Pharmaceutical Serialization: An Implementation Guide

By Joe Whyte, Global Serialization Lead, Rockwell Automation

Global pharmaceutical companies lose an estimated $75 billion annually to counterfeit, gray market and stolen product. Impending regulations aimed at protecting public health, intellectual property and national security will require pharmaceutical, medical device and consumer packaged-goods manufacturers to track and trace products across the supply chain.

This white paper gives in-depth descriptions of the:

- Challenges driving new serialization regulation.
- Pending regulation requirements and deadlines.
- Implementation and interoperability challenges in pharmaceutical serialization solutions.
- New holistic pharmaceutical serialization solution from Rockwell Automation® built on a modular and scalable off-the-shelf control and information platform.
- Business benefits of the common data source created by pharmaceutical serialization.

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Summary

No corner of the world is safe from counterfeit pharmaceuticals. In the United States, contaminated blood thinner medication killed dozens of Americans and sickened many more in 2008. In New Zealand, women who bought do-it-yourself Botox on the Internet in 2011 were disfigured by impurities – including cooking oil – contained in the bogus injections. In sub-Saharan Africa today, according to the Centers of Disease Control, an estimated 30 percent of all drugs are counterfeit, and often contain little or none of the active ingredients patients need to battle malaria, tuberculosis and other life-threatening diseases.

While the human suffering caused by counterfeit drugs is incalculable, experts estimate that global pharmaceutical companies lose an estimated $75 billion annually to rogue dealers, including those involved in organized crime and even terrorist groups.[1]

That total doesn't include less tangible but still substantial losses to pharmaceutical manufacturers from diminished brand value caused by damaged public trust.

Pharmaceutical companies lose an estimated $75 billion annually to rogue dealers … a total that does not include losses from damaged public trust and diminished brand value.

By all accounts, trafficking in illicit pharmaceuticals – including sham, stolen or otherwise diverted prescription medications – is far more lucrative than selling illegal drugs. The U.S. Department of Commerce estimates that a $1,000 investment in counterfeit prescription drugs can result in a $30,000 return – ten times the profit margin for heroin.

Alarmed by the proliferation of counterfeit medications – as well as fake medical devices and contaminated consumer products, such as baby formula – countries around the world are taking action. Impending regulations aimed at protecting public health, intellectual property rights and national security will require pharmaceutical, medical device and consumer packaged-goods manufacturers to track and trace products across the supply chain.

Until now, only production-related information, such as the expiration date and lot codes, has been printed on products and their final packaging. However, serialization – the application of a unique alpha or numeric identifier on every pharmaceutical package down to the unit level of sale – is a common requirement among the otherwise disparate international initiatives scheduled to take effect in the next several years.

These unique identifiers must be stored in a database along with other information about the item, including manufacturer and batch details. Using unique serial numbers, the authenticity of items can be verified against the database at every step in the distribution chain, from the manufacturer to the consumer.

Brazil is leading the serialization charge. All packaging on prescriptions sold in the country must carry a two-dimensional (2-D) code to enable monitoring from the factory to the pharmacy – including identification of the individual who purchased a particular drug.

But that's just Brazil. GS1, an international organization that develops and maintains standards for supply and demand chains across multiple sectors, has created many standards to support serialization – down to what a 2-D barcode looks like. GS1's EPCIS does provide details on managing and sharing data between parties who have EPCIS certified systems. However, there is no global agreement on a central or distributed database or data ownership model.

[1] http://www.stimson.org/images/uploads/research-pdfs/Full_-_Counterfeit_Drugs_and_National_Security.pdf

To ensure compliance and patient safety, pharmaceutical manufacturers need a flexible technology and new expertise to help them navigate the production and cultural complexities of emerging serialization regulations. They need seamless interoperability among all machines, devices, business systems and databases that together comprise the pharmaceutical supply chain.

A new holistic serialization solution from Rockwell Automation, which can be globally deployed and supported consistently, helps pharmaceutical manufacturers overcome these challenges. That's because it is built on a modular and scalable off-the-shelf control and information platform that can be easily integrated into drug makers' existing production lines.

The solution integrates with GS1 Electronic Product Code Information Services (EPCIS) certified central database to seamlessly and securely share data from the enterprise, to supply-chain partners and the retail point of sale – and potentially, right to the customer.

The business benefits of this holistic solution extend well beyond stopping counterfeiters and thieves. With a clear line of sight through the supply chain, drug makers can optimize their manufacturing, supply chain processes, and their product inventories, to meet real time consumption demands. Manufacturers can also improve the accuracy and reduce the scope of product recalls. Finally, the common data source created by serialization can yield valuable, actionable intelligence for departments, ranging from finance to sales to marketing.

Human Harm

Nearly a decade ago, the World Health Organization (WHO) launched the International Medical Products Anti-Counterfeiting Task Force (IMPACT) to "halt the production, trading and selling of fake medicines around the globe."[2]

IMPACT members included international enforcement agencies, pharmaceutical manufacturers' associations, and drug and regulatory authorities. Since 2006, members have collaborated on international criminal investigations, helped countries strengthen their detection and enforcement systems, and worked with industry to develop prescription supply-chain protections, such as secure, high-tech pharmaceuticals packaging.

Still, the number of people harmed by counterfeit, contaminated, stolen and otherwise compromised medications has continued to grow, along with the sophistication of the criminals who peddle them.

Using advanced and readily available technologies, it's easy for counterfeiting criminals to produce a pill or a vial that looks like the real thing and create copy-cat packaging that appears authentic.

That was the case in 2012, when the U.S. Food and Drug Administration (FDA) reported that a counterfeit version of cancer drug Avastin had invaded the U.S. supply chain. The fake injectable serum – seized mostly from unsuspecting doctors, clinics and hospitals – contained cornstarch, acetone and other chemicals, but no active ingredient to fight cancer.[3]

[2] **http://www.who.int/medicines/services/counterfeit/overview**

[3] **http://www.wsj.com/articles/SB10001424052702303879604577410430607090226**

Overall, industrialized countries are less vulnerable to counterfeit prescription drugs than less developed nations. An estimated 10 to 30 percent of medicines sold in developing countries are fake, according to U.S. Centers for Disease Control (CDC), but less than one percent of prescription drugs sold in America, the European Union, Japan, Canada, Australian and New Zealand, are counterfeit.[4]

In the developed world, most manufacturers are diligent about quality control and adhering to good manufacturing practices (GMP). However, under-regulated wholesalers and re-packagers are increasingly involved in the prescription supply chain. The explosion in Internet pharmacies has given counterfeiters unprecedented access into the already complex and fragmented prescription supply chain.

Case in point is a 2013 analysis by the National Association of Boards of Pharmacy, which accredits online pharmacies. It showed that 97 percent of the more than 10,000 online sites selling prescription medications were operating illegally or not following pharmacy laws and standards. According to the WHO, more than 50 percent of prescription medicines purchased over the Internet from illegal sites have been found to be counterfeit.

Rogue Agents

Drugs in almost every therapeutic category have been counterfeited, but certain types of fake medicines are more prevalent in different parts of the world.

In developed nations, counterfeiters tend to focus on expensive lifestyle medications, such as erectile dysfunction and anti-allergy drugs. In one of many such cases, three British men were sentenced to prison in April 2015 for selling fake Viagra.[5] The judge in the case said the men were part of a "highly organized, large-scale criminal enterprise" that used a bogus mail-order fishing-tackle business to reap an average of £60,000 a week.

In the developing world, counterfeiters tend to target drugs used to fight infectious diseases. For instance, a 2012 study published in the journal Lancet showed that up to 36 percent of anti-malarial drugs collected in Southeast Asia were falsified, while in sub-Saharan Africa, a third failed chemical analysis.[6]

The lack of trace-and-track transparency in the prescription supply chain leaves open questions about the quality and efficacy of gray market medicines. As the FDA notes, "It is unknown how these drugs are stored and handled, or whether they are expired, counterfeit or otherwise substandard."

Counterfeiters aren't the only rogues in the pharmaceutical business.

Gray market companies operating outside the legitimate drug-distribution chain buy and sell prescription drugs. "When critical medications become scarce and are no longer available through a hospital's usual channels of distribution, unscrupulous gray market distributors have been quick to jump in with inexplicably obtained supplies of these drugs that they are more than willing to sell to health care providers at exorbitant costs," according to the Institute for Safe Medication Practices.[7]

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[4] http://www.cdc.gov/features/counterfeitdrugs
[5] http://www.theguardian.com/uk-news/2015/apr/13/fake-viagra-gang-members-sentenced-criminal-enterprise
[6] http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(12)70064-6/fulltext
[7] https://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=3
[8] http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm277747.htm

Meanwhile, illicit prescription-drug dealers – ranging from organized gangs, to corrupt doctors, to teens raiding their parents' medicine cabinets – are fueling an epidemic in prescription opioid addiction. Abuse of narcotic painkillers, such as OxyContin, Percocet and Vicodin, kills 45 people per day in the U.S., according to the CDC. That's more than deaths from heroin and cocaine overdoses combined.[9]

Regulatory Sea Change

These stark human realities, combined with lost profits and a lack of security in the world's drug supply chain, have led to an international transformation in prescription medicine regulations.

In 2015, South Korea joined Turkey and Argentina in requiring prescription drug items sold in their countries to be serialized. They must now include both human- and machine-readable symbols, such as a GS1® DataMatrix and a unique serial number for each item.

GS1 standards are the most widely used in supply chains across the world. Its identification system includes globally unique identification for products, assets (objects) and locations, as well as its standards for capturing and sharing visibility and traceability data between supply-chain partners and other key stakeholders. Virtually every country besides China has adopted GS1 standards for pharmaceutical serialization "to minimize fragmentation and instead increase harmonization worldwide."[10]

Industry organizations, such as the European Federation of Pharmaceutical Industries and Associations, are drafting and piloting technological solutions to meet the serialization mandates.

In Brazil, government officials are developing a requirement in which drug makers must provide serialization and tracking data for three batches of products.

In the United States, new requirements for serialization and traceability under the Drug Supply Chain Security Act of 2013 will be phased in over a decade. At the beginning of 2015, the government began requiring that manufacturers incorporate product-transaction data into a single document that is available, either electronically or on paper, each time ownership is transferred. By November 2017, that information must be available electronically, and the product identifier must be affixed or imprinted on the label at the product and case level.

By 2023, U.S. mandates will require manufacturers to be able to exchange transaction information and transaction statements in an interoperable electronic manner. A full transaction e-pedigree will be defined by the FDA prior to the required implementation in November 2023.

In the European Union, with the publication of the Delegated Act on safety features in February 2016, manufacturers have to comply until 2019 with new Serialization regulations outlined in the Falsified Medicines Directive (FMD).

These changes comprise just the first wave of new track-and-trace legislation. Pharmaceutical serialization requirements are in various stages of development in more than a dozen counties from China to Mexico to Saudi Arabia.

[9] **http://www.cdc.gov/drugoverdose/data/index.html**

[10] **http://www.gs1.org/docs/healthcare/Joint_Industry_Position_Paper_on_Serialization_and_Product_Verification_Final_November_2013.pdf**

[11] **http://www.healthcarepackaging.com/playbooks/pharmaceutical-serialization-playbook**

Interoperability Challenges

For pharmaceutical companies, these deadlines have created a huge quandary. The major challenge: While the regulations spell out serialization as the solution to protect the pharmaceutical supply chain, they don't specify how to implement a serialization solution.

Pharmaceutical Serialization: Defining Terms

Product Serialization is the application of a unique alpha or numeric identifier on every pharmaceutical package, from the unit level of sale to the pallet. Serialization will be required under impending international mandates aimed at protecting the prescription-drug supply chain from counterfeiters, thieves and other threats.

Aggregation is the relationship between the primary package and every subsequent container or package used to ship the saleable unit of a prescription drug. In serialization, aggregation is both a physical relationship and a data relationship. For example, each carton, case and pallet that contains the unit of sale requires a unique serial number. Those associated serial numbers are collected in a database, and used to track prescriptions throughout the supply chain, from the point of manufacture to the consumer.

E-pedigree is a chain-of-custody document that identifies each prior sale, purchase or trade of a drug, including the date of those transactions, and the names and addresses of all parties involved.

Electronic data interchange (EDI) is the transfer of data from one computer system to another by standardized message formatting, without the need for human intervention. EDI permits multiple companies – possibly in different countries – to exchange documents electronically. It is the most common method used by drug makers today to share serialization information and serialized content-to-container relationships with trading partners.

Electronic Product Code Information Services (EPCIS) is a GS1 standard that enables supply-chain partners to store and share physical event data, including the what, when, where and why about physical observations (events), independent of the technology used to capture that information. This allows companies to associate and share additional information, or events, relating to an object's identity. For example, companies can associate information, such as the time and date that a bar code was scanned or an RFID tag was read, the location of that scan/read, and whether the object was being shipped or received.[12]

There also is not an agreed-upon data format for capturing aggregated track-and-trace information and sharing it among multiple trading partners in the global supply chain.

Within the four walls of the factory, implementing the new regulations requires tracking at every stage in the end-of-line packaging process down to machines, printers, labelers, bar-code scanners and vision systems.

At each stage in the finished goods packaging process, a unique serial number – represented by a 2-D barcode or RFID tag – must be applied to the product's package. Depending on the industry or customer need, there can be up to five levels of parent/child aggregation, with serial numbers applied to the item level or unit dose, up to the pallet.

The unique serial number at each stage in the packaging process must be married to all the unique serial numbers contained in the package. Therefore, each pallet serial number (parent) is paired to all the unique case serial numbers (children) on the pallet, creating the aggregated parent/child relationship. Likewise, each case serial number (parent) is paired to all of the unique carton serial numbers (children) that are in the case, and so on.

The unique serial number at each stage in the packaging process must be married to all the unique serial numbers contained in the package.

Accurately applying and associating these new and complicated sets of individual identifiers poses interoperational challenges for many drug makers. That's because historically, pharmaceutical companies have invested in "black box" solutions at the packaging-line level. Those can include unique hardware – such as their own versions of printing and vision systems – as well as custom software drivers, custom application software and proprietary networks.

For data generation and acquisition, serialization is complicated by the massive need for unique applied numbers (preferably randomized), the high volume and speed of the data-handling process, and the wide range of products, formats and country requirements.

Serialization also adds extra layers of information that must be integrated into existing production processes and information systems. Information must flow between control systems, manufacturing execution systems (MES), enterprise resource planning (ERP) systems, inventory management and supply-chain systems.

Beyond the pharmaceutical plant, products can change ownership as many as 10 times within the supply chain before reaching patients.[12] These transition points in the supply chain are essentially the vectors of attack for anyone sophisticated enough to steal or otherwise divert prescription drugs from the legitimate supply chain.[13]

Effectively meeting the new government mandates will require a holistic serialization solution to track and trace prescription drugs through the entire supply chain.

Today, electronic data interchange (EDI) is the most common method used by drug makers to share serialization information and serialized content-to-container relationships with trading partners. However, EDI file-sharing wasn't designed for tracing supply-chain event data. It has no query mechanism, no exceptions processes, no global format, and most important of all, it is not extensible without Standards action, which would require a multi-year process. Extensibility is a software design principle defined as a system's ability to have new functionality extended, in which the system's internal structure and data flow are not affected, an essential element if a platform is to adapt to new and emerging regulatory requirements. EDI doesn't amount to much more than a text file combined with an advance shipping notice, much like how consumers track their FedEx packages today.

GS1 has developed EPCIS to overcome shortcomings with EDI and accommodate the growing volume and complexity of data required by emerging serialization legislation. EPCIS enables supply-chain partners to store and share physical event data, including the what, when, where and why of events, independent of the technology used to capture that information.[14]

[12] **http://www.pharmacompliancemonitor.com/global-pharmaceutical-product-serialization-taking-steps-against-counterfeiting/8831/**

[13] **http://www.healthcarepackaging.com/playbooks/pharmaceutical-serialization-playbook**

This allows companies to associate and share additional information, or events, relating to an object's identity. For example, companies can associate information, such as the time and date that a barcode was scanned or an RFID tag was read, the location of that scan/read, and whether the object was being shipped or received.

Ultimately, as a product is scanned through the supply chain, if a serialization identifier shows up somewhere else in the system, it's a red flag that there's a counterfeit in the market. This enables manufacturers to take action before it gets into the hands of the consumer.

A Holistic Serialization Solution

A new holistic serialization solution from Rockwell Automation enables pharmaceutical manufacturers to comply with the current regulations and standards with the flexibility to adapt to those on the horizon.

The solution is built on industry standards (IEC 61131, ANSI/ISA-88, ANSI/ISA-95) and uses open network and communication protocols, and commercial off-the-shelf technologies, eliminating the need for black-box proprietary control solutions and the associated custom interfaces and custom drivers that they require. This open approach allows Rockwell Automation to deliver a modular, re-usable and scalable solution anywhere in the world, using local resources

This turnkey solution aligns to the ISA-95 multilayer data model. More specifically, it contains key modifications/additions to the packaging-line data structure to:

- Completely separate machine control and data functionalities.
- Create a single database that manages information throughout the serialization process.
- Provide the required data links and Web services to connect serialization data to the ERP layer and the Supply Chain Cloud.

ISA-95	Serialization Levels
Level 0: Production process data (e.g., I/O, devices)	Printers, Labelers, Vision Systems & Bar Code Scanners: Serialization numbers printed and inspected
Level 1: Sensing/testing equipment or instrumentation (e.g., HMI, sensors)	Unit Level Controller and HMI Stations: Serialization and aggregation data management per station
Level 2: Control the production processes (e.g., SCADA, HMI, batch)	Line controller serialization and aggregation data management for the entire packaging line
Level 3: Work flow/recipe management, electronic records, production management (e.g., MES)	Site Server: Serialization and aggregation data management for the entire facility
Level 4: Business planning and logistics (e.g., ERP)	Business planning and logistics: Serialization interface to ERP and MES
	Level 5: Supply Chain Track and Trace Serialization Data Event Repository

Serialization-relevant data is widely distributed over control and information systems across many levels or layers. Rockwell Automation identifies these layers based on the enterprise and control system levels of the ISA-95 data model.

The system integrates with EPCIS certified supply chain repositories to specifically meet serialization regulatory requirements.

[14] **http://www.gs1.org/docs/GS1_Anti-Counterfeiting_White_Paper.pdf**

Here's how the holistic Rockwell Automation solution works at each level of its ISA-95 aligned data model:

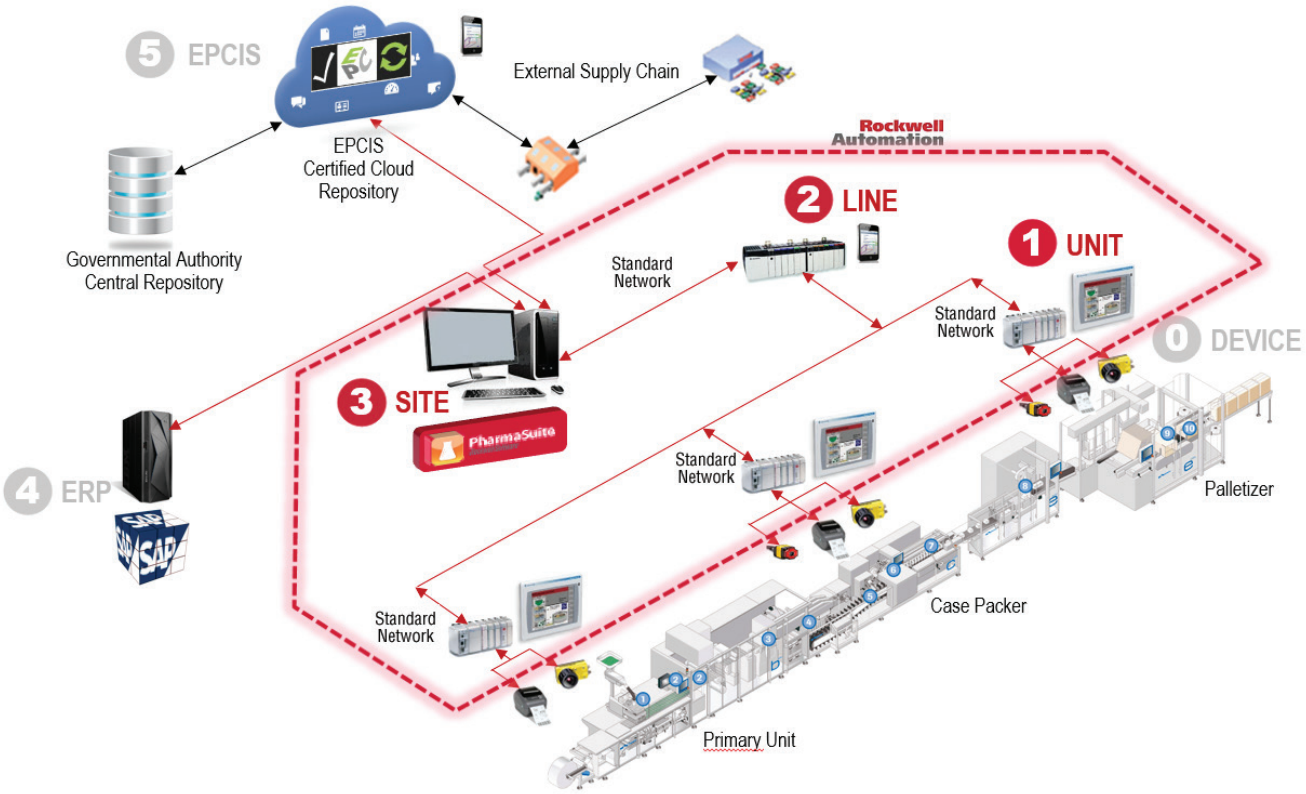
Level 0, according to the traditional ISA-95 standard, is the device level that includes pieces in the packaging machine, such as vision systems, printers and radio-frequency identification (RFID) systems.

Free of proprietary equipment and networks, pharmaceutical producers can choose from a wider selection of OEMs for troubleshooting or repairs.

The Rockwell Automation solution expands Level 0 to include the packaging machine itself, which was separate at Level 1 in the traditional ISA-95 model. This modification keeps all the equipment responsible for packaging the product on the same level. To ensure all the machines and their components operate seamlessly – and allow the solution to be scalable and repeatable – all the physical assets are commercial off-the-shelf (COTS) technology.

Separating the machine functions from the data functions not only creates a consistent information solution – it also empowers OEMs to deliver serialization-ready machines without the complexities entailed in adding IT data capabilities. With the Rockwell Automation solution, the machine-controller level isn't responsible for managing data or generating serialization identifiers as they do on many existing packaging lines. The Rockwell Automation solution keeps those critical and increasingly sophisticated data functions above Level 0.

A side benefit for packaging-machine end users: Free of proprietary equipment and networks, they can choose from a wider selection of OEMs, Systems Integrators and Solution Providers to provide and integrate Level 0 devices and packaging machinery or to provide deployed system repairs or troubleshooting support services.



Level 1 in the Rockwell Automation architecture is home to a serialization Allen-Bradley® CompactLogix® processor – a COT – that manages the serial information interface between the data layers and the Level 0 devices and packaging machinery and acts as a serialization data buffer between the data and equipment layers. Level 1 dedicated programmable automation controllers (PACs) manage the serialized data at each stage in the Level 0 packaging process (from primary to palletizer packaging), and send the printed and verified numbers to the Level 2 line controller where the required parent-child data relationships are created and managed.

Level 2 is the line controller responsible for managing the data associated with each packaging line's dedicated PACs. Rockwell Automation uses an Allen-Bradley ControlLogix processor – a COT – that operates as a data concentrator and acts as a serialization data buffer. It manages the serialized numbers specific to each packaging aggregation unit on the line during a production run and creates the required parent/child data relationships.

The level 2 line controller receives those unique, random identifiers from the site server at Level 3, and then distributes them among the different controllers on Level 1. Not all those numbers will be used during the production run because of bad prints or rejected products. The Level 2 line controller maintains a "good" list until the run is completed. This ensures only good products are included in the next packaging aggregation unit. These results are buffered and continuously uploaded to the Level 3 site controller which operates as a central database.

Level 3 is the site server, which manages all of the serialization data for a manufacturing plant and ensures that the right serial number is at the right place, at the right time throughout the facility. The site server is the only plant level database in the Rockwell Automation solution, which helps ensure data integrity for the entire system.

The site server identifies, quantifies and classifies the serial numbers to be sent to the packaging line, based on a production order. It marries that production order to the serialization information that needs to be applied to all the products and all the packaging levels in one location. It then provisions that data to the appropriate machines on the plant floor via the line controller on Level 2.

Level 3 uses a dedicated serialization module built on top of the FactoryTalk® PharmaSuite™ software application. It uses the ERP Integration Gateway to provide the required connectors to MES, ERP or cloud-based track-and-trace systems. .

Level 4 is the corporate IT business layer where ERP systems track business resources and convert customer orders into production runs. Once serialization data enters the Level 5 supply chain, drug makers can use the product tracking data to improve business operations throughout their enterprise. They can optimize everything from inventory levels to product promotions to rebates and chargebacks. All this is possible by taking serialization data from a nonproprietary platform and seamlessly integrating it into business information systems.

Level 5 is the cloud-based, supply-chain event repository where a company's serial numbers for each production site should originate and to which all authenticated aggregated serial data should be sent for storage. The Level 3 Site Server can directly interface to any Level 5 system, thus providing customers with a robust and secure central database with worldwide availability. Once products leave a manufacturing site, all supply-chain events associated with each package are tracked and stored in the event repository as the products move to the final point of sale.

The Rockwell Automation serialization solution includes an interface to a Cloud-based repository, which gives manufacturers the flexibility to implement the appropriate Level 5 solution that allows them to provide the required information to regulatory bodies. Certain countries will have exceptions. China, for instance, is expected to create a central government repository.

By using the Cloud to maintain their databases, manufacturers have the ability and the server capacity to manage their product's chain of custody from anywhere in the world via a Web portal.

Cloud-Based Data Event Repository

Deploying a successful supply chain cloud solution requires a disciplined process. That's why the Rockwell Automation serialization solution provides an out-of-box connector to cloud-based serialization and track-and-trace platforms. The Level 5 cloud-based, supply-chain, event repository server is EPCIS-certified, meaning it meets GS1 guidelines for providing global drug pedigrees and for interoperability with IT service standards.

The Level 5 platform can offer cloud-based event repository, packaging-line serialization configurations, and front-end applications to derive business benefits from serial numbers.

The platform is designed to accommodate the additional data required to conform to EPCIS standards, as well as the current data exchange associated with EDI. The challenge of generating and managing the millions of random numbers required for serialization is complex. The Level 5 platform integrates with the Rockwell Automation solution, delivering serialization numbers to the central site server at Level 3. This helps automatically track those unique numbers – including those provisioned but not used on the packaging line – to ensure the integrity of the system and prevent any redundancy.

To conform with emerging chain-of-custody regulations, the path of prescription drugs through the supply chain must be tracked and recorded at every step – by distributors, hospitals, pharmacies, etc. the EPCIS cloud-based event repository automatically uploads scanned serialization information and updates the customer's database.

The platform has applications that allow drug makers to perform analytics on their supply chain data to identify counterfeit or diversion activities. Pharmaceutical companies also can explore the data-mining capabilities of cloud platforms to potentially streamline processes and identify business opportunities.

Microsoft, a Rockwell Automation Strategic Alliance partner, has developed its Azure platform as a globally distributed and redundant cloud environment with more than 150 data centers worldwide. These geographically dispersed data centers comply with key industry standards, such as ISO/IEC 27001:2005, for defense-in-depth security and reliability.

Microsoft's data centers are managed, monitored and administered with 24/7 continuity by operations staff who have years of experience in delivering the world's largest online services.

Delivery and Support of Mission Critical Assets

Once the regulatory deadlines are past, if any part of the serialization system in a plant stops working, the entire production line can no longer produce product. That's a mission-critical production asset down.

Rockwell Automation can help get that key asset up and running quickly by leveraging its core capabilities of secure remote access and serialization application diagnostics.

Because the Rockwell Automation serialization solution is based on a standardized model, its data solution allows Rockwell Automation support, locally based OEMs or system integrators to remotely access pharmaceutical facilities through a firewall controlled by the in-house IT department.

Users with black-box control or custom control systems often encounter long-term support challenges, as well as parts and knowledge transfer issues.

With the regulatory deadlines rapidly approaching in many countries, many pharmaceutical companies will need to deploy serialization solutions in multiple locations simultaneously. Only a solution that uses commercial off-the-shelf technology that is easily deployable and supportable can meet this challenge.

Rockwell Automation control systems are built on an open architecture that provides the modularity, scalability and flexibility needed to comply with impending serializations regulations. The Rockwell Automation solution also allows companies to reap the business benefits that extend from a fully integrated serialization system.

Reverse-Logistics Benefits

A holistic and interoperable serialization solution can deliver reverse-logistics benefits from more accurate and efficient recalls to improved forecasting and more customer-specific marketing programs.

For example, imagine a pharmaceutical company discovers a supply-chain partner did not store a specific ingredient for a drug at specified temperature or humidity levels. Today, the producer would need to review data to understand which batches were impacted. They would likely add the previous and trailing batches to the recall to be safe, determine which pallets those were shipped out on, and guesstimate what happened to those pallets after they were received by a third party. They would need to rigorously publicize the recall and impacted batch numbers to ensure product was not consumed as they couldn't directly contact the point-of-sale outlets.

With a holistic serialization solution, the producer could use the data thread to track backward along their distribution chain. They could quickly and easily utilize their cloud-based data repository to determine which cases or packages were on pallets that shipped, as well as where they were shipped from there onto the final point of sale. Those retail outlets could be contacted directly to remove the damaged product and only the damaged product from the shelves. If the point of sale had information on the consumers who purchased the damaged product, they could potentially reach out to the consumer directly to prevent any complications from the defective medicine.

But the solution offers more than this. Pharmaceutical innovators are following initiatives like the Smart Manufacturing Leadership Coalition, Industrie 4.0 and China's Manufacturing Intelligence 2025. Admittedly, though, many don't yet have a clear strategy in place to operationalize these initiatives.

Success today requires greater process knowledge – the kind locked deep inside production systems. Accessing that data and converting it into useful information can yield tremendous benefits, but information alone isn't enough.

Cross-departmental activity between plant-floor and front-office systems has become particularly necessary in the life sciences industry, as tracking and reporting has evolved from a nice-to-have to a must-have. Rockwell Automation refers to this as The Connected Enterprise. It's the creation of a unified control and information system architecture to harness production intelligence and improve operations across the product life cycle – from formulation to factory.

Because the new Rockwell Automation holistic serialization solution is fully integrated across the supply chain, all enterprise and control system levels, and potentially directly to the customer, its common serialization data thread provides real-time visibility to a company's products and customers. What pharmaceutical producers can do when empowered with this information is only limited by their imagination.

Resources

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