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Serialization across the business: *Visibility & Value*

Supply chains are under siege. Counterfeit drugs. Recalls. Returns. Security breaches. Complex challenges at a colossal cost. Counterfeits alone cost the industry $46 billion each year. And that's just the cost to the business. Patient safety comes with its own price.

But don't count your losses, adopt a business value approach and see what you stand to gain.

Forward-looking companies have used the California ePedigree 2011 requirements to spur gains in efficiency.

Companies such as GSK, Pfizer, Purdue Pharma, and Biogen Idec who pursue both track-and-trace capability and end-to-end visibility, understand that when process and strategy come first, compliance and business benefits follow. As Hussain Mooraj of AMR Research stated, "Life sciences leaders are looking at these regulatory requirements as an opportunity to improve business process and operations, enhance patient safety, and protect the brand."

Others, however, find priorities in flux with compliance imperatives often pushing up against their quest for supply chain excellence and measurable, sustainable value. By focusing too heavily on technology and timelines, many fail to realize that solutions such as serialization can uncover many opportunities to deliver quantifiable business benefits.

Serialization is a top priority for current state and potential FDA compliance reasons and now also with suppliers to Sam's Club, who have a two-part serialization mandate in October 2009 and October 2010, respectively. But again, while compliance is often the

catalyst, this is a business information alignment issue. Those that embrace it that way and strategically transform serialization data into near real-time insight and knowledge will be able to bring value to the business as a whole not just within their supply chains.

Where are the Value Opportunities?

Unlocking knowledge through serialization extends beyond the downstream flow from manufacturer, to wholesaler, to pharmacy. It includes discrepancies that occur within the stream and the reverse stream flow. As stated by Eric Newmark of IDC Health Industry Insights:

"Revenue lost throughout the later stages of product lifecycle management (PLM) continues to be a silent killer for many pharmaceutical companies. Lack of item level serialization currently costs pharmaceutical manufacturers 4.5 percent of revenue annually. As products travel through the channel, dollars literally leak out through inefficiencies surrounding chargeback discrepancies, duplicate chargebacks, omitted reverse chargebacks, return discrepancies and concealed shortages. Many companies suspect this leakage exists, but have little visibility into its occurrence and do not know how to prevent it. Item level visibility and improved data integration across the value chain resulting from these initiatives will help close these gaps."

Remember, supply chain processes represent only a fraction of the equation. By isolating your serialization information within the supply chain, you hamper visibility and stifle your competitive advantage. On the flip side, if you share information across your business via metrics, dashboards, etc., it will flow throughout your enterprise, yielding opportunities for growth and innovation (see Figure 1).

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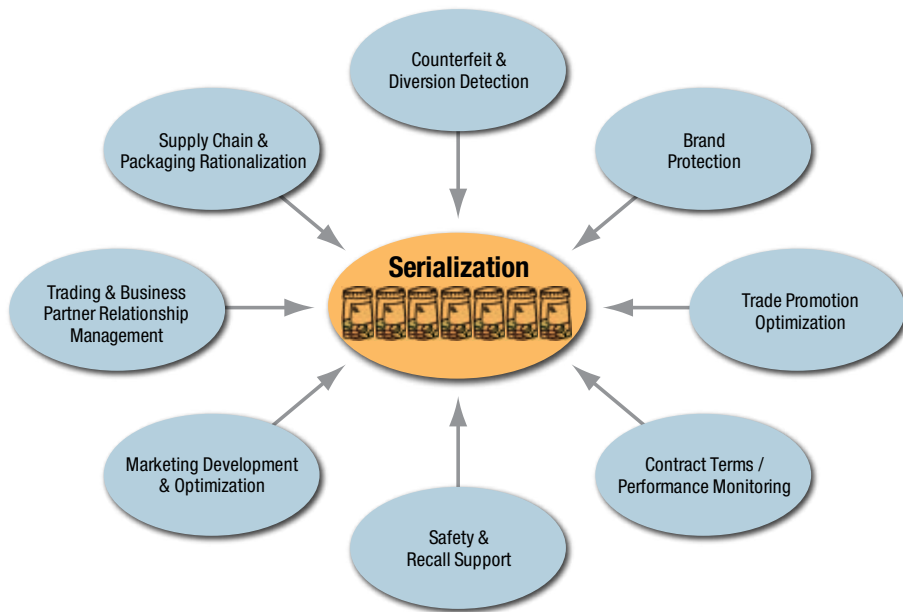> **Eric Newmark**
> IDC Health Industry Insights

Figure 1: Sharing of Data from Serialization

Gain more insight into the events associated with your products and you can use the data to improve all areas of your business. For example, in marketing and sales, you can use this information in discrete product tracking, versus batch and lot, for all parties (manufacturers, wholesalers and pharmacies) to determine how and when product moved in the sales cycle, depicting sales movement of all parties (manufacturers, wholesalers and pharmacies). This could, in turn, be used to measure promotional effectiveness and flush old products from the market. In a collaborative relationship, serialized data can help manufacturers see when the wholesaler sold their products and when the pharmacy sold their products. Over time, plotting finite trends of actual sales histories through serialization and The Electronic Product Code Information Services (EPCIS) will help you facilitate more accurate forecasts and streamline your forecasting and analysis processes.

What if you could provide granular product movement event data to your sales teams beyond just a sold and ship date? What if you could effectively track the products sold/distributed and match those against the rebate claims of your distributor? Or what if you could track

returns to the licensed dispensing level and provide a means to reject invalid return products? And imagine if, for all of these scenarios, you could also provide the analytics and the metrics to guide business changing decisions? You can. And that's just the beginning when you look at serialization strategically.

Another way to consider your value opportunities is from a financial perspective. Here is a representative sampling of the financial impacts of serialized data:

Increased Revenue:
• Faster time to market
• Improved product availability
• Improved dose dispensing accuracy
• Reduced losses from theft & counterfeit
• Improved script and POS data capture

Increased Capital Efficiency:
• Improved inventory turns
• Improved cash flow management
• Faster development cycles
• Improved asset utilization

Or consider areas of operational improvement. Even in companies where much has been done, to improve internal operations (e.g. Six Sigma or lean

manufacturing), untapped potential for greater efficiency exists. Demand-planning, forecasting, and logistics planning can significantly improve when you establish synergy between you and your trading partners' supply chains. The broader value, however, comes when your strategy and vision take advantage of all the opportunities that exist.

Data Becomes Intelligence

When the information flowing throughout your supply chain helps you make immediate fact-based business decisions, you have real business intelligence. Simple in theory and yet, far too many companies fail to extract what they need from data that grows exponentially in their organization. In fact, Gartner estimates that, over the next two years, more than 25% of critical data in Fortune 1000 firms will be flawed (inaccurate, incomplete or duplicated). The impact of that is far-reaching, from increased costs and attrition to a myriad of missed opportunities.

With serialization your data multiplies quickly. How then do you manage and mine it appropriately so that it transforms into intelligence? The EPCIS standard is a promising step forward. With it, you gain access to a single way to capture and share data, all based on the "What, Where, When, and Why" of your supply chain events." And taken one step further with "Supply Chain Intelligence" (SCI), a key application in product movement and event data, you can actually collaborate online with your supply chain partners and deliver real-time analytics. Combine the EPCIS events with the information contained within the serialized data at the pallet, case and unit levels, and you not only gain the data you need to feed SCI, you'll extract business value that wasn't even available in other systems.

SCI will obtain this information from the data repositories (either centralized or distributed) as the product moves both intra-company and from one trading partner to another. Each movement will

create the event data, as discussed earlier, with its associated serialized package (pallet, case and unit). Companies will be able to use an SCI type application to access that data and provide product information to the areas of the supply chain and business operations that desire it most.

Forrester comments that: "SCI is the convergence of products and services enabling companies to leverage 'rear view' performance management, real-time Supply Chain Event Management (SCEM), and forward-looking predictive analytics to gain meaningful insights. An extension of traditional business intelligence (BI) solutions, SCI includes data structures, preconfigured metrics, and role-specific views to supply chain end users."

This event data and SCI can provide visibility at a granular level you've never seen before. The SCI application provides the required access to the data. But visibility is just the first layer of the opportunity (see Figure 2). As you gain consistent event information and build patterns of process and supply chain behavior, you will be able to address the frequent "exceptions" that cause many pain points today. Many "lean" and "JIT" supply chains have limited capabilities in their response to the exceptions that happen in the real world of product movement between multiple trading partners. As a result, it can take great effort to resolve those exceptions. As most supply chain managers know, the first questions asked about each exception event are: what, where, when, and why? As the intent of EPCIS events that would accompany the pedigree and serialization, it should sound familiar. Serialization can provide you with an unprecedented level of detailed data. One that is associated with key events and, depending on your technology, relayed in a near real-time status. And again, with the right SCI tools in place, you will be able to make certain decisions automated, based on specific types of events.
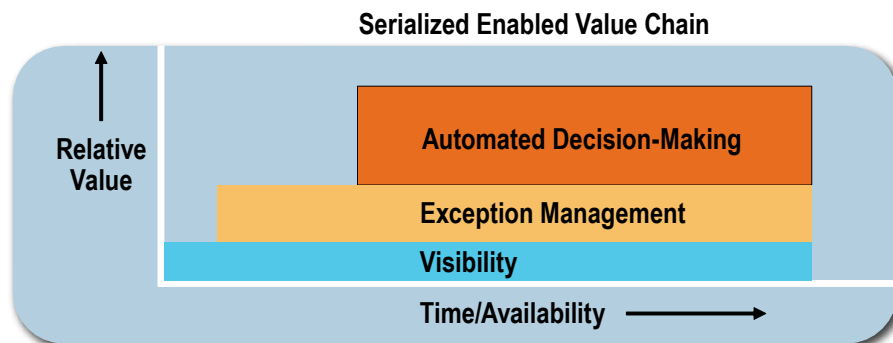

Serialized Enabled Value Chain

Automated Decision-Making

Exception Management

Visibility

Relative Value

Time/Availability →

Figure 2: Event Visibility as a Foundation

There Will Be Challenges

With the sheer volume of data you can expect, sorting, extracting, and using it strategically to improve your supply chain is critical. For example, a single bottling line can generate 7 million - 18 million serialized units in a year. If you are a one-product company with one packaging line these numbers may not be too daunting. However, if you have many products, each with multiple packaging configurations and unique SKU numbers, you will quickly start to see the scope of the data you are dealing with. And if you are in the pharmaceutical industry, add in pedigree data and the events associated with the product movement and the numbers start to grow significantly.

Another challenge is data access. For example, envision your serialized item as it reaches a pharmacy chain. What needs to happen so you can see the e-trail of product events associated with its pedigree and the saleable units? A recent HDMA report titled "Rules of Engagement" suggests using various levels of "local registries" would enable access to the data through a main trading partner (e.g., wholesaler) and that trading partner would then allow others access as needed. But HDMA admits there are challenges associated with this type of approach. Whether the perspective by this report is the best route to follow is yet to be determined. The GS1 Healthcare group and the pending federal law (H.R.5839) will both have influence on the model that industry eventually adopts.

And how collaborative is collaboration? In a trading partner relationship, if the data falls short of your expectations, will your trading partner be willing to provide the additional data you need to make a significant impact? Can you in turn provide data (beyond the serialization/ events) that can improve your partner's supply chain? This is where adding data to the negotiation process comes into play. But these discussions need to happen as early in the design as possible so your data needs are not tied to the expiration of current contracts. In a broader sense, consider designing your distribution network to fully engage with your major trading partners. What is downstream visibility worth to your organization? The value may differ based on product profitability, business impact, life cycle, etc. Therefore, segmenting your product base and linking it to your track and trace/serialization strategy will help you unlock additional opportunities.

Think Ahead – Act Now

Now is the time to lay your foundation for where you will be, and what you want to be able to do, in two-three years. Your serialization efforts will give you access to volumes of data but unless you determine how you can use the data both internally and with your trading partners to create value across the supply chain and across other business functions, you risk losing market share to those who do. In addition, you are losing visibility, which exposes you to the risks of counterfeiting and diversion, the costs of an inefficient supply chain,

and potential erosions in profits. Beyond the projected impacts of serialization to your core supply chain processes such as demand-planning, purchasing, manufacturing, logistics and customer service, the knowledge you gain through serialization throughout the process is key. It will provide detailed supply chain intelligence, and used wisely, a much-needed competitive differentiator in a continuously pressurized market.

Regardless of how the data access model unfolds you may want to consider adopting collaborative purchasing agreements between your trading partners. The data exchanged will now become part of the negotiation portion of the buying/selling process. The serial number section, which contains product information, along with the corresponding EPCIS events data, can provide value to the serialization-enabled business. The serial number/EPCIS data, when interpreted correctly, will provide key insight regarding the history of that pallet/case/item for your trusted trading partner. This is where performance analyses can make a difference. The face value of the serialized data alone will have limited value.

Start With the End in Mind

As you blueprint your complete e-pedigree and serialization project or your supplier compliance initiative, look at the end game and how you want to get there. There is an old adage that says, "You can't get there from here but you can get here from there." Visualize your company and supply chain in two-three years and what you want it to be like. Now look back at what you did to get "here from there." Did you take the minimalist approach by simply implementing the basic technology to be compliant? Or did you look to the future and think about how you could improve both your business and your trading partner relationships by collaborating and truly leveraging your serialized data appropriately?

Adopt a strategic approach as you align your metrics and KPIs across multiple enterprises, interpret serialized data, and transform the data into knowledge (and power in the marketplace). As you review the data/events, map out the value to your supply chain and then determine how you will specifically use it to gain advantage. To derive value from the data, you must invest in analytical resources. Supply chain organizations today are grossly underinvested in this area, limiting their insight into forecasting and demand planning. Forward-thinking companies, however, can seize competitive gains by analyzing downstream data and applying it strategically across their organization.

Do the minimum to simply be compliant and you will receive the minimum benefit, if any. The approach you take now will determine what return you receive. Design a value extraction approach and gain the competitive advantage you need. The intelligence you are about to gain access to should not be lost in a data warehouse or storage repository somewhere. Start now. Assess the value of your serialized data and how your supply chain and entire business can benefit. The choice is yours. There are two approaches – wait and see or visibility and value.

About Clarkston Consulting

Clarkston Consulting is a different kind of management and technology consulting firm. We deliver a unique experience for market leaders within the Consumer Products and Life Sciences industries. Considering professionalism, expertise, and value as prerequisites, we take service a step further through our unyielding commitment to the success of people as individuals, both our clients and our employees. By combining integrity, adaptability, and a whatever-it-takes attitude, we have achieved an extremely high rate of referral and repeat business and a client satisfaction rate of 97% over the past five years as measured by The Conference Board.