events with action ADD or DELETE will be replicated. The remaining events with action OBSERVE will be provided to the BADI interface and can be added selectively by the customers own logic. In case we allow events to be removed and/or data to be changed, we need to include logic to check data consistency.
Functional Comparison
SAP Auto-ID Infrastructure / SAP OER versus
SAP Advanced Track and Trace for Pharmaceuticals
## Functional Comparison

<table>
<thead>
<tr>
<th>Functionality</th>
<th>SAP Auto-ID Infrastructure/ SAP Object Event Repository</th>
<th>SAP Advanced Track &amp; Trace for Pharmaceuticals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Master Data integration with SAP ERP</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Integration with Warehouse operations</td>
<td>Cumbersome via AII with limited functionality</td>
<td>Yes – delivery of a warehouse toolkit</td>
</tr>
<tr>
<td>Object Event Data Model</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Accommodation of EPCIS 1.1/ CBV</td>
<td>No – on EPCIS 1.01 – no core business vocabulary</td>
<td>Yes</td>
</tr>
<tr>
<td>Event Management on event milestones</td>
<td>Yes</td>
<td>No – focus is on a lean object event data model built for performance and that scales with data volume</td>
</tr>
<tr>
<td>Business Monitoring function and error resolution for the business user</td>
<td>No – just technical monitoring in PI</td>
<td>Yes – achieved with SAP AIF as a software component – a restricted user license is part of the SAP Adv Track &amp; Trace license</td>
</tr>
<tr>
<td>Optimized lean data model for high volume</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Encoding/ decoding</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Randomizer with various algorithms</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Delivery of regulatory reporting specific functionality and reporting formats</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Direct ERP transactional integration</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Out of the box ERP batch integration</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Support of out of the box lot traceability for US DQSA</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Single instance platform design option</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Where to find information

SAP Help
http://help.sap.com/attp

About Archiving
http://help.sap.com/saphelp_attp100/helpdata/en/e1/31f75487034d55e100000000a4450e5/content.htm?frameset=en/e1/31f75487034d55e100000000a4450e5/frame...current_toc=en/09/31f75487034d55e100000000a4450e5/plain.htm&node_id=3&show_children=true#jump3

Service Marketplace
https://websmp104.sap-ag.de/~form/handler?_APP=00200682500000002672&_EVENT=DISP...700000011284&_HIER_KEY=701200252311000003919&

Installation Guides
http://service.sap.com/instguides > Focused Business Solutions > SAP Advanced Track and Trace for Pharmaceuticals > SAP Advanced Track and Trace for Pharmaceuticals 1.0.

Relevant SAP Notes
• Installation Note STTP: 2203586
• Installation Note STTPEC: 2213945

Software Download Center
https://support.sap.com/swdc

Search: SAP ADV TRACK TRACE

PAM
https://apps.support.sap.com/sap/support/pam?hash=pvnr%3D6783820010900007708%26pt%3Dq%257Cd

FBS availability
Thank you

Peer Laslo

Business Development Manager
Track & Trace in Process Industry

SAP Deutschland AG & Co. KG
Rosenthaler Straße 30
10178 Berlin

Mobile: +49 160 90823032
Mail: peer.laslo@sap.com