Securing the Life Line

Mass Serialization Strategies for the Pharmaceutical Industry

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ChainLink Research, Inc. is a Supply Chain research organization dedicated to helping executives improve business performance and competitiveness through an understanding of real-world implications, obstacles and results for supply-chain practices, processes, and technologies. The ChainLink Inter-Enterprise Model is the basis for our research; a unique, real-world framework that describes the multi-dimensional aspect of links between supply chain partners.

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Acsis delivers end-to-end products, solutions and services that help pharmaceutical manufacturers and distributors ensure safe, secure and efficient supply chains.

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Executive Summary

Six million counterfeit cosmetics/personal care products and 1.2 million foodstuffs and beverage products were seized at the European Union (EU) border last year. In addition, counterfeit medicines had 2.7 million products stopped at the border. Stateside, U.S. Customs and Border Protection’s (CBP) Office of International Trade announced that the domestic value of counterfeit and pirated products seized by CBP and U.S. Immigration and Customs Enforcement (ICE) increased by 2.7 percent in mid-fiscal year 2008 over 2007.1 And, according to Department of Homeland Security’s (DHS) Secretary Michael Chertoff, “failure to protect intellectual property rights costs the US economy $200-250 billion a year.” That is a staggering impact to the global economy. And hidden behind the economic numbers are the tragedies of loss—lost lives, sickness, jobs and innovation. What is causing this huge increase?

Globally, major enterprises have sought low cost country sourcing as a major strategy. For example, as of 2008, 460 of the U.S. Fortune 500 companies have operations in China. These firms market in China, and also ship directly to US distributors and retailers. India expects their drug manufacturing presence on the global basis—mostly manufacturing the US and EU pharmaceutical patents—to grow to 50B, becoming 11%2 of the total world drug supply by 2011.3 This could be a concern, although 86% of the customs seizures are from Chinese sources today.

In spite of concerns in developed nations about these issues, many fake drugs are sold in the world’s poorest countries where price sensitivities are felt most keenly. The cost of recovery to industry and government is increasing significantly on a global basis. “Fake medicines are reckoned to account for almost 10% of world trade in medicines.” 4 And firms are turning to the already over-burdened FDAs and law enforcement organizations to deal with the worst offenders.

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1. Between FY 2003 and FY 2007, the domestic value of seizures for violations of intellectual property rights rose 109% — that’s from $94B to $197B.
2. Product share varies from 11% to 30% depending on product.
3. A good example of what is happening is the drug Lipitor, which will come off patent shortly. It takes less than 2¢ to make branded Lipitor in India vs. 10¢ in other markets. Generics could take the world by storm.
4. EU Report
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Solving the problem earlier in the supply chain would be a more effective approach—containment at the source—before tragedy strikes and huge costs of recovery are incurred. And if a breach does occur, to be able to trace it quickly to the source, rather than a catastrophic disruption of the world supply of foodstuffs and valuable, sometimes life saving, drugs. But in order to do this, we need significant changes in process and technology deployed by companies themselves—creating item identification and then tracking those items through the supply chain—mass serialization. Attention is mounting by government and industry, and many efforts are either in use, in pilot or being legislated.

Containing the damage—both human and financial—are real goals for the global pharmaceutical firms and governments. The enterprise has a lot to gain—both strategically and quantitatively—by taking this next step in data management and product tracking.

But gaining value from mass serialization strategies takes preparation. In this report, we will discuss the concepts, obstacles and benefits of Mass Serialization in Pharmaceuticals, Food and Beverage industries.

5. 2008 disruptions and recalls have cost US food markets over one half billion dollars, not including tax payers’ costs from FDA or USDA expenses
6. Tractability is the law in the EU for food; and pharma and food traceability is the law in Canada. Pharma ePedigree is the law in the US, but techniques vary by state, with the most stringent in California.
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We have a rising concern about the authenticity and safety of the global pharmaceutical and food suppliers—our very life lines!

We are concerned about sourcing from illicit chains. But many issues arise out of purposely designed, yet poorly monitored supply chains that lack visibility. Only 67% of the firms in our surveys of the Life Sciences industry indicated that they use some kind of documented methodology with their direct, tier one suppliers. This surety rapidly falls off as we look upstream, to a very poor showing of 34% of tier two suppliers and beyond—visibility and documentation of requirements.7 And survey respondents indicated that over 90% of recalls where caused by supplier errors of some kind.8 In addition, significant loss of life saving products occurs due to improper handling in the distribution chain.9

Clearly, although we talk about visibility, risk management, quality, and performance optimization of the supply chain, the reality is that the information we collect and share is not enough to manage risk in today's global chains. The data you collect today is insufficient to solve the problem.

In another survey,10 we asked hundreds of companies about the importance of having a distributed database with multiple instances, tracking their products, with technology to synchronize the data across these multiple instances. Seventy seven percent of our respondents believe that multi-instance, synchronized databases are key to sharing information across the supply chain. Clearly, there is a gap between the stated goals and the current reality. But that will change in the next few years.

There is a rising crescendo of consumers, government agencies and enterprises that have identified securing the pharmaceutical chain as a top priority. More funding by FDAs around the world, government agencies and organizations,11 as well as the

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7. Many ingredients in the pharmaceutical and food supply chains come from the unsecured and less stringently regulated chemical industry and ingredients that were never made for human consumption are showing up in our food and medicines.
9. Failure to document and identify items, their storage and handling requirements, temperature requirements, their location, and management of the chain of custody. Upstream, many ingredients that ultimately become a pharmaceutical are volatile compounds requiring the manufacturing and delivery to be in unexacting conditions, as well.
11. WHO, OECD, IFPMA, WTO, Pharmacia, The Board of Pharmacy, the Pharmaceutical Security Institute, Coalition Against Counterfeiting and Piracy, SFDA (China’s FDA), Interpol, FDA, USDA, Department of Home Land Security, and various states in the United States, most notably Florida and California.
companies with so much to lose—in brand, reputation and recovery costs—are seizing
the moment.

Government action is growing, with California and Florida laws, as well as DHS, EU,
and WHO. Also, the US Customs has coordinated the opening of the National
Intellectual Property Rights Coordination Center (IPR) to deal with counterfeiting, piracy
and other IPR violations. Since most of these are international in scope, Interpol has
taken an active role in tracking and apprehending criminal counterfeiters. But
organizations such as these only have so much person power, scale and reach. So we
must seek other solutions in our medicine chest of remedies that can scale.

**Remedies**

Mass serialization is seen as a solution to traditional supply chain problems, as well as
product integrity issues. Leading firms have been driving towards both data and
technology standards in the industry for many years. The journey continues with the
most recent evolution, the California regulation by their Board of Pharmacy. But wheels
have been in motion for many years. This initiative won't be the last. And compliance
issues are poor motivators at best. As stated above, the problem has gone global.
Therefore, although this is a really interesting development, broad thinking must be
applied. It is interesting, however, to focus for a moment on this initiative.

So briefly, what is California’s remedy to these concerns? In order to prevent illicit
medicines from entering the market place, then moving on to patients, the regulation
requires that all medications sold in the state of California have a unique, serialized
identifier that can be electronically read for the purposes of authentication. In addition,
the pedigree data must be collected so that compliance audits can be conducted and, in
case of incident, tainted products can be isolated and traced. Solutions recommended
are 2-D barcodes or RFID. Pedigree reporting is an FDA mandate, as well, so although
technologies evolve over time, the timely collection and availability of the data becomes
the real objective here. Later in this report we will discuss, in more detail, how this
should be done.

It is interesting to note that, though quite progressive, this California concept is similar
to other RFID programs envisioned by Wal-Mart, the DoD, EPCglobal and others. For
high value items there must be consistency in labeling, data management, etc. and the
data must be transmitted downstream to the recipient trading partner (in the form of an
advance ship notification). Right now there are debates on how to modify regulations in
the food industry to take traceability to the next step.
Companies that are obsessive about data—clean data—timely data—(Wal-Mart and Dell come to mind) invest heavily in the unglamorous “grunt work” required to get timely and useful data, and usually reap considerable benefits. The hard work of cleaning data, and convincing your partners to do likewise, is a pre-requisite for global success, supply chain effectiveness and security in today’s global supply chains. But it can’t be done manually—it’s too massive, and firms are just too ‘international’ in dealing with language and educational barriers across the world and across the workforce. Eliminating manual processes that introduce errors can be a huge help here!

“We need better, actionable information, not just more bad data.”
Interveiwed executive

“Real threats and errors come one pill at a time”, one interviewed executive told us, item level intelligence—or fine grain data is his goal. Knowledge of the life of the product, from raw material—where many impurities are introduced—through to the last inch, is the goal now. This requires not so much of a technical challenge—though there are investments to be made—but a willingness to take a fresh look at systems, data bases, integration programs and APIs, as well as on the ground processes and techniques that collect that data. It is interesting to note that the California ePedigree requirements—the most progressive to date—do not stipulate the type of technology required. They are focused on the data—what data and when and where it is collected to assure a secure traceable and auditable supply chain and a safe product. This is the fine grained data provided by serialization. The vision for this is not new.
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**WALKING THE PROCESS TO IMPLEMENTATION**

How can we make it work, what should we focus on? How must we work with trading partners on these issues? Let’s look at the end to end process in figure one.

Once we put a structure in place, as illustrated in Figure 1, what can we do with it?

Most firms are still mired in thinking of data as transactions vs. information that can help manage business activities and events. Supply chain activities are filled with a world of physical events that happen between the traditional transactions. This includes data about the objects—raw material, products, people, etc., and their condition—location, temperature, direction, etc.

The next leap in the granularity and timeliness of available data enables a number of capabilities as show in Table 1. Here we also share results from several surveys we have done on the use and value of RFID and also data sharing methods across the supply chain.
### Table 1 - Mass Serialization/Tracking Data and Benefits

<table>
<thead>
<tr>
<th>Capability</th>
<th>Comments</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alerting</strong></td>
<td>This data can be used to alert appropriate parties when things are not going according to plan. It can help in detecting failures earlier by looking at auto-captured data and analyzing the reason for failure. The earlier you know something went wrong, more choices available for mitigation and containment.</td>
<td>Reduce time and cost of recall. Reduce impact of recall. Effective mgmt of recall process. Reduce time. Improve/save the brand!</td>
</tr>
<tr>
<td><strong>Process / Environmental Monitoring</strong></td>
<td>Environmental monitoring is another area that is industry-specific—almost 40% of Pharma Mfg and 29% of Aerospace firms plan to share environmental monitoring data (temperature, humidity, shock, etc.) with trading partners. These vertical segment differences illustrate how data-sharing differs for different industries, depending on their needs.</td>
<td>Containment. Reduce errors. Improve product quality.</td>
</tr>
<tr>
<td><strong>Process Improvements</strong></td>
<td>Analysis of auto-captured data can be used to improve the end-to-end processes and to look for excess dwell times, unnecessary handling, poor execution, etc. The rise of RFID has encouraged the development of these types of analytic tools.</td>
<td>Cycle time reductions. Quality improvements. Productivity. Handling improvements.</td>
</tr>
<tr>
<td><strong>Electronic Proof of Delivery</strong></td>
<td>Sharing of auto-captured data can increase compliance with retailer/customer requirements, as well as reduce time and energy wasted in dispute resolution.</td>
<td>Reducing charge-backs. Administration.</td>
</tr>
<tr>
<td><strong>Lot/Batch Tracking</strong></td>
<td>Plans to share lot and batch tracking data were surprisingly high—on average 32%—and especially high in industries like Aerospace &amp; Defense (65%) and Pharmaceuticals (45%), where traceability is key. There are a number of different problems being solved by sharing this kind of data. The problem being solved has an impact on the requirements (equipment, process, infrastructure).</td>
<td>Product Integrity/ Quality. Reduce cost of recalls. Mgt Reporting.</td>
</tr>
<tr>
<td><strong>Regulatory Compliance</strong></td>
<td>Highly regulated industries like Aerospace and Pharmaceuticals collect reams of data and expect to share more of this data with supply chain partners to ease overall supply chain compliance. Many firms today are updating their codes of conduct, their compliance manuals, and conducting more audits within their supply chains. Government funding for regulatory personnel to do more inspecting, as well as new forms of legislations are being contemplated regularly across the globe. Trade management systems (import/export, tariffs, duties and reporting) can also use this kind of data, and firms can assure that they are complying in a timely way with global—ever-changing—customs regulations.</td>
<td>Use technology and data collection techniques to reduce the time and cost of reporting. Audit preparation Fast lane status.</td>
</tr>
<tr>
<td><strong>Expiration Mgt</strong></td>
<td>For limited shelf-life products, the batch number may be used to determine EOL and help enforce FEFO (First Expired First Out), FIFO, not sell after sale date or other inventory management disciplines across the supply chain. This may require various supply chain partners (e.g. 3PL, distributor, retailer) to capture, monitor, communicate, and act on expiration data.</td>
<td>Reduce obsolescence. Reduce returns. Improve replenishment planning accuracy.</td>
</tr>
<tr>
<td><strong>Returns</strong></td>
<td>Lost in the forest of returned goods is real profit or loss. Many firms suffer from receive goods they did not sell, nor build. Yet they now have to incur the costs of handling, refunding, repairs, delivering, etc., these goods.</td>
<td>Reduce cost of returns.</td>
</tr>
<tr>
<td><strong>Recall Mgt</strong></td>
<td>Recalling tainted or defective products is a challenge common to many manufacturing industries. If the distribution of batches/lots is not tracked through distribution and retail channels, then recall cannot be done precisely, requiring costly general recall of all products. Lot tracking throughout the channel is currently not done effectively in Consumer Products, Food, Pharmaceutical and other industries.</td>
<td>Reduce impact of recall. Effective mgmt of recall process. Reduce time. Improve/save the brand!</td>
</tr>
<tr>
<td><strong>Failure Analysis</strong></td>
<td>When a part fails, the manufacturer may want to trace it back to the manufacturing lot in order to analyze the reason for failure. This information may also be used in decisions about whether to recall the rest of the parts in that lot. This requires that the service partners who are doing repairs and maintenance are diligent and accurate in capturing and communicating “as serviced” information when they swap out parts. Auto-captured information, barcode, or RFID, can reduce the errors in entering this information.</td>
<td>Rapid diagnostic and recovery.</td>
</tr>
<tr>
<td><strong>Service/Warranty</strong></td>
<td>Establishing and managing warranties, service history, etc. Feeding data to service and quality systems.</td>
<td>Reduce time/cost to repair. Establish correct ownership (avoid warranty/repair for units not mfg by company).</td>
</tr>
<tr>
<td><strong>Supply Chain Planning</strong></td>
<td>Inventory visibility allows firms to better predict when and where to replenish product. It allows them to assess all types of merchandizing issues from displays, to distribution patterns, etc.</td>
<td>Accurate and timely source data.</td>
</tr>
<tr>
<td><strong>Authentication Services</strong></td>
<td>Of course, as we are discussing in this report, authentication protects all members of the supply chain from acquiring counterfeits or purchasing expired products.</td>
<td>Brand protection. Customer protection.</td>
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Challenges and Obstacles

Even with pending compliance and concerns around brand erosion\textsuperscript{12} and consumer protection, certain challenges remain. First, across enterprises in the pharmaceutical supply chain, there has not been an agreement on standards.\textsuperscript{13} EPedigree, per se, does not require RFID frequency standards, since firms are expected to work these issues out amongst themselves and also collect and manage their own data. But it does stand to reason that we need to read and write (based on security restrictions, of course) our trading partners’ labels.

The main challenge, therefore, is that the mutual parties need to agree on approaches—the basics are already there. Most firms already use barcoding and have agreements on types, location of labels on shipping units, etc. But in order to leverage this investment to gain an economical advantage, more data, and some process changes do need to be agreed on.

In addition, firms told us that they had issues, such as infrastructure maturity and readiness, and are still doing or recovering from other IT projects such as major ERP roll-outs,\textsuperscript{14} mergers, establishing new plants, etc. that zap the attention and time of the enterprise.

More interestingly, many firms are truly looking at the issues of sharing multi-tier, multi-enterprise data and grappling with the challenges and barriers—how to make sense of the data and looking across the supply chain to understand what is it really telling us. These learnings take time. But some dramatic cases have come forward with expected and unexpected benefits.

Another aspect is the priority placed on this endeavor. For many firms, these types of projects are not a high priority, and some executives are not convinced that this will address the market problems that we have discussed. However, from firms that have gone forward, we have seen striking benefits that can be gained beyond compliance. Brand protection and risk mitigation are a high priority of CEOs in most global firms.

Is building stronger relationships a benefit or an obstacle? The oft-repeated issue of trust was hands-down the most frequently and forcefully raised obstacle to sharing data. Getting past this barrier is one of the biggest hurdles to changing the business model, as illustrated by various comments from our surveys: “\textit{This will take some time from a philosophical perspective—trust and protection of intellectual issues will need to be addressed.” \textit{Point-of-use data may be proprietary and players may not necessarily...}
be willing to share this with others.” “Standards are one thing, but then sharing environmental or process data up the chain will be a whole different hurdle to cross.”

These types of data sharing lead to a more intimate group of trading partner strategies, where firms can work to solve, step by step, their mutual problems and gain benefits together. Collaboration and coordination—no easy task—among key players in a product supply chain can then be enabled by leveraging standards and incremental, but directed, investments.

More than Compliance -- Getting the Benefits

Although we have focused much of our discussion on the compliance and security issues, most businesses have a way to go in improving their supply chain effectiveness. If the old adage of 'garbage in, garbage out' is still the sad refrain, could we not significantly benefit from improved decision making from accurate—at the right level of granularity—data?

But the hard questions keep surfacing—show me the money! Ask yourself, how would my process or business benefit from more granular, accurate and timely data? We asked and were impressed by benefits gained. Some areas of demonstrated improvements:

- In the distribution process, improved inventory management processes—rotation, FIFO methods, reduced losses and shrinkage, reduced spoilage and obsolescence.

- Warehouse management—improved order fulfillment, productivity, data accuracy and reduced shrinkage.

- Transportation—trace and track has added value of managing merge in transits, reallocation of inventory to other locations by using ASNs. The ASNs can be leveraged through these types of bar-coding and RFID projects, which can improve yard management, inbound receive, shorten cash to cash cycle times and reduce charge-backs (what to say of tedious debates on proof of deliveries, etc.)

- Once goods are labeled, a whole host of other systems can be supported in the clinical environments—more accurate dispensement of drugs is key, reducing medical errors.

- In the retail setting, improving point of sales and customer experience, as well as store operations systems is already in use.
Securing the Life Line --

Overall supply chain systems benefit from visibility across the supply chain as goods move through the distribution systems aiding in sales, replenishment inventory managing and manufacturing systems.

This discussion, and the solution to the many issues surrounding a more secure and safe life line, needs to be addressed in an atmosphere of partnership. Many firms invest much time in establishing collaborative supplier networks and refining their eco-system relationships, then improving their compliance programs, because it works—not just for the brand protection—but for improving their mutual go-to-market opportunities. Tighter, more compact relationships with trading partners are impossible, though, to manage without facing up to the data standards and technology issues.
Conclusion — Time to Act?

Mass serialization is the next step on the journey that firms have embarked on over the years in data standards, barcoding, EDI, collaborations, etc. Although many firms have not worked the level of granularity that we have been talking about in the upstream supply chain, package and item level labeling does get done in the supply chain, but usually at the retail or clinical level. So, what we are talking about now is a redistribution of work, but one that will lead to a more effective over-all supply chain as well as a more secure life line.

WHERE THERE IS SMOKE, THERE IS FIRE!

At this point, we would be hard pressed to find a government agency that has not had a hearing and is not contemplating some form of legislation on more rigorous traceability in the U.S. China, a major source of pharmaceutical supplies, has over five thousand low cost producers of pharmaceuticals and over twelve thousand distributors, who are basically unregulated, and the effects of this laxness is being felt world-wide.

Around the world, legislation on selling counterfeits, and enforcement of associated penalties is so lax as to be laughable. However, government actions will be centered on increasing the penalties as well as securing the process. Agencies involved in monitoring and recovery are demanding larger budgets, which ultimately lead to more regulated environments—prevention—versus post event investigations.

A word about the role of government—is it friend or foe in this journey? The role of government as catalyst is so important—it is the one unifier and leveler of the playing field. To comply, all players need to invest at least a minimum. Further investment is then optional, but the whole industry must then act on a fundamental level. Private money follows compliance and regulations ensuring a real market to sell solutions. For a manufacturer or distributor, it is advisable to get involved in consortia, standards works, and attention to regulatory meetings etc., which can allow firms to get their needs attended to.

15. Many consumer products today already use this technique at item level.
16. Beyond agencies mentioned earlier, HHS (Health and Human Services) and their office of special legislation the GAO (Government Accountability Office); various congressional committees: the ERS/USDA (Economic Research Services of the USDA); USDA’s FSIS (The Food Safety and Inspection Service); the US Senate Committee on Commerce Science and Transportation; The U.S. Consumer Safety Commission; the US Treasury; and of course the FBI, CIA and DEA. Outside the US: Europe’s MHRA (Medical & Healthcare Products Regulatory Agency – Formerly Medicine Controls Agency.) which is responsible for monitoring and enforcing regulations in the EU; China’s SFDA (State Food and Drug Administration), China’s FDA.; and Industry groups like US Pharmacopoeia (USA) which makes recommendations for the manufacturing, packaging and distribution of pharmaceutical products. Once approved, these become enforceable by law and create a framework for the FDA validation, EPCglobal.
18. To assure that firms don’t have a competitive disadvantage from regulation.
**PROTECT THE BRAND!**

Consumer protection is the first order of business. Therefore, protecting these *life lines* is critical. Each consumer incident raises the awareness of society and increases the costs of recovery. No doubt, ROI is important to firms, otherwise they would not have been seeking low cost country sourcing. But that has opened the door to the vast illicit supply chains, that can act with more or less impunity, leaving the brand company to deal with the aftermath.

The Pharmaceutical industry has a lot to lose. With blockbuster drugs so elusive, the impact of ‘imitation’ is destruction of the brand! So, compounding costs of market losses, recalls and recoveries, the benefits of taking the next step can be clearly justified.

I generally find it amazing, knowing full well that most mega trend endeavors are never finished, that firms fail to grasp the ‘journey vs. destination’ concept. The leaders do. They begin, learn, refine and move forward, evolving, acting vs. over studying. Knowing that many of your products come off patent and get commoditized or are OTC already, *it is really your brand that makes the sale.* Imitators, counterfeiters and errors can rob that brand and your full position, therefore, in the market place going forward. It is no accident that the leading brand companies have been on the RFID journey since its inception. And it is no accident that companies obsessed with data management generally lead in their category—customer data, supply chain data, product data, and the analysis and refinement of that data.

Today’s global supply chains in many ways are accidents waiting to happen. You may outsource, but you don’t outsource the accountability and responsibility to ensure a safe and secure supply chain.

*Five years ago, the cold chain requirements were simpler— “The insulin needs to be cold.” Now the requirements are much more exacting. We are required to monitor the temperature range and prove that it has been maintained throughout the whole journey from factory to pharmacy.*

IT Director, Major Pharmaceutical Company
“Understanding expiration data is critical for short life products in healthcare. For example, we never want to waste blood products, some of which have a life of 42 days. Small hospitals, with less frequent consumption, typically need the “long dated” product, the units with almost the entire life left. But a big hospital can use short dated products. They can buy blood with less than 2 weeks of shelf life at better prices. The real answer is not just knowing that a unit is going to expire, but how are you going to channel those products to where they will get used before expiration. Creating the visibility is helpful, but you also need established protocols, for example letting smaller facilities rotate out the short date units that won’t get used in time and send them to a place where they will be used. You have to understand the utilization patterns, each hospital’s inventory levels and consumptions. In a perfect world, you would know where all the product is at any point in time and where to send it.”

SVP, Major Healthcare Group Procurement Organization
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