This whitepaper provides an overview of the regulatory landscape and technical IT requirements for serialization. It also covers how to drive value from serialization, details on the SAP® Advanced Track and Trace for Pharmaceuticals application and how to manage a pharma serialization project.

SERIALIZATION OVERVIEW
The pharmaceuticals industry has struggled to ensure the integrity of its products as they are transferred between the different stops on the value chain from contract manufacturers to wholesalers to dispensers and finally to the patient. This is particularly true as products move across international borders. And the problem has been growing. More money is lost to counterfeiting with each passing year. Product theft is also on the rise – Freight Watch International has released statistics suggesting that drugs account for approximately 15% of the estimated US$8 billion to US$12 billion of annual cargo theft, which amounts to well over US$1 billion annually.

Preventing theft and counterfeiting have therefore become a key industry focus. Early approaches included tamper-proof packaging and 3-D holograms, but these are now considered too easy to manipulate, so these methods are no longer considered sufficient. Today, regulations include assigning a unique identification number to the smallest unit of sale (for example, a bottle) and tracking that product
and affiliated serial number all the way through the supply chain so it can be authenticated at any point. These regulations have been in place in markets like Turkey and China for some time, and more recently markets such as India, the United States, and EMEA have added similar laws to require serialization and track and trace solutions over the next several years.

To make matters more complex, global data standards are still evolving in some major markets. We see three major models for serialization and track and trace reporting. These include:

- China Food & Drug Administration (CFDA) serialization requirements, which use government issued serial numbers that are reported back to a central government database
- The EU’s European Stakeholder Model, which is based on the European Medicines Verification System (EMVS) where manufacturers upload serialized information to a central institutional hub for verification
- The U.S. model which requires lot traceability shared with each member of the value chain in 2015, individual saleable package serialization by 2017 and verification at the point of dispensing by 2023
- Indeed, within the next three to five years, we anticipate that at least 65% of the global market (by value, as of 2014 revenue data) will require serialization in the supply chain

**BUSINESS CHALLENGES OF REGULATION MANDATES**

Serialization regulations will of course go a long way toward protecting patients from dangerous counterfeit drugs, and life sciences companies from lost revenues and potentially brand disrupting recalls. However, achieving compliance does not come without its own set of business challenges for those in the life sciences value chain.

First, pharmaceutical manufacturing companies have spent the last decade or more investing millions to implement and fine-tune their typically deep, complex, and validated supply chains. Compliance with the new regulations now requires them to make large investments in serialization technologies while also potentially making significant business process changes - they will have to change everything they do today to manage finished goods. This comes at a time when pharmaceutical manufacturers are facing increasing pricing and margin pressures.

Significant investments will be required, for example, to make packaging lines capable of managing serialization. We have seen estimates anywhere from $250,000 to $1,000,000 per line depending on the complexity and level of pre-existing automation such as auto bundlers and palletizers. These lines will experience downtime while changes to buildings and packaging lines are made. Warehouse management processes will also change significantly with aggregation as the mandate requires an integrated application to handle both serialized and non-serialized items together in the same transaction. Second, many pharmaceutical companies leverage contract manufacturers (CMOs) to manage capacity. However, given the large investments required, some CMOs might not be ready and this could require the Marketing Authorization Holder (MAH) to switch CMOs to meet demand and avoid revenue loss or make significant capital investments to upgrade the CMO’s packaging lines.

Third, serialization will generate massive amounts of data for global companies that will need to be retained for many years to meet compliance requirements. This serialized information will need to be readily accessible and highly responsive to support business processes that require sub-second authentication, and to provide easy access for regulatory compliance, including investigations and statutory reporting. We believe serialized data will also provide a rich repository of information for business value and insight, not only in terms of supply chain integrity but also for improving responsiveness, insight and financial transparency in areas such as contracts and chargebacks. (This will be highlighted later in this paper.)

Finally, we see pharmaceutical supply chains and distribution channels becoming increasingly
complex. Creating a global, scalable serialization architecture to manage a complete end-to-end business process is critical. The solution must be deployed rapidly, must be scaled quickly, and must manage the exchange of serialized information across your supply chain with no disruptions in day-to-day business activities.

**DRIVING BUSINESS VALUE FROM SERIALIZATION**

Despite these challenges, we believe there is significant business value in supply chain data beyond compliance now that serialized product data is becoming pervasive in global markets. Areas of value include better patient care, inventory visibility, the ability to identify diversions in the supply chain, and improved business processes in areas such as: reverse logistics, returns processing, product recall, product authentication, and brand protection.

Cognizant and SAP have been working with the pharmaceutical industry to explore and define additional dimensions for creating business value and increased returns on investment (ROI) from their serialization compliance-related investments. Serialization compliance infrastructure provides two primary capabilities in terms of supply chain and consumption visibility, which can be leveraged for additional use cases and value drivers as shown in the figure below:

In addition, based on their experience from other customers and on other benchmarks, Cognizant

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**How Serialization and Track and Trace Can Drive Business Value**

- Optimizing recalls and returns
- Inventory optimization
- Supply chain operations monitoring
- Addressing illegal diversions
- Sales and marketing effectiveness
- Patient-centric engagements
- Demand forecast improvement
- Brand loyalty
- Supply chain visibility
- Consumption visibility
- Serialization and track and trace infrastructure
and SAP anticipate that companies can look to the following key performance indicators (KPIs) and improvement ranges to build their own business cases:

**TOTAL COST OF COMPLIANCE**

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<th>Category</th>
<th>Value Lever</th>
<th>Typical Range</th>
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<tr>
<td>Revenue</td>
<td>• Increased revenue</td>
<td>0.2%-0.3%</td>
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<tr>
<td></td>
<td>• Reduced stock outs</td>
<td>3%-5%</td>
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<tr>
<td></td>
<td>• Eliminate duplicate chargebacks</td>
<td>20%-40%</td>
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<td></td>
<td>• Reduction in lost sales due to more precise recall management</td>
<td>5%-7%</td>
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<tr>
<td>Increased capital efficiency</td>
<td>• Reduced days in inventory</td>
<td>1%-3%</td>
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<tr>
<td></td>
<td>• Reduced days sales outstanding (DSO)</td>
<td>1%-2%</td>
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<tr>
<td>Cost reduction</td>
<td>• Reduced overall supply chain planning (% of rev)</td>
<td>2%-4%</td>
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<tr>
<td></td>
<td>• Reduced inventory carrying costs</td>
<td>1%-3%</td>
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<tr>
<td></td>
<td>• Reduced inventory obsolescence</td>
<td>1%-2%</td>
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From a budgetary standpoint, manufacturers need to look at shop floor systems and the associated engineering driven investments in packaging lines as well as the larger supply chain ecosystem such as warehouse edge systems. Enterprises must factor in project cost elements such as software licensing, maintenance, support and project implementation. Significant investments are also required in internal resources because serialization touches a significant part of the order-to-cash business process within the typical pharmaceutical company. Our experience is that engineering and implementation are major cost drivers in serialization projects. Selecting the right implementation partner is just as important as selecting the right serialization software.

Thus, costs related to serialization upgrades cannot easily be called out in isolation. Additionally, serialization devices should ideally be integrated with manufacturing lines in order to be fully aligned with overall product and production segmentation strategies with an ongoing focus on global requirements of the evolving serialization regulatory requirements.

However, at the corporate level, a business case that focuses on cost and value across a common companywide solution should be defined. This is preferable to a patchwork of local manufacturing and warehouse solutions that comply only with specific regulations and that are likely to involve a more complicated deployment and higher operating costs. Significant risk mitigation and lower overall total cost of ownership can be obtained with a single integrated solution.

**UNRAVELLING THE TECHNOLOGY LANDSCAPE**

As the life science industry undergoes a massive transformation to outcome based healthcare,
enterprises are increasingly evaluating the cost, complexity, and performance of their IT solutions. Today, companies have a number of options when it comes to deployment of new solutions and capabilities. These options include cloud or on-premise software, global or regional deployments, centralized or distributed systems, and in-memory or relational databases. As the number of regulations has increased, implementing a point solution for each regulatory mandate is not a sustainable strategy in terms of compliance or cost. An evaluation of the current state of serialization regulations indicates that between 15% and 20% of pharma stock keeping units (SKUs) are serialized today, but in several years’ time more than 65% of the world’s pharmaceutical products will contain a unique serial number. This explosion in data is expected to have a significant impact on the pharmaceutical technology landscape.

This growth in serialization volume, the interest in insight and business value to be gained by tracking unique serialized events, and the number of unique regulatory requirements will create an interesting and challenging landscape for the pharmaceutical industry over the next three to five years.

Supply chain, manufacturing, and IT executives need to consider the following factors:

- Complex serialization regulatory requirements and deadlines for global supply chains to report to regulatory authorities
- Significant project activities from enterprise systems to plant level systems to support serialization
- Increasing complexity in packaging facilities and warehouses operations and an accelerating number of SKUs driven by serialization
- Increased collaboration between all members of the pharmaceutical value chain
- Increased regulatory scrutiny in the area of serialization

While implementing separate track and trace systems at each packaging facility or even in each region is feasible, most companies are concerned about the inefficiencies of a federated serialization application landscape. Topics of concern include future compliance in a global supply chain, business process efficiency of cross system shipments, and total cost of ownership.

These concerns are similar to other well understood IT harmonization initiatives that companies have undertaken in the past to optimize business processes and reduce costly business process variations. In our experience, serialization solutions should - beyond the compliance aspects - be designed with a global perspective to achieve regulatory compliance and business process efficiency.

The real question, therefore, is whether there is a software platform available in the market today that provides the necessary functionality to simultaneously address the differing regional serialization requirements, while also being flexible enough to accommodate future changes required to stay in compliance with the evolving regulatory requirements and timelines. Similar to the tight coupling that is required across the supply chain landscape, the chosen software solution must have the flexibility, reach, and optimized landscape to meet these evolving and complex regulatory challenges - and this involves the ERP, middleware and manufacturing line systems, as well as warehouse management (WM), extended warehouse management (EWM) and serialization software. There is an increasing need to formulate a robust solution that addresses enterprise-wide requirements, including mobile access of serialization data from authorized sources.

Pharma companies need to start planning and implementing their serialization and track and trace initiatives now. The U.S. and EU regulations will require serialization starting in November 2017 through 2018 and these markets constitute almost 65% of the world’s pharmaceutical volume. Although many companies have experience in some markets, such as Turkey, where serialization regulations are already required, the relative size of the U.S. and EU markets, and the complex global supply chains that serve them, will likely present significant
design challenges.

It is our experience that it is often too risky and time consuming to implement solutions of this nature in a “big bang” approach. Therefore, the choice of technology implementation partners needs to be made after taking into consideration the ability of such integration partners to support phased implementations of serialization projects across global dispersed inhouse packaging facilities and CMOs. Importantly, the solution should also support migration of serialization data events with archival capabilities, and the ability to manage billions of serialized events in a responsive and scalable data repository with responsiveness for point-of-distribution authentication in the near future. Finally, any such solution must take into account and support global and regional data standards and specifications while simultaneously supporting a wide range of data carriers ultimately converging onto the GS1 2D barcode.

**MOVING TOWARDS THE RIGHT SOLUTION**

Enterprises are looking to identify a robust, all inclusive solution that can help address enterprise wide needs for a serialization solution that reduces overall risks, timeline, and costs versus a more expensive and risky hybrid approach. In this regard, SAP’s co-innovation efforts have led to a new solution that fulfills all of the known - current and upcoming - global regulatory requirements for track and trace in the pharmaceutical supply chain while also effectively addressing most if not all of the challenges highlighted so far in this paper. The name of SAP’s new application is SAP® Advanced Track and Trace for Pharmaceuticals.

SAP Advanced Track and Trace for...
Pharmaceuticals was developed in a co-innovation model with SAP customers, and the software was released to the market on September 15, 2015. The co-innovation group includes 13 global companies, including 9 of the top 20 pharma Marketing Authorization Holders (MAH) and one of the three large U.S. wholesalers. The co-innovation group is a sub-set of SAP’s serialization round table, a consortium of more than 40 pharma companies, with 14 of the top 20 pharma companies participating.

FULLY INTEGRATED ADVANCED TRACK AND TRACE SOLUTION FROM SAP

SAP’s product offering is specifically designed to enable compliance with global regulatory mandates requiring serialization of pharmaceutical products. The application can be scaled to address the massive volumes of data that will be generated from unit level serialization, while also providing comprehensive “out-of-the-box” country reporting to global agencies, and seamlessly integrating contract manufacturers and packagers into the end-to-end process with flexible and easily configured interfaces built around a robust business rules framework.

The application supports the generation and management of serial numbers, master data integration with SAP ERP and non-SAP ERP systems, integration with warehouse management systems, integration with packaging lines for serial number provisioning and the transmission of commissioned serial numbers into a central EPCIS repository, as well as integration with CMOs, third-party logistics providers (3PLs) or other external parties. The solution is designed to support MAHs as well as CMOs or mixed setups where a company executes both roles. Integration is facilitated by the embedded SAP Application Interface Framework tool, which supports message monitoring. A restricted license of SAP Application Interface Framework for use with SAP Advanced Track and Trace for Pharmaceuticals is included in its license.

‘Volume’, ‘speed’, and ‘flexibility’ are the three underlying design principles on which the application has been developed. In terms of volume and speed, the entire application has been designed to manage the anticipated volumes of serialized data and events while providing a responsive performance for both user activities and automated backend processes such as data transfer from packaging lines or regulatory reporting to authorities or supply chain partners. The application is targeted at customers that handle between 1 million and 10 billion serialized items a year. It provides for maximum flexibility and is ERP and warehouse management system agnostic. Imagine a repository that needs to store billions of records and additionally requires analytics on top of those billions of records. It becomes a prerequisite for the repository to handle large data volumes without impacting overall performance or responsiveness. On the other hand this repository is most likely not going to be loaded on day one with such large data volumes. They will more likely grow over a period of time and hence the repository should be capable of running in traditional relational databases to begin with and should then slowly evolve to an in-memory database as required. SAP Advanced Track and Trace for Pharmaceuticals perfectly meets such contrasting requirements as it runs both in traditional databases and in-memory databases such as SAP HANA® for which it is optimized.

It additionally supports the creation of ad-hoc reports to meet evolving business and regulatory requirements that can be easily accessed by any authorized stakeholder via browsers. It also has enhanced features to update child objects based on the parent object updates, and such events are stored against individual objects. With this version of SAP Advanced Track and Trace for Pharmaceuticals, SAP has also expanded the features to support objects such as LGTINs (Lot GTIN’s for batches).

With the evolving nature of serialization mandates across the globe, it will be critical to choose an enterprise software partner that is actively participating in such global discussions and workshops and staying abreast with all of
the latest updates coming from these global markets. SAP has committed to support any upcoming legislation and is also investing in the development of evolving regulations such as EU regulations where it is spearheading such developments. Thus SAP Advanced Track and Trace for Pharmaceuticals not only supports existing mandates but continues to develop content for every country where regulations are evolving and changing.

Given that pharmaceutical package serialization will generate billions of data events, good archiving processes are an important prerequisite for the enterprise product. SAP Advanced Track and Trace for Pharmaceuticals has proven archiving concepts included as part of its core feature set whereby high volume transactions related to objects, events, serial numbers, etc., can be archived with minimal effort. For future releases, SAP is committed to continuing to work with its co innovation and roundtable customers to meet evolving regulatory and business requirements, thus making an investment in the SAP Advanced Track and Trace for Pharmaceuticals a good long term decision from a customer standpoint.

Additional features support master data management as well as ERP integration for master data and transactional data. All components are tightly integrated and explicitly designed to handle the large data volumes expected to arise in the pharma track and trace processes. The application can be used by MAHs as well as CMOs and also in a mixed mode where a company executes both roles. The setup is identical, which makes it easy to maintain.

STRATEGIC QUESTIONS FOR AN ENTERPRISE PREPARING FOR A SERIALIZATION AND TRACK AND TRACE INITIATIVE

### MIGRATION PLANNING

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<td>When should you migrate to SAP Advanced Track and Trace for Pharmaceuticals?</td>
<td>• Ideally you should plan to migrate prior to initiating serialization for EU and U.S. regulations because these markets are expected to generate significant data volumes that your current solution may not be able to cope with. Additionally by migrating early you avoid the incremental costs and overhead associated with a large data migration effort and you also preempt the risk of not finding experienced deployment partners at the last minute.</td>
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| How do you simultaneously tackle the evolving global regulations? How do you follow up with the necessary continuous enhancements of your software versions? | • Staying connected with peers, industry groups, and experienced systems integrators such as Cognizant will help ensure that you are not blindsided by the rapidly evolving global regulations.  
  • SAP’s serialization roundtable is one such forum that has been around for over eight years now, and it has proved effective in aligning on existing and upcoming legislation among the pharma community.  
  • The EPCIS repository embedded in SAP Advanced Track and Trace for Pharmaceuticals is flexible enough and extensible enough to be able to handle any upcoming requirement. Additionally, the SAP Advanced Track and Trace for Pharmaceuticals product release roadmap will deliver country packages for upcoming regulations that will address the decoding/encoding of barcodes (in case barcodes deviate from standard GS1) as well as the required regulatory reporting rules and message mappings. |
| What is the approximate duration required for the implementation of these regulations? Are there key learnings derived from similar implementations that could be leveraged? | • Working backwards from the start date for the regulation, check whether the legislation mandates that you ‘cannot ship’ or ‘cannot produce’ any non-serialized items. In the event that you cannot ship anymore non-serialized product, you need to factor in the time it takes to sell the last non-serialized batch.  
  • In order to give yourself some room for project delays, your planned go-live date should be at least three months prior to that date.  
  • Depending on the complexity of the regulations and the size of the market, implementations can take anywhere from a few months to a year assuming that the packaging lines are already capable of serialization (and aggregation where necessary). |
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| What if you already have existing products such as SAP Auto-ID Infrastructure (SAP AII), SAP object event repository (SAP OER), TraceLink, or Axway deployed? Can existing configuration/data from other SAP or non-SAP serialization repositories be easily migrated to SAP Advanced Track and Trace for Pharmaceuticals? | • Yes, there are many different ways to do this. You can either adopt a big bang or step-by-step strategy. Your approach depends very much on your unique setup.  
• You could even consider starting with a limited deployment of SAP Advanced Track and Trace for Pharmaceuticals (for example, for serial number management), then replace SAP object event repository with SAP Advanced Track and Trace for Pharmaceuticals next to take advantage of the pre-defined regulatory reporting before moving to a full SAP Advanced Track and Trace for Pharmaceuticals setup.  
• SAP offers many different built-in tools to assist with migration of historical data from legacy systems.                                                                                                                                 |
| What are the considerations to be taken into account while considering migration of existing configuration/data to SAP Advanced Track and Trace for Pharmaceuticals? | • Planning a migration is a complex task that needs to take into account all of the factors listed below that could be unique to your situation. We strongly recommend leveraging an experienced systems integrator such as Cognizant to advise you during the planning and readiness phase.  
• Look at the timing of upcoming legislation and already planned projects or project steps.  
• Have you already planned sub-projects?  
• Are you currently outsourcing certain country requirements and want to bring those back into your standard solution? When do you need to perform that step?  
• Are those projects still relevant should you decide to move to SAP Advanced Track and Trace for Pharmaceuticals?  
• Can these projects be postponed until SAP Advanced Track and Trace for Pharmaceuticals is in place?  
• Are you already live on an existing solution or are you still in the midst of implementing? Or will SAP Advanced Track and Trace for Pharmaceuticals be the first track and trace solution you will be implementing?  
• How many plants/packaging lines are already connected to an existing solution compared with those that are not yet connected?  
• Did you standardize on your packaging line providers and line/site servers?  
• Did you standardize on your warehouse management systems and processes? Are you running SAP or non-SAP warehouse management software?                                                                                                                                 |
| What is the effort involved and how much re-work will need to be done?  | • Moving to SAP Advanced Track and Trace for Pharmaceuticals is not just an upgrade, it is a new implementation but SAP offers migration tools that help migrate data from SAP OER to SAP Advanced Track and Trace for Pharmaceuticals.                                                                                                                                                                                                  |
| Should you allow SAP Advanced Track and Trace for Pharmaceuticals release 1.0 to stabilize before you deploy it or can it already be considered stable enough? | • SAP Advanced Track and Trace for Pharmaceuticals was designed in close co-operation with co-innovation customers. These co-innovation customers also executed a test week during which 30 participants from the co-innovation customers tested the solution for an entire week across all required business scenarios.  
• SAP already has extensive experience on serialization solutions over the last decade with its SAP AII and SAP OER solutions, and it has successfully leveraged this experience into the new SAP Advanced Track and Trace for Pharmaceuticals application.  
• All early projects will be safeguarded by SAP. What this means is that SAP will establish a steering committee as well as a dedicated development contact that can be easily reached in case of problems or questions from the project team.  
• Implementation, or the transition roadmap also depends on the level of standardization at the packaging line level. If you have one packaging line provider with a capable line server and dedicated site serialization servers, it is probably easier and less risky to connect to SAP Advanced Track and Trace for Pharmaceuticals in a short timeframe.  
• SAP is investing heavily in training its partners, such as Cognizant, to be fully ready to support your implementation projects from day one.                                                                                                                                 |
### PACKAGING INTEGRATION

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<td>How should you prepare for the standard interface to securPharm/EU-Hub (functional tests are already successfully done)?</td>
<td>The EU currently executes tests through a Web UI. It has published some simple interface specs and SAP has access to those. The pre-defined interfaces to the European hub for SAP Advanced Track and Trace for Pharmaceuticals will be included with a future version that is currently planned for release in 2016.</td>
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| If you are a pharma manufacturer or a CMO, how should you prepare for unit level serialization and aggregation? | With US regulations for unit level serialization and aggregation around the corner we strongly recommend that you initiate work immediately on packaging line enhancements such as installing printers that are capable of printing variable data at high speed plus scanners to verify the print.  
• Plan for these installations and any associated line downtime and do estimate and take into account lower initial OEE.  
• Work on aggregation stations in parallel to serializing your lines.  
• Check the serialization preparations of your customers (if you are a CMO) and of your CMOs and 3PLs.  
• Do not delay this step as we expect significant lead time for procuring line level serialization equipment as the U.S. deadline nears.  
• We also expect availability of trained resources to assist with installation of the equipment and associated line/site level serialization software to become more limited in the future.  
• In anticipation of this last minute rush to comply, Cognizant has built up a robust serialization practice with a large contingent of experienced serialization subject matter experts that can assist with line level serialization upgrades, site level serialization system deployments, and all of the systems integration between line, site, and enterprise level systems. |
| What interface concepts are in place to integrate different manufacturing execution systems (MES) or even packaging lines directly at small subsidiaries? | • SAP Advanced Track and Trace for Pharmaceuticals requires an underlying system, be it an MES or a line/site server that is capable of managing raw serial numbers as well as commissioned data.  
• Such an underlying system should be able to request, receive, and store raw serial numbers and hand them over to printers or other underlying systems. The system should be able to automatically request more numbers (or ranges) once it is close to running out of numbers.  
• It should also be able to collect data from scanners and send larger packages of commissioned data to SAP Advanced Track and Trace for Pharmaceuticals.  
• This underlying system should be able to manage incomplete transmission, connectivity interruptions and so on. This could optionally also be done using appropriate middleware solutions. |

### WAREHOUSING INTEGRATION

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| How well does SAP Advanced Track and Trace for Pharmaceuticals integrate with SAP warehouse management (WM) and extended warehouse management (EWM) systems? Will SAP Advanced Track and Trace for Pharmaceuticals integrate with non-SAP warehouse management systems? | • SAP Advanced Track and Trace for Pharmaceuticals includes a WM toolbox that allows you to plug pre-delivered ERP business functions into your existing WM or IM processes. Core ERP functions connect to SAP Advanced Track and Trace for Pharmaceuticals services through OData. Additionally, the product roadmap for SAP Advanced Track and Trace for Pharmaceuticals includes plans for a similar toolbox for EWM as part of the next release.  
• The built-in OData services in SAP Advanced Track and Trace for Pharmaceuticals can also be utilized for integrating with non-SAP WM systems, but bespoke interfaces will need to be implemented as part of your deployment project. |

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### Question and Answer

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| What are the implications for bar-code scanners and other edge systems such as pick-to-light in the warehouse? Do they need to talk directly to SAP Advanced Track and Trace for Pharmaceuticals or should they transact everything through the WMS? | • None. Basically you run the same processes, maybe modified to fit the nature of serialized products and just execute another posting from the RF screen. In the past you posted into a WM transaction now you post an additional EPCIS message to SAP Advanced Track and Trace for Pharmaceuticals. The ERP function modules contained in the WM integration include a toolbox (versus out-of-the-box solution) support highly configured WM-implementations as well as non-SAP warehouse management solutions and customer-specific processes.  
• Depending on the size/volumes and level of automation in your warehouse, we recommend considering a site level serialization solution as an intermediate layer between your edge systems (for example, barcode scanners, auto picking systems) and your enterprise level serialization solution (for example, SAP Advanced Track and Trace for Pharmaceuticals).  
• In order to avoid double scanning, we believe that you should plug-in the included SAP function modules into your existing (or maybe even slightly modified) WM transactions. Automated picking systems such as pick-to-light and pick-to-voice will most likely require an additional scan to record the serial numbers of the items/cases being picked. |

### Architecture

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| Should you setup only one centralized enterprise level instance or should you also plan for regional local instances of SAP Advanced Track and Trace for Pharmaceuticals? What are the pros/cons and how would you go about architecting such a decision? | • SAP Advanced Track and Trace for Pharmaceuticals is capable of handling worldwide operations in one instance but also supports a two-tier approach out-of-the-box. This includes the distribution of master data and serial numbers as well as the collection of commissioned data in a central place.  
• While a two-tier approach can ease the dependency on global downtimes and may provide a slight performance improvement, central deployment will ease on-going operational support and maintenance. |
| What are the implications if you are not yet on SAP HANA but are considering going to SAP HANA? Should you deploy SAP Advanced Track and Trace for Pharmaceuticals on SAP HANA now or wait until your ERP instance is on SAP S/4HANA? | • The choice to move SAP Advanced Track and Trace for Pharmaceuticals to SAP HANA depends more on your data volumes than on the systems you plan to integrate with. It doesn’t really matter whether your ERP is on SAP HANA or whether you run SAP S/4HANA. It’s more a question of volumes (beyond 1 billion items per year we strongly recommend that you at least consider SAP HANA) as well as your SAP HANA maturity level (do you already have significant experience supporting a SAP HANA instance)? |
| What master data harmonization considerations and pre-work should be taken into account? | • GTINs must be 100% accurate because the entire GSI system is based on them and other key master data elements such as Good Clinical Practices (company prefixes) and Global Location Numbers (locations).  
• SAP Advanced Track and Trace for Pharmaceuticals provides master data integration for materials (trade items), customers, vendors, and locations. |
LOOKING AHEAD BEYOND COMPLIANCE

As enterprises implement their serialization solutions, they will gain real-time visibility into all of their serialized products moving across the value chain every day and at every moment of the day. For example, this fully integrated “best-in-class” track and trace solution from SAP will provide the pharmaceutical industry with serialized inventory data to validate claims from the wholesaler as part of its complicated sales contract processes. This will, in turn, help curb counterfeit and parallel trading that has become a global threat to brand protection. The data will help unlock tremendous opportunities to not only protect patients and their brand but also to generate tremendous value for organizations.

FEATURED SPEAKERS

Pari Sanghavi, Global Practice Head - Supply Chain & Manufacturing, Cognizant Life Sciences

Pari Sanghavi heads up the Supply Chain & Manufacturing practice for the Life Sciences industry vertical which focuses on deploying key emerging technologies and building platforms for the Digital Supply Chain, Internet of Things, Pharmaceutical Serialization & Track/Trace, and other key Supply Chain & Manufacturing capabilities for Pharmaceutical, BioTech, and Medical Devices Companies. He has 20+ years of experience both consulting and working in the industry in various roles including leading a global SAP ERP deployment, successfully completing several acquisitions and divestitures, and heading up an Enterprise Mobility CoE, amongst others.

Jack Schmidt, Life Sciences Industry Director, SAP

Jack has over 25 years in the Life Science Industry working in the Pharmaceutical, BioTech and Medical Device Industries. He started my career at Johnson and Johnson in operations management and took on progressively more responsibility in supply chain and operations management. At SAP, he is responsible for identifying emerging industry trends and guiding SAP solution investments in these innovation areas. This includes automating & extending enterprise business processes through new capabilities such Pharma Supply Chain serialization, Patient Engagement solutions and Predictive Analytics for actionable insight.

Dr. Oliver Nurnberg, Product Owner, SAP Life Sciences

Oliver has over 18 years’ experience at SAP. In his current role as Product Owner SAP Life Science Industry Oliver manages the SAP Portfolio for the Life Sciences industry which covers Pharmaceuticals, Biotechnology and Medical Devices. He has deep experience with the “Track & Trace for Pharmaceuticals” and the “Pharma Network” solutions having played a key leadership role in bringing these products to market with SAP’s development team. He has also worked extensively in supporting Go To Market activities through AE and Partner education and enablement.

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