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Checklist:

What Pharmaceutical Companies Should Look for in a Serialization Provider

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The Drug Supply Chain Security Act (DSCSA) offers a unified federal approach to implementing unique identifiers at a drug's lowest salable unit, allowing the industry to have visibility into a product's lifecycle as it moves through the supply chain, starting with manufacturers and ending at the dispenser. By utilizing a standardized protocol created by GS1, the industry-standard group, the pharmaceutical industry can communicate information regarding millions of products that flow through the supply chain.

Pharmaceutical manufacturers and product brands have been racing to adopt serialization solutions to ensure efficient product traceability, better monitor their supply chains, reduce product diversion, and ensure DSCSA compliance . These manufacturers and contract manufacturers/ packagers are facing increasing pricing and margin pressures to meet the stringent regulations for implementing serialization and the growth in the number of packaging-related product recalls.

Luckily, there are industry-leading serialization vendors for pharmacuetical companies to partner with for their DSCSA compliance. Read on for a checklist of what pharmaceutical companies should look for in a serialization provider.

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How to Assess Serialization Providers

It is critical to thoroughly assess a potential serialization provider to determine if they have the capacity to support the specific demands of the DSCSA project and if they are a match to company requirements.

Here is a checklist of things to look for when evaluating a potential track and trace solutions provider:

1. Exemplary Customer Support
2. Ability to Scale
3. Nonproprietary Equipment for Plug & Play
4. Single Source Provider
5. In-house Serialization and DSCSA Experience & Expertise
6. High Performance
7. Costs

1. Exemplary Customer Support

Every software deployment sometimes needs support from its vendor and exceptional engineering support is imperative for a complex project such as DSCSA compliance and its government-mandated deadlines.

Specifics to Look For:

✔ **Timely Response to Inquiries**
Go with a partner that will manage all support tickets without delay and one that will cater to your requests. Fast turnaround times on your queries should be encountered throughout your entire project, not just during the initial honeymoon stage with your vendor. Increasingly elongated ETAs to resolve technical issues are a red flag that you are not a priority to your vendor.

✔ **Proactive vs. Reactive**
Seek out a partner that actively works on your behalf with your trading partners and finds issues before they become a problem for you. Likewise, your service provider should catch problems before they enter your network.

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2. Ability to Scale

Pharmaceutical companies are often on the cusp of a significant drug release and are targeting expansion. Therefore, a serialization partner that can sustain growth is an important aspect to consider.

Specifics to Look For:

✔ **Scale as You Grow**
A critical factor in choosing a track and trace provider is that they can scale with you as you grow. You need to be able to add components and change the configuration as you grow and move forward.

✔ **Add and Manage New SKUs**
Look for a solution provider that allows you to seamlessly add and manage new SKUs without the need to modify current workflows in place drastically.

✔ **Future Systems**
The service provider should understand your current systems requirements and be able to anticipate your future needs as you grow.

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3. Nonproprietary Equipment for Plug & Play

A serialization vendor that uses nonproprietary equipment is preferable. This eliminates the need to purchase specific equipment for the project and allows you to utilize existing systems. Plus, integration is always easier with nonproprietary equipment.

Specifics to Look For:

✔ **Uses Nonproprietary equipment**
Seek out a provider that uses off-the-shelf equipment that is nonproprietary to the vendor.

✔ **Industry Standard Interfaces**
Look for a system that interfaces with industry-accepted printers and verifiers without using proprietary hardware.

✔ **Easily Integrates with ERP Systems**
Seek out a system designed to integrate into existing or future ERP systems easily.

✔ **Up and Running Quickly**
Make sure your system is designed to be up and running within hours and provides all the components required for serialization operations in a compact and easy-to-use system.

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4. Single Source Serialization Provider

A single source serialization provider allows you to interface with just one vendor.

Specifics to Look For:

✔ **Full Integration**
A solution provider that offers hardware and software, and allows you to work with just one vendor, simplifying implementation and ongoing support.

✔ **EPCIS Certification**
Seek out a solution provider that offers an EPCIS- certified cloud serialization with available gateway solutions to external EPCIS providers.

✔ **Comprehensive Solution**
Your solution provider should offer everything you need to set up a comprehensive serialization solution for tracking from the primary package to the pallet.

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5. In-House Experience and Expertise

Pharmaceutical companies often do not have serialization expertise, so partnering with a vendor who has an in-house team of experienced DSCSA serialization experts is paramount to a successful project.

Specifics to Look For:

✔ **In-house Experienced Experts**
We are in the midst of a tight labor market, and companies are having trouble hiring and maintaining employees, especially engineers. Ensure your track and trace vendor has an in-house staff of engineers with deep serialization and DSCSA expertise to solve supply chain challenges, optimize technology products, and implement new processes quickly and cost-effectively.

✔ **Guidance and Attention**
Ensure your provider can give you the necessary guidance and attention throughout your serialization project. You may need some hand-holding on this project, ensure that your serialization provider will share their knowledge has the staff to ensure your project is a success.

✔ **Entire Supply Chain from Manufacturer to Dispenser**
The staff should have expertise with the entire supply chain from manufacturer to dispenser.

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6. Performance

System performance throughout the packaging site and the supply chain should undoubtedly be the most evident concern for any organization implementing serialization. Therefore, it is imperative that your system perform at the high level intended.

Specifics to Look For:

✔ **Serialize Automatically at High Speed**
Seek out a system that can be configured to serialize automatically at extremely high speeds in addition to a manual or semi-automatic packaging line.

✔ **Designed for Flexibility**
Look for a solution designed for maximum flexibility to meet a wide range of packaging applications.

✔ **Positive Production Results**
Ask to speak with customers regarding their test and production results. You want to ensure that your vendor has no ongoing performance issues. Confirm that customers are not experiencing failure on the packaging line level.

7. Costs

Due to a maturing serialization market, cost-competitive solutions are now readily available. One should not imply that lower-priced solutions are inferior to higher-priced services and vice versa. When searching for a solution, one should consider the overall costs for implementation, maintenance, and separate fees that may accrue (e.g., connecting new trading partners, adding additional SKUs, after-hour support, etc.). Contract length and flexibility to terminate an agreement should also be considered.

Specifics to Look For:

✔ **Costs Align with Budget**
The total cost of your serialization solution should align with the budget allocated by your company.

✔ **All Projects Costs Included**
One should consider the overall costs for implementation, maintenance, and separate fees that may accrue (e.g., connecting new trading partners, adding additional SKUs, after-hour support, etc.). Find out which costs are included in your serialization contract. Ask if you will be billed separately for services such as support and if there are subscription fees (recurring costs to maintain your service).

✔ **Flexibility**
Seek a vendor that offers flexible financing options that can lower upfront costs, enabling companies to quickly start on their serialization journey. Contract length and flexibility to terminate an agreement should also be taken into consideration.

✔ **Peer Recommendations and References**
Ask your peers for recommendations and request your prospective service provider to provide references for organizations with similar business models to yours.

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AuthentiTrack is a complete product serialization solution (Levels 1-5) designed to make it easier for manufacturers to meet compliance needs, maximize uptime, and ensure product integrity.

AuthentiTrack Enterprise

Ideal for companies that have multiple lines within their facility that need to be serialized, the AuthentiTrack Enterprise solution encompasses the site, line, packaging units — and the devices within the packaging unit — to provide a complete serialization operation at the plant level. The AuthentiTrack Enterprise solution offers connections to your ERP system for the automated exchange of product-related master data required for serialized product . After the merchandise is packaged and shipped, a connection to the AuthentiTrack Cloud provides serial number provisioning and an event history repository.

AuthentiTrack Prime

AuthentiTrack is a complete product serialization solution (Levels 1-3 and 5) designed to make it easier for growing manufacturers to meet compliance needs, maximize uptime, and ensure product integrity with semi- automatic or manual, low-volume packaging operation. Designed to be up and running within hours, AuthentiTrack Prime is a standalone system and can be placed next to the production line without more complex integration . It also can be easily transported and set up in new locations and is very competitively priced.

About Covectra

Covectra provides complete serialization, track & trace, and authentication technologies to secure, trace and manage products across the entire supply chain, extending to the unit dose level. Transforming supply chains with end unit traceability from the packaging line to the cloud, we enable customers to ensure brand protection, product safety and supply chain integrity in the pharmaceutical, food & beverage, luxury goods, and tobacco industries. With over 4 billion serial numbers issued worldwide, Covectra helps to combat counterfeiting & product diversion and to facilitate product recalls.

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