

SAP® Support of the Healthcare Supply Chain's Ongoing Effort to Ensure Patient Safety and Drive Business Value

A Detailed Look at SAP's Support for the Center for
Healthcare Supply Chain Research® Blueprint for
Data Management & Data Sharing



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Executive Summary

The Center for Healthcare Supply Chain Research (formerly the HDMA Research & Education Foundation) recently published an important study concerning data management and data sharing in the healthcare supply chain¹. The key conclusions of the study are paraphrased below:

1. The primary goals of the healthcare industry are to ensure patient safety and to deploy processes and systems that are compliant with the various state and federal requirements. To this end, certain data must be shared among trading partners.
2. Industry recognizes the enormous potential business value of leveraging shared data to enhance the efficiency and effectiveness of supply chain processes through enhanced visibility. To the extent possible, industry would prefer to leverage the investments made in safety and efficient compliance to also accomplish these business goals.
3. The recommended Blueprint for industry to achieve these goals is to develop a phased approach and architecture that leverages an important new EPCglobal standard for data exchange called electronic product code information services (EPCIS).

EPCIS is a standard mechanism for inter-company collaboration and data sharing, which can enable healthcare trading partners to deploy solutions that not only meet the short-term mandates driven by patient safety, but also to lay the foundation for long-term business value. Furthermore, the same infrastructure that is recommended in the Blueprint for data sharing and external collaborative business processes also is applicable to many internal processes, so that companies can begin capturing value from these investments now.

The remainder of this paper is organized as follows:

- A brief introduction to some relevant background topics, as well as a summary of the major concepts of the Blueprint.
- A review of short- and long-term business improvement opportunities that can be gained by leveraging EPCIS.

¹ Reference to *Rules of Engagement: A Qualitative Business Case for Data Management & Sharing in the Pharmaceutical Supply Chain* and *Rules of Engagement: Phase II • The Blueprint for Data Management & Data Sharing*

- A closer look at SAP’s serialization architecture, and how it can be used to support data management and data sharing as outlined in the Center for Healthcare Supply Chain Research’s Blueprint.

Background

Blueprint Briefing

The Center for Healthcare Supply Chain Research began an industry initiative in 2005 to address the issue of managing and sharing data across the healthcare supply chain.

After an initial Phase I², which indicated a baseline consensus for the need and value of product data sharing, a comprehensive Phase II study was undertaken³, executed by Forrester Research. Phase II surveyed 90 organizations across all sectors of the healthcare supply chain. Based on these survey results, a Blueprint was recommended to guide healthcare companies through the efforts to achieve the objectives of enhanced patient safety and increased business value.

The Blueprint provides a three-level “Roadmap.” Figure 1 explains how each level adds incremental business value, and provides an example-use case.

Figure 1: Incremental Value Realized by the Phased Approach

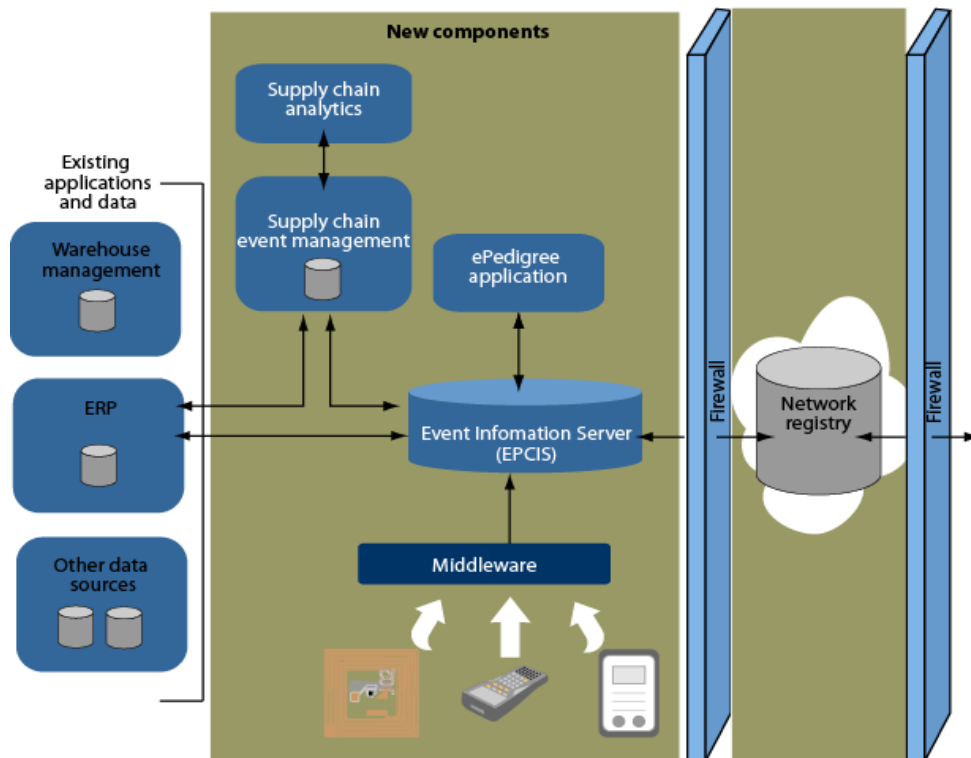
Phase of adoption	Incremental value	Example use case
Level 1 Pedigree compliance through a direct-connect model.	<ul style="list-style-type: none"> • The combination of “push” and “pull” or “on-demand” data flows ensures compliance. • Businesses can move to a purely on-demand data flow, should future regulations permit. 	A manufacturer can produce electronic pedigree information and push them to downstream supply chain partners. In addition, distributors will be able to review pedigree information on receipt to ensure its authenticity.
Level 2 Extend the direct-connect model for on-demand event visibility.	<ul style="list-style-type: none"> • Build on the basics of compliance to achieve visibility to supply chain events. • Use more on-demand data sharing. • Expose process inefficiencies and transform them into operational gains. 	Visibility to supply chain events or condition checks like temperature and location are the key capabilities that turn basic event information into meaningful insight. The collaboration between retailers and manufacturers can also help improve demand forecasts.
Level 3 Add proactive supply chain intelligence and adopt a network registry.	<ul style="list-style-type: none"> • Move from a reactive to a proactive state of event management. • Incorporate supply chain analytics and intelligence. • Incorporate a network registry to coordinate end-to-end visibility. 	As manufacturers, distributors, and pharmacies gain cross-supply chain visibility, they will have a much better understanding of their points of vulnerability and be equipped with the information required to close those gaps.

² Reference to *Rules of Engagement: A Qualitative Business Case for Data Management & Sharing in the Pharmaceutical Supply Chain*

³ Reference to and *Rules of Engagement: Phase II • The Blueprint for Data Management & Data Sharing*

The Phase II study also included a recommended architecture for the Blueprint, shown in Figure 2.

Figure 2: Level 1 Recommended Architecture



A key component of this architecture is the Event Information Server, which is based on the EPCIS standard.

EPCIS

The EPCIS standard⁴ from EPCglobal was ratified in April 2007. EPCIS describes a data model and a reference architecture for capturing and sharing information about serialized objects (products, assets, documents identified with unique serial numbers) and their associated events. The standard is a cross-industry framework, suitable to a broad set of applications requiring supply chain visibility.

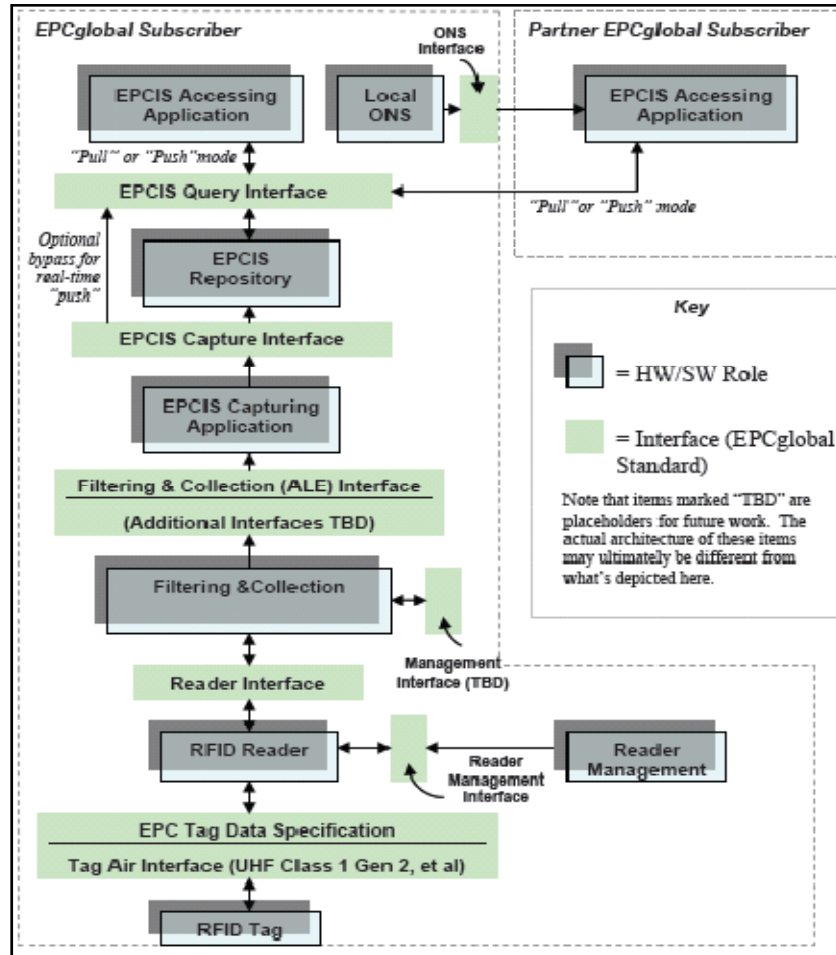
⁴ Reference URL for EPCIS standard and FAQ

The EPCglobal reference architecture⁵, shown in Figure 3, is the cornerstone for the Center for Healthcare Supply Chain Research's Blueprint. The EPCIS architecture consists of the following major elements:

- A set of devices deployed in manufacturing plants and distribution centers that read or write serial numbers (RFID and/or barcode), which connect through standardized interfaces to a "Filtering and Collection" system (often called "Middleware")
- An EPCIS Capturing Application, which interacts with the middleware, executes the relevant business process (packaging, shipping, receiving, kitting, repackaging, etc.), and sends information about the EPCIS events to the repository
- The EPCIS Repository itself, which stores object and event information and provides standard interfaces for capturing and querying events. This is the basis for data management and data sharing within and between companies.
- A set of EPCIS Accessing Applications, which query the EPCIS Repository and uses the information for collaborative business purposes.

⁵ URL for EPCglobal architectural framework

Figure 3: EPCglobal Architectural Framework



This EPCIS framework assumes the concept of serialization such that each item/case/pallet is identified by a unique serial number according to a standard format, which is referenced in data sharing documents, such as the Advanced Shipping Notice (ASN) and electronic pedigree (e-pedigree).

Within the EPCIS Architecture, the EPCIS Capturing Application is a critical component responsible for executing the business processes to manage serialization.

Serialization

Serialization is a required element for many patient safety initiatives, including the current California pedigree requirements, as well as other state and international requirements. Serialization offers a way to individually identify products with certainty, which provides the foundation for supply chain partners to defend against counterfeiting and diversion.

While the tracking benefits of serialization are intuitive, the implementation of serialization is less straightforward, and has a profound influence on how companies execute their supply chain business processes. There are two main elements:

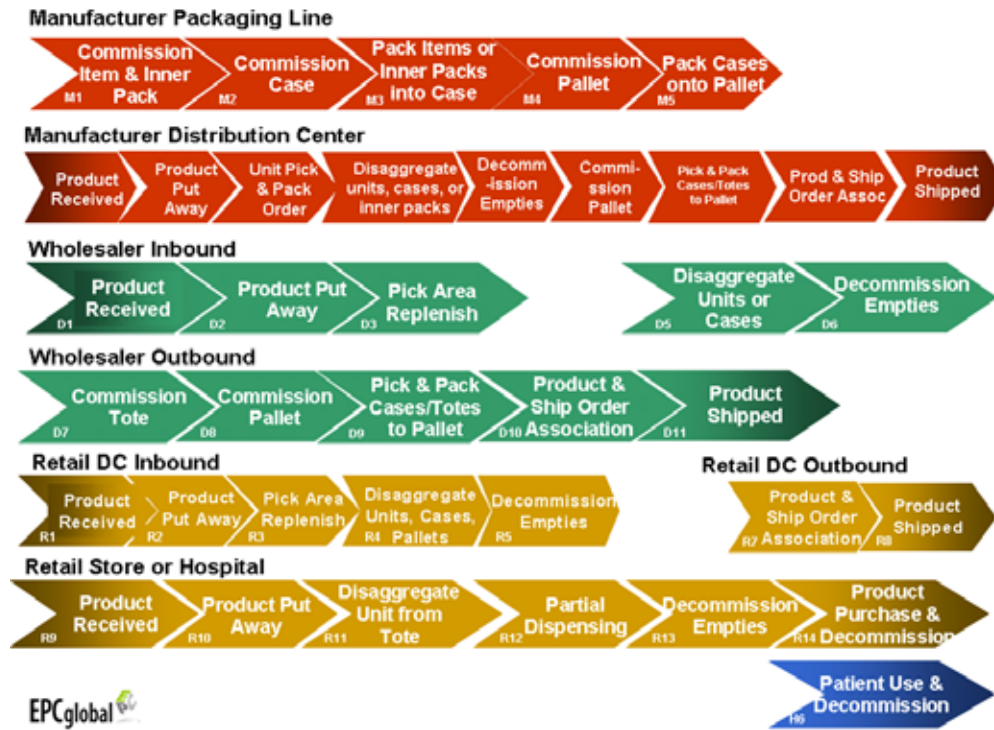
1. **Serial Number Management:** For serialization to work, every number applied to an item, case or pallet be unique. This means that companies applying serial numbers must keep track of what numbers have been already used, and must allocate numbers to various manufacturing plants and distribution centers in non-overlapping number ranges.

A related requirement is that numbers be formatted according to standard formats so that they can be read by trading partners. For the EPCglobal process, the primary formats are Serialized Global Trade Item Number (SGTIN) for items and homogeneous cases, and Serialized Shipping Container Code (SSCC) for mixed cases and pallets.

2. **Business Process Execution:** Manufacturers, distributors, retailers and hospitals that handle serialized product will need to integrate serialization steps into their normal business processes. The list of business process that are impacted by serialization include packaging, receiving, picking/packing/shipping, kitting, repackaging and inventory movements and adjustments (See Figure 4 for the preliminary set of healthcare business processes impacted by serialization, as defined by the EPCglobal Healthcare/Life Sciences workgroup)

Each of these business processes operates today in a non-serialized way; for example, picking and shipping typically are done against an order document. With serialization, there are additional tasks required to capture the serial numbers and make sure that they are aligned and consistent with the orders. For example, additional steps must be taken to check that the count of serial numbers scanned matches the order quantity. In summary, accuracy and granularity must go to a new level. It is not sufficient to have accurate inventory counts. It also is required that each individual item is correctly identified.

Figure 4: Serialization Impact on Healthcare Business Processes



EPCIS Application Support

Information about serialized events is generated by the EPCIS Capturing Application during the execution of the business process, and is stored in an enterprise EPCIS repository. The EPCIS repository then acts as the hub to enable data sharing, and to make key supply chain information available to trading partners under appropriate security and authentication rules. It is these applications that ultimately will deliver the business value and the innovative supply chain capabilities that are envisioned by the Blueprint.

One such application is e-pedigree. While e-pedigree can be supported today via EDI and the Drug Pedigree Message Standard (DPMS, ratified by EPCglobal in January 2007), the data shared using this standard are contained in a format that makes it difficult to use the data for other purposes. For this reason, a GS1 US Healthcare workgroup is defining guidelines that will allow for communicating e-pedigree data via the EPCIS standard. This guideline, expected in late 2008, will be important for the realization of the Blueprint, as it will support companies' ability to leverage e-pedigree investments to further enhance business processes. Once serialized product tracking data are available in EPCIS, market deployment and adoption of these other applications (recall and expiration management, chargeback reconciliation, forecasting and replenishment, asset tracking, clinical trials, cold chain and many more) will accelerate.

Short-Term Value Opportunities

EPCIS and serialization will ultimately enable a variety of data sharing applications, but in the interim, they can be used today for internal applications that already generate return on investment. Many companies in healthcare and other industries are deploying serialization projects today. These projects do not depend on setting up a large-scale, collaborative business process with one or more trading partners.

One such opportunity can be realized by leveraging the use of RFID. Although none of the e-pedigree mandates today strictly require RFID and many companies are pursuing compliance based on serialization using various 2-D and linear barcoding formats, RFID should be considered an important productivity driver. The U.S. Food and Drug Administration (FDA) has recommended RFID, and many trading partners in the healthcare supply chain are using it today, although there are still open questions about its use for certain biologic products and challenges about its application where liquids or metals are involved.

RFID does offer direct business productivity benefits, based on two facts:

- RFID tags can be read at a distance, without direct line of sight, meaning that data collection can take place with little or no human intervention; and
- RFID tags can be written to and can carry “user information” in addition to the serial number, which can be useful in certain business processes.

A number of trading partners have implemented serialization using RFID in such a way that they can reduce labor requirements by automating data collection tasks previously requiring barcode scanning and/or data entry at a terminal. These systems have been set up to automatically capture various business transactions in ERP and WMS systems by virtue of an RFID-tagged case or pallet passing through a portal, which would have previously been captured manually. Such automated business processes speed up overall supply chain velocity, and improve data accuracy.

A second class of opportunities has to do with improved statistical analysis for process improvement based on the tracking and measurement of serialized objects. It is a fundamental tenet of “lean” supply chain operations that process measurements can support analyses that will drive process improvements, and when serialized objects are tracked, outliers can be specifically identified, and the causes of unacceptable variances can be traced back to the source. For example, one company has used serialized product tracking to identify products in a warehouse that were not shipped according to strict “First Expire, First Out” sequence. By identifying the serial numbers involved, the company was able to determine exactly what happened, and correct a flaw in their business process.

A third class of opportunities involves the internal tracking and tracing of assets, product and/or employees. As intermediate materials move from manufacturing to

assembly/packaging, or as controlled substances move from packaging to the vault and then to the shipment dock, companies are finding value in serializing products to capture information on the internal movements. These activities provide full visibility and accountability as to the location and status of the tracked products. With the recurring recalls and emergencies in areas such as food, livestock and pharmaceuticals, upstream (ingredients), internal and downstream tracking are becoming important capabilities, which can be implemented today using serialization and EPCIS.

A related application opportunity that healthcare companies can pursue is counterfeit detection. Companies are applying various overt and covert anti-counterfeiting measures to the packaging of their products. Some of these measures involve matching serial numbers, while other measures involve other technologies such as copy-protection patterns. Company agents in the field, who today must physically send suspicious product back to a lab for assessment, will be able to access various types of online and offline tools to determine product authenticity. One feature of such tools is the ability to upload a picture of the suspicious product to have a server-based algorithm (which may be integrated with an EPCIS) determine if the product is genuine or has been copied.

A fourth class of opportunity is the tracking of returnable assets such as pallets and containers. By serializing and tracking these products, it is possible to keep track of the current location and status of returns. For example, companies can assess whether they have to be cleaned, inspected, repaired; or whether they have been out at a customer site for a prolonged period of time; or whether they should be requested to be returned; or whether an invoice should be sent.

It is a small step from tracking returned goods to tracking additional environmental factors, such as temperature, and thereby improve the cold chain process. These types of applications are also being implemented via an event repository equipped with event management capabilities.

Long-Term Value Opportunities

Once data sharing models are in place between trading partners in the healthcare supply chain, opportunity exists for a wide variety of collaborative applications leveraging EPCIS.

The basic premise of all of these scenarios is extended visibility – i.e., the ability for a company to know the location, quantity, and status of products not only within their four walls, but to have access to similar information in the marketplace, including information about its products in its customers', and even its customers' customers' locations.

Some of the collaborative applications that can be based on EPCIS are described briefly below:

- **Authentication:** This is the ability for any downstream trading partner to perform a query to the manufacturer to check that serial numbers, as well as other information found on product packaging, matches the numbers on the item. Such a check is one way to confirm authenticity and to detect possible criminal activity. This service is already in place using proprietary systems at some pharmaceutical companies, but most trading partners are waiting for the widespread implementation of a standards-based system (EPCIS) before adopting an authentication process. Also, authentication is a growing requirement in Europe, where it is likely to be linked in with national medical reimbursement processes.
- **Visibility Applications:** A number of opportunity areas will arise from the ability of healthcare trading partners to have extended visibility into the supply chain. These opportunities include:
 - *Proof of Delivery* – The ability for companies to exchange serialized receipt confirmations could eliminate the wasted effort and revenue leakage associated with deduction claims based on not having received invoiced product.
 - *Recall and Expiration Management* – There are many opportunities to eliminate waste and improve security through improved recall and expiration management. Companies needing to recall products will be able to precisely identify where the product has been shipped and more specifically target recall notices. They also will be able to recall less than full-batch quantities based on serial numbers. Further, they will be able to verify that the returned/destroyed product is exactly the product that was recalled, and they will be able to credit the correct invoiced price, based on the specific identification of the original shipment and invoice.
 - *Chargeback Reconciliation* – A significant percentage of revenue is lost each year verifying rebate claims⁶ to ensure that the product has not been

⁶ Eric Newmark, IDC, *Revenue Leakage: Plugging The Holes In The Pharmaceutical Channel*, 2006.
3-5% duplicate chargebacks, 15% reverse chargebacks not captured

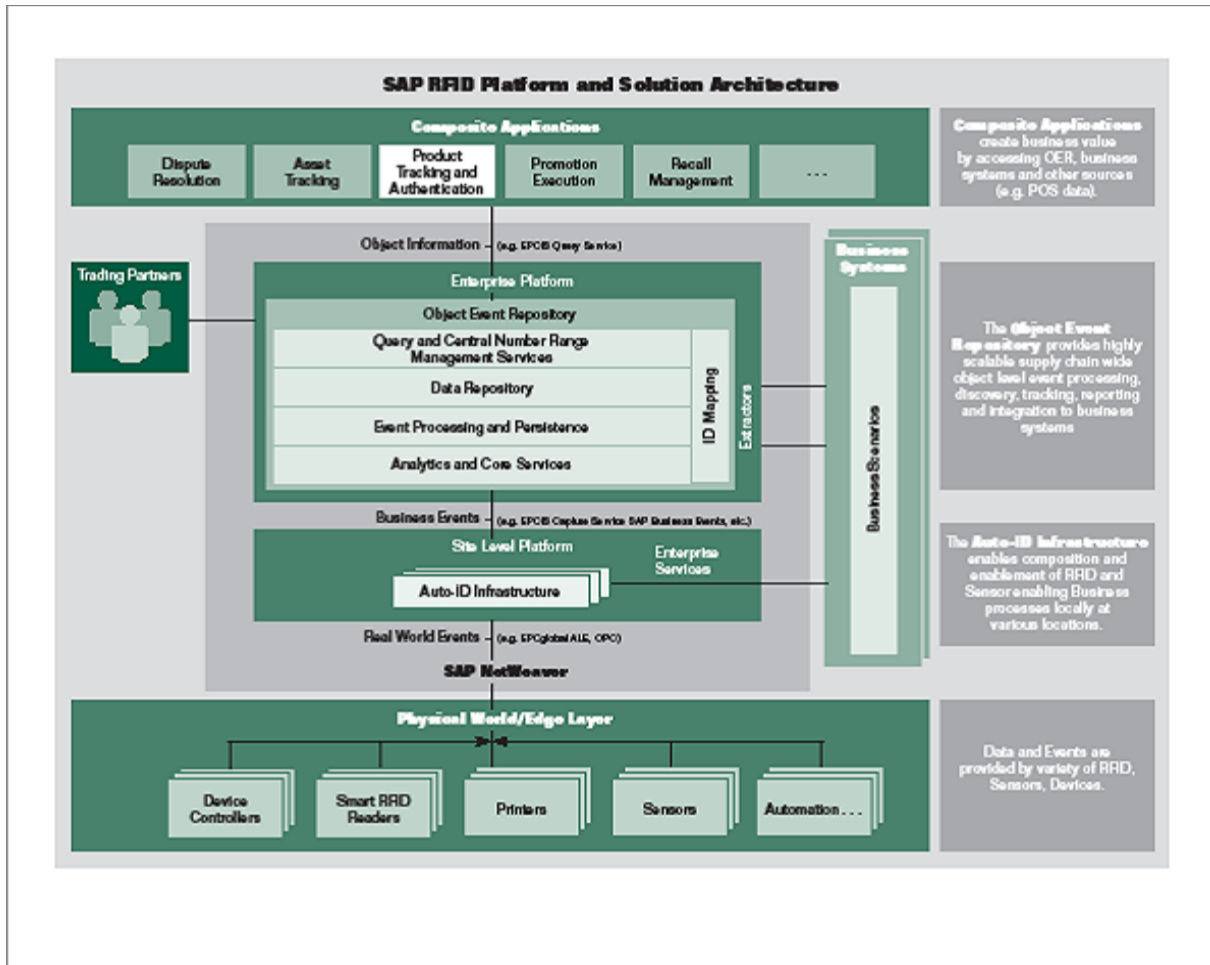
returned and/or reshipped, that the rebate request was not duplicated and that the rebate dollar amount is correct based on the actual invoiced price. All of these checks could be potentially performed by leveraging EPCIS event information about serialized products.

- **Supply Chain Applications:** In addition to leveraging serialization for track-and-trace purposes, there also are many supply chain management opportunities. It is these types of opportunities that the consumer products industry has been pursuing for some time based on EPCIS models. These opportunities include:
 - *New Product Introduction Management* – This is the ability to track and verify that new product has been received by the target retailers ahead of a major product announcement or launch.
 - *Forecasting and Replenishment* – Enhanced visibility in the supply chain has been identified as a major driver of inventory reduction and customer service improvement. Supply chain theory has identified the “bullwhip” effect as the amplified peaks and valleys in inventory that result due to time lags and visibility gaps in the supply chain. Extended visibility from EPCIS observations will enable forecasts and replenishments to be more accurate and timely.

How SAP Enables the Blueprint

The architecture of the SAP solutions for auto-ID and item serialization, available today and shown in Figure 5, maps very well to the Center Blueprint architecture, providing some additional capabilities to support the compliance goals, while enhancing the ability to achieve business value.

Figure 5: Architecture of the SAP Solutions for auto-ID and item serialization



Working from the bottom up, the major elements of the SAP serialization architecture are described below.

Middleware and Device Management

More than 20 of the leading device management and middleware suppliers for the healthcare industry have SAP-certified interfaces between their products and the SAP serialization architecture components.

Auto-ID Infrastructure – the EPCIS Capture Application

Auto-ID Infrastructure, or All, is a rules engine that executes the serialization business processes. It fills the role of the EPCIS Capture Application, as defined in the EPCIS Reference Architecture. The All receives events from the middleware, and based on configurable rules, commissions, aggregates, maintains and translates serial numbers,

performs validations and maintains the relationships between the serialized data and the business data residing in the business applications (whether from SAP or not). The All is delivered with pre-configured business processes, such as in-bound receiving, out-bound shipment, returnable transport items and others.

Object Event Repository

The Object Event Repository (OER) is the enterprise-level serial number repository for serialization data. Together with the Auto-ID Infrastructure, this repository is intended to be the system of record for all enterprise serialized information. It is based on the core requirements specified by EPCglobal, including the EPCIS Capture Interface and the EPCIS Query Interface.

The main elements of the Object Event Repository are:

- Capture and query interfaces based on the EPCglobal EPCIS specification
- Data repository for events, observations, hierarchies and associated business information
- Event Management Engine, which tracks the entire product lifecycle of each serialized object, enabling the configuration of alert notifications if a process does not execute as expected
- Central number range management to distribute valid and unique EPC number ranges to each instance of the Auto-ID Infrastructure, from which they can be distributed down to edge devices
- Analytics, including predefined content, which allows for the tracking and reporting of a range of information derived from serialized events.

Note that two of the key elements called out in Center for Healthcare Supply Chain Research's Blueprint, event management and supply chain analytics are supported as standard elements of the Object Event Repository.

Serialization Applications

At the top of Figure 5 are the set of current and future applications that deliver business value based on the serialized data within the EPCIS. Two of these applications exist today, and many others are under development.

The two applications existing today are e-pedigree, and product tracking and authentication.

E-pedigree: The leading e-pedigree application providers in the healthcare market have partnerships with SAP, and have received SAP certification to interoperate with All and OER.

Product Tracking and Authentication (PTA): This application provides basic track-and-trace capabilities based on the Object Event Repository. This module provides functionality to track events against serialized objects, both internally, and externally. It also offers services to authenticate that serialized product originated from a trusted source and arrived at the intended destination.

Other Business Applications: A critical success factor in making the Blueprint a reality is the integration between the serialization architecture and the back-end business systems, including ERP, supply chain management and other applications. While it is important to have a repository storing the basic data about products, aggregations and events, this information is not sufficient to implement the variety of business applications that drive business benefits. Additional information from the business systems must be accessed in order to execute these processes. For example, many applications have been identified in which the invoiced price of a serialized item must be retrieved from the ERP system to process a return or perform a chargeback calculation. This requires that the serial number be related to a business document (e.g., the order) and then tracked back to find the invoice and the specific price that was charged.

For this reason, the SAP Object Event Repository is not a stand-alone EPCIS, but is designed to integrate with back-end business systems through pre-defined links and through a set of enterprise services that will enable these new applications.

Conclusion

The industry owes thanks to the Center for Healthcare Supply Chain Research for providing a Blueprint that will help meet short-term needs while providing a long-term vision that will provide substantial business value.

The SAP serialization architecture and strategy are in substantial alignment with the Center's Blueprint.

SAP has been working with many customers in all sectors of the healthcare supply chain and has identified some important findings, which have been shared in this paper and are summarized below.

1. Although much of the discussions tend to be about IT and data, many of the challenges associated with serialization and e-pedigree come from changes to current business processes. Companies that currently perform receiving, shipping, packaging, kitting, etc. will have to learn to perform these processes with a much more granular and detailed focus on accuracy than in the past. More time should be dedicated to designing these new processes and there needs to

2. It is important to take pragmatic short-term steps, yet anticipate the long-term value proposition associated with data management and track-and-trace technologies. Specifically:
 - Even if a company starts with e-pedigree, it should anticipate serialization in their process design and interface design (Level 1 of the Center's Blueprint). Some e-pedigree requirements today do not involve serialization, but this will be the major trend going forward.
 - Companies that start with the DPMS document model should anticipate EPCIS to gain the business benefits from supply chain collaboration above and beyond e-pedigree compliance.
 - Companies should look for internal opportunities to capture value from serialization and EPCIS, as opportunities exist today (Level II of the Center's Blueprint).
3. Business data integration is critical. Business value captured from data sharing and internal applications based on EPCIS will deliver value over the long term, but only if EPCIS data are used in the context of other business data. EPCIS repositories that cannot integrate with back-end systems will be challenged to achieve the benefits of visibility and collaboration.