RFID in Pharmaceuticals—
An Idea Whose Time Has Come

The discussion has moved from *if* to *how* for many major pharmaceutical manufacturers. The barriers to adoption are down and the benefits are up. So you may have a good reason to look at solutions now.

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Introduction

It seems every Pharmaceutical and Life Science conference and publication has something about product quality and the benefits of effective cold chain management, serialization, and product traceability. And that's good. The conversation has begun. But with California's e-pedigree regulations for 2015 looming, and increased growth in temperature sensitive biopharmaceutical products, major pharmaceutical and distribution firms have been declaring their plans to implement serialization and case/carton level RFID.[1]

There are a number of catalysts to adoption, including the many real and growing concerns (see figure 1) that RFID can solve for the industry. In aggregate, these concerns provide substantial motivators to act now. The Center for Medicine in the Public Interest (CMPI) stated that in 2010 $75B—that's billion—of revenue was lost due to counterfeits in the US alone.[2] And that does not include the potentially life-threatening impacts on human beings, what to say of the costs for investigation, recalls, insurance, and damage to brand and trust. Government agencies across the globe have declared stricter regulations and have stepped up their vigilance. Violations span from the merely mundane (such as improper labeling) to life-threatening events such as counterfeit ingredients that are not effective or cause death.[3]

Growing Concerns and Drivers for Pharmaceutical RFID

Risk Management:
- Anti-counterfeiting and Diversion
- Quality/efficacy
- Patient Safety
- Custom Control--Border Seizure Cost $500B+ loss to the industry

Regulatory/Compliance:
- EU - Good Manufacturing Practices and Good Distribution Practices
- FDA Globalization Act of 2008 and associated regulations
- California SB1307

Figure 1 - Drivers for Pharmaceutical RFID

In addition, the cost of managing the global pharmaceutical supply chain is astronomical. From the global economies to the local municipalities, as well as healthcare providers and payor organizations are all putting pressure on the industry to reduce costs. That won't happen without a granular (stockroom and shelf-level) yet global view across the chain. A lesson learned from industries that have more integrated supply chains is that 30% to 50% of supply chain costs can be cut while increasing their services and markets. That means real profits. Profits that can be put into innovating the next generation of life saving cures.

Early projects at many companies have centered on implementation of packaging lines. But for e-pedigree, with its inherent supply chain requirement, cross-enterprise solutions have been created that are often now part of the pharmaceutical industry's projects. These inter-enterprise solutions hold the key to moving from merely a compliance project to one with significant additional benefits in cost reduction, increased sales and, of course, patient safety.[4]

The discussion has moved from *if* to *how* for many major pharmaceutical manufacturers. Those who have not had a fresh look at RFID in the last year or two may not be aware how far the industry has come. The barriers to adoption are down and the benefits are up. So you may have a good reason to look at solutions now.

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[1] J&J, Pfizer, Biogen, Mylan, McKesson, Sanofi-Aventis, Teva Pharmaceutical, Cephalon (also owned by Teva), Astellas Pharma, Eli Lilly, and EMD Serono, to name of few.

[2] You can get more information on issues in trade and counterfeiting from the CMPI site here.

[3] In the last few years, as inspection techniques have improved, US Customs has had a year-over-year increase in border seizures of about 10% each year. Their last report showed around 25,000 seizures of counterfeits.

[4] You can read more on benefits of serialized data here or temperate sensitive/cold chain technology here.

In this article we will discuss these issues and the changes in the RFID industry that have taken it from a technology in isolation to solutions for the enterprise and beyond. We will discuss:

- Moving from technology to solutions: How RFID technology and markets have evolved.
- How the RFID solutions providers and user community have reduced barriers to adoption.
- Inter-enterprise solutions: Raising the value proposition for RFID in the pharmaceutical industry.
- Conclusions: Thinking beyond mandates and getting started.

Stage 1—Moving from Technology to Solution

Technology Maturity—From Science Projects to Solutions

It is worth a brief discussion on how technology evolves to create a market of scale. These concepts have been discussed in the past from several vantage points,[5] but have never been adequately discussed in a multi-enterprise, supply chain context. That has relevance in e-pedigree and cold chain applications. We will use this four stage model (see Figure 2 - *Market Development Stages*) as a reference point through this article.

Market Stages	Market Factors
Stage 1 Engineering Phase	"Science experiment." Early stage customers validate the technology and speculative use cases.
Stage 2 Component Integration Phase	Early adopters and visionary customers provide revenue and expand/validate use cases.
Stage 3 Solution Maturity Phase	Solution for Enterprise. Integrated, packaged and Interoperable.
Stage 4 Network Phase	Inter-enterprise. Cloud with mobile end-points to integrate across the network. Designed for on-boarding trading partners and serviceability.

Figure 2 - Market Development Stages

Promising technologies enter the market—Stage 1—with early adopters who often get engaged in solving the technical challenges with the inventors. If a value proposition is achieved by the customer and the inventor has the ability to scale, the market may advance. In Stage 2, a growing ecosystem of implementation tools, partners, and approaches solve larger projects and broader use cases. This

[5] A technology adoption model was first posited by Everett Rogers, a sociologist, in his 1962 book "*Diffusion of Innovation*." This idea is often erroneously credited to Geoffrey Moore, author of *Crossing the Chasm*. Sociologists and economists actually have important insights on whether a certain technology will reach mass adoption, often more so than technology inventors themselves. Other interesting models include: The Capability Maturity Model and the Technology Readiness Level proffered by the US government as a method of assessing and assuring risk reduction in the adoption of the technology—in essence, will the technology being considered work and will it be safe in operation? There are some business maturity models out there that try to position an end-user organization's taste for technology and its success at deploying and transforming itself through technology.
These models are interesting, and they are good at representing observable market behavior, but they don't tell us why something will or won't be adopted. Assuming that products that reach certain investment thresholds are useful, there has to be a driving, sustaining business value—for both provider and customers—and a low barrier to adoption. In other words not too many inhibitors and lots of catalyzing factors.

For B2B processes that involve multiple enterprises—such as financial/payment, supply chain, e-pedigree, product integration, and quality management—a more relevant model for adoption is the *network effect*, where the value of a networked solution goes up as the number of end-point members of the network increases. Of course this network effect is mirrored after the economist *economies of scale*. Scale is often catalyzed by technology. Technology helps improve utility of the product, reduces the cost of production, and thus the cost of adoption. Economies of scale and also Moore's Law—the price performance curve of devices—all are relevant to thinking through the RFID adoption market. Mass adoptions of specific technologies in supply chain are also influenced by the need for standardization. Solutions need to comply with agreed to approaches. Lack of agreement on standards for B2B communications dampens adoption.

ecosystem of players gains valuable, shareable, repeatable expertise and ultimately creates scalable solutions with rich functionality. Then mass market customers—Stage 3 buyers—enter, but only after the 'kinks have been worked out,' there is ease-of-implementation, and lower risks before they purchase.

Not all solutions—or customers—need to proceed to Stage 4, which is the domain of inter-enterprise processes and solutions, such as financial funds transactions and supply chain process. Here the threshold to success is standardization, extremely easy on-boarding, and a critical mass of trading network membership.

Stage 2—Lowering the Barrier for RFID

So how does this apply to RFID in the pharmaceutical industry? RFID has evolved through these innovative stages of increasing power, versatility, and standardization to create strong, integrated solutions. As the market has matured, users have seen a broadening of use cases (see Figure 3), consistent and workable projects, and are now focused on large scale deployments of RFID whose value increases in cross-enterprise solutions.[6]

Use Cases and ROI for RFID in Pharma

Supply Chain
- Cold chain
- Electronic Proof of Delivery
- Recall management
- Safety stock/vendor managed inventory
- Distribution metric improvements, such as on-time delivery and cost improvements
- Supply chain effectiveness through visibility

Sales Enablement
- Inventory positioned in forward distribution and customer locations
- Ease of multi-industry labeling from manufacturing thru retail

Patient/Hospital
- In-hospital accurate dispensing
- Record keeping for controlled substances
- Inventory management
- At home dispensing and treatment monitoring

Product/Financial Planning
- End-of-Life/Off-patent
- Monitoring global supply of finished goods to monitor manufacturing and decisions about EOL

Figure 3 – Use Cases for RFID in Pharma

The RFID technology industry and the user community have invested heavily to discover and reap the benefits of the vision of value. They had to agree on a scalable goal. There had to be an agreed to way to work across multi-site, multi-enterprise problems and solutions. In 2003 we witnessed the DoD and Walmart making major announcements to demonstrate this intent, which further catalyzed the market. Global standards groups[7] have engaged a broader community to create and ratify standards. In particular the pharmaceutical industry has had its own use cases beyond the supply chain goals of the apparel industry. These have become more urgent as US and global regulatory agencies crack down further on counterfeiting and qualities issues.[8]

During the last decade, the RFID market has comprised a cumulative spend of well over $50B on solutions.[9] Much of the funds, along with investor dollars, were plowed back into technology advances, such as dealing with:

[6] The pharmaceutical industry has major cost and efficiency opportunities as it continues to focus on supply chain improvements. For more on this, see Rethinking Healthcare.

[7] From the MIT Auto-ID Center to standards groups such as EPCglobal (now GS1) and ISO.

[8] Recent noteworthy issues from the headlines include: October 2012: FDA shut down thousand of ecommerce pharmaceutical sales sights; China arrested 2,000 counterfeiters and sellers of counterfeit drugs and health products; Oct 8th the Indonesian National Drug and Food Monitoring Agency cracked down on scores of counterfeiting distributors. You can get more of the FDA counterfeit drug reports here.

[9] This is the approximate total amount spent on RFID solutions from 2003 to 2012. This number does not include investment in R&D, by big device and semiconductor companies, or the ecosystem dollars of consortia or standardized group memberships and expenses, market research, media, and conferences. VC investment dollars have topped $1.8B so far. Now that the market is progressing again, we have seen more investors come back into the market.

- ***Readability in challenging environments***–such as water, metal and the ability to penetrate and ensure reads deep within packaging. There has been tremendous progress and innovations to address these challenges, including new antenna technology and innovations in battery-assisted passive tags[10] that can be used to read center-of-pallet cartons (see *Carton-level Temp Tracking for Cold Chain Pharma*). This is especially important to move to item level RFID and for challenging cold chain environments.
- ***Read ranges***—smaller but more capable chipsets, consuming less power, combined with antenna and reader improvements, ensure consistent read rates as well as longer distances (in some use cases consistently greater than 10 meters for passive and 100 meters for battery assisted passive).
- ***Read and write speeds***—being able to read more tags per second, higher rates of encoding (important for commissioning tags on a high speed production line), higher write speeds through software and the innovations above.
- ***More relevant and complete data***—an increase in the size of memories on RFID devices, enabling richer user applications such as pedigree data or service and repair records; and adding sensors to RFID to create richer data—beyond item identifiers—allows for data collection and condition monitoring technologies of vibration, temperate, humidity, and light.
- ***Security features***—innovations here include lowering the power consumption required to do encryption, using the semiconductor's unique and unforgeable physical characteristics to create the encryption key, and other advances to make security more affordable and practical on passive RFID.

RFID readers are having their day too, with improved sensitivity, noise tolerance, and performance, reducing the need for onsite engineering, customizing, and tweaking. Innovations include:

- ***Portability to multiple device form factors—***the combination of RFID with other types of devices—smart phones and embedding into equipment, computers, and mobile devices so that where and how things are read increases in utility and universality. From hard to reach places (fully loaded trucks, inside of machinery), hazardous location or remote environments, fields, construction sites, large yards, or at a customer site—more versatile devices have been developed to assure reading, writing, and completion of a transaction cycle can occur wherever needed.
- ***Ready-to-go readers***—smaller form factors, application-specific (engineered and pre-configured for a specific environment or application), power-over-Ethernet for ease of installation, refinements in antenna design to improve readability.
- ***Locating technology***—smarter algorithms within the readers to calculate direction and location.[11]
- ***Data integration***—connectivity to site operational and communications systems. The maturity of the middleware with the ability to easily collect data from any device, and integrate into any system, allows for universally smarter processes.
- ***Interoperability***—standards-based interoperability, with certification organizations for ongoing interoperability testing, not only makes it easier to mix and match components into a solution, but more critically allows tags to be read as they travel across the supply chain between different enterprises and heterogeneous infrastructures.

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[10] While pure passive and C1G2 only battery assisted passive have experienced issues with reliable read/write through containers/pallets, newer ISO Class 3 (ISO 18000-6:2010) battery assisted passive solutions are proving reliability up to 100%.

[11] There have been many Innovations in locating algorithms. These are often implemented using DSPs (digital signal processing) to analyze and extract information from the incoming antenna signals.

All these innovations support large scale projects and moved us yet closer to 'plug-and-play', easy-to-implement technologies.[12] These innovations focused on devices. But what about applications/enterprise solutions?

Stage 3—Creating the Enterprise Solution

The broader user community really clamors for Stage 3—full solutions! CIOs and end users demand a '*come and solve my problems'* provider market. Many buyers are saying '*I want one solutions provider to come with it all.*'

To address this demand, the Stage 3 RFID providers today have built industry-specific solutions with software and services, not just the hardware, to address specific problems and use cases. Also the traditional applications providers—especially warehouse management, store operations, inventory management, and cold chain systems—have included RFID integration in their solutions. Another option for serialization at the packaging line, site-level serial number encoding, is provided by partnerships between RFID providers (makers of the tags, sensors, and readers) with the pharmaceutical packaging line automation companies (the providers of process and test equipment for the line).

These all have resulted in the accumulation of many solutions and successful projects ranging from the packaging lines, to warehouses, to the hospitals. Today these projects are successful in everyday occurrence.[13] Several key catalyzing growth factors helped firmly establish RFID in Stage 3:

- ***Ecosystem of partners and solutions***—There is now a rich and deep ecosystem of companies to deliver the complete solution required—the devices (chips, tags, readers); the software (middleware, applications, networks) and services (education, certification, label converters, source-tagging services, industry-specific and application-specific consultants, systems integrators and implementers); as well as automation equipment providers embedding or partnering with RFID and software providers to provide manufacturing and distribution capabilities.
- ***Standards***—ISO has approved global standards for all the commercial RFID frequencies. GS1 has industry groups for Retail, Food, Pharmaceutical, Apparel, and other industries focused on Item level issues and the leverage of the EPC UHF standards for successful industry-wide processes.
- ***Industry oriented solutions***—Speaking the language of the customer (the industry focus), application-specific solution providers have emerged with expertise in Food, Pharmaceuticals, Medical Devices, Hospital and at-home medical care—from the supply chain to the consumer.

And what about that one elephant in the room–*price?* During the past 10 years, prices on tags have fallen by about 10X – i.e. a 90% reduction in costs. Reader prices have fallen dramatically as well. This is not only

[12] For RFID, the passage through Stage 2 has really taken about six years. Beyond the technology challenges mentioned above that the industry needed to work on the many lessons learned from user deployments, such as what it takes to integrate, train users, and manage change.

[13] The innovations and investment to get here helped finally push the larger (and smaller) organizations to declare full-scale rollouts such as American Apparel, JCP, Macy's, Bloomingdales, Walmart, Dillard's, VF Corporation, Jones Apparel, Levi Strauss, Li and Fung, and many brand companies across the world from consumer products to luxury goods. Massive adoption has occurred in the mega markets of apparel supply chains (billions of tags so far and growing), public transportation systems around the world (billions of tags), and steady growth across other industries such as auto manufacturing (millions off tags per year).

due to innovations, but the scale of the market. And with scale, industry insiders are predicting yet further drops in price per unit. Thus the life science industries can enjoy the benefits of the scale and therefore cost reductions that have been enabled by the production of billions of RFID tags for other industries in the last few years, along with the supporting technologies that manage them.

All the above increase the enterprise value proposition. For the manufacturer—faster kitting, quality, receiving, manufacturing management, employee safety, and recalls; for the healthcare provider—patient care and safety as well as asset optimization, all benefits that the life science industry is now enjoying, enabling the industry to reach Stage 4.

RFID Enters Stage 4 for The Pharmaceutical Supply Chain

The bigger promise for RFID and of major interest to pharmaceuticals has been cold chain and traceability across the chain. That presents additional obstacles to implementation: engaging trading partners in the conversation and convincing them to invest and implement. That is a key 'stalling point' to chain-wide implementations—a 'reverse network effect' if you will, where everyone waits for the others to go first.[14] Building a joint system needs agreement and mutual benefit among the key players. Without early joint investment, how can things move forward?

These people, process, and policy issues are the biggest obstacle to adoption of supply chain-wide systems. These are not technical issues per se. The issues in dialog and agreeing to go forward just take time. It is a lot of little things, as each company contemplates not so much the purchasing of technology, but organizing and aligning internal teams, stake holders, investment, and the data management between the trading partners. This approach is made more difficult by the one-by-one support required for each and every instance of trading partner integration and systems to support. That can be very daunting for the suppliers.

So, then how is technology breaking the log jam of these inter-enterprise stalling points? Again, the industry has not been sitting still. Further innovations in the industry are enabling adoption. For example:

- ***Cloud-based platforms***—This has several critical elements:
    - *On-demand and subscription-based pricing*—reduce upfront large capital outlays and risks. This enables communities of connected trading partners to share a 3rd party managed platform. An example is the Intelleflex ZEST Data Services.
    - *Cloud database for the mapping of cross-industry data*—an issue for the pharmaceutical industry, which has multiple labels that often pass through several industry standard symbologies (from pharma to retail, for example). Cloud can store and map the data and trading partners can access this data as products move through the supply chain from manufacturing to packaging, distribution, the clinical setting, and ultimately to the patient.
    - *Inference methods*—for the California 2015, this method of aggregating and mapping has the benefit of providing lower cost--2D bar-coding at the item level, aggregated up to a RFID tagged

[14] The reverse network effect is the opposite of the network effect. Instead of "*everyone else is connected so I should connect too,*" it's" *none or so few of my partners are connected, so I'll just wait until they connect before I do.*" This has been the largest obstacle for trace type applications, such as secure supply and cold chains, for example. However, the market has been here before with e-commerce and B2B hubs of various types. Eventually the compelling value proposition and other catalyzing events create momentum.

shippable unit such as the carton, case, and pallet. This aggregated information is then accessible across the supply chain.[15]

- *Interoperable access*—any kind of mobile device or system can access this information.
- *E-pedigree*—a cloud-based platform makes it easier to share the information associated with each chain-of-custody hand-off as product flows between multiple enterprises across the supply chain.
- *Actual real-time condition data*—temperature and other condition data recorded at each stage of the product's journey, regardless of whether the product is being handled by the manufacturer, or a specific carrier, distributor, healthcare provider, or retail pharmacy. Capturing and maintaining this data is considerably easier to do on a shared cloud-based system than on a single company's behind-the-firewall enterprise-based system.

- ***Mobile technology***—Supply chains are defacto out of the office. So while products are in motion, mobile devices can read condition and location-based information, feeding the cloud in real-time through the logistics process. This enables visibility, as well as making midcourse corrections to save products at risk, protecting the patient and the brand.[16]
- ***BYOD (bring your own device)***—BYOD is not just a consumer phenomenon. Contractors, trading partners, and service providers, such as transportation and delivery services, and manufacturer's reps, have their own devices such as GPS, cell phones, tablets, as well as readers that can read and scan and communicate directly to the cloud. This helps with trading partners who may not be ready to integrate or cannot afford to invest in technology at this point.

The cloud is the real catalyst for Stage 4, since multiple user organizations don't have to engage and agree on buying decisions on many technologies such as middleware and multi-layered software, e-pedigree applications, and servers, which they may not be ready for at this time. The cloud helps bypass the need for one-to-one integration with trading partner's systems. Instead, users can connect with a browser over the web. This creates a simpler technology stack and provides cost saving and faster time-to-benefit. Users can subscribe directly to the data. Working with supply chain product data can be fluid. Notifications of urgent issues can be pushed to the appropriate users and standard product data is accessible from anywhere.

Cloud systems in the life sciences industry for serialization and traceability already have the appropriate data models and standards, and often provide prebuilt connections to trading partners. This is important since legacy systems in the enterprise often have brittle data models and programs that are not responsive to the current and evolving needs.

Importantly, connecting directly to the cloud also helps create better monitoring in real-time. You don't have to wait days for data to flow serially from system to system. This is important for the application of cold chain. Users want to know that products are effective and safe *before* they process shipments, stock shelves, or prescribe to patients. If the data arrives *after* the fact, safety and efficacy can be compromised.

[15] Inference relies on a trustworthy system/database/process for associating items with the container they are put into. This association is typically done on the production/packaging line, at the time and place that the items are put into the container. A tamper-evident seal is then immediately placed on the container. After that, if anyone reads the RFID tag on the container (carton or case) and the seal has not been broken, they can infer that the original items are still there in that container.

[16] This helps address the challenge of instrumenting the supply chain. It may not be necessary to invest in a network of fixed readers, peppered throughout the chokepoints of your supply chain, if the workers operating the chain already have a reader in their pocket or on their belt.

Conclusions

Getting Started: Moving beyond the Mandate

The innovation in technology and progress from the business community that has happened should encourage you to look more broadly at RFID as a solution—not just a mandate.

1. ***Solutions-based market*.** Users no longer have to deal with complex technology stack decisions for servers, data centers, networks, and software—all that is replaced with cloud platforms. Industry-specific functional software and analytics have been developed for decision support.

2. ***Cross-functional collaboration.*** These types of projects can get off the ground. Suppliers can now take on a greater role in traceability with nominal disruption to the downstream trading partner. This breaks the stalling point, making it easier to get cooperation and buy-in.

3. ***Funding and procurement of technology*.** In the past, the upfront purchasing process usually involved a drawn-out internal funding, evaluation, and justification process, that often took longer than the actual implementation itself. Users now have on-demand options by which they can quickly procure and turn on the solution. This also helps with inclusiveness—getting smaller but still important members of the supply chain onboard.

4. ***Performance of devices*.** We have moved beyond the science experiments. The kinks have been worked out. We have application or environment-specific devices that just work.

5. ***Pricing and total cost of ownership***. The actual net price of the technology continues to decline. Overall options on how the technology is procured—on-demand subscription vs. upfront capital investments reuse of devices, and leverage of BYOD—all reduce the cost of ownership.

6. ***Cloud vs. code benefits***. Significant benefits accrue to the cloud vs. in-house enterprise software approach.[17] Key to this discussion is reduction in IT investments, as well as reducing the obstacles now and in the future for evolving standards-based information. Integrating with trading partners takes a lot of time and work, so shortening that time and expense is significant.

Next steps: Recommendations

All the innovations aside, new technologies for your organization take time and attention to absorb. So even though you may have future plans for an RFID project, you should consider starting the process now. We interviewed and researched dozens of players in the pharmaceutical industry that are gearing up now. There are many lessons learned to share.[18] Here are a few recommendations:

[17] For a detailed list of cloud benefits you can read about *Cloud Economics* here.
[18] This paper is not intended as a 'how to' guide for project management, but rather presents an overarching philosophy for adoption and value realization.

Project management attention—Create a knowledge center, Center of Expertise, or project management center. Capital budgeting and vendor selection take time, cutting into your schedule to make the California 2015 deadline. These take time to organize, gain funding and determine goals, scope and plans.[19]

Pharma companies have so many manufacturing lines, packing lines, and distributors. Just organizing a conversation on changing the business takes time. Often the 'people and planning cycle time' is longer than the actual technology implementation. Get organized early.

We also recommend creating the rapid learning cycle for multi-location projects by conducting pilots and harvesting the lessons. Set the expectation that this is your mode until you get sure footed. This enables a more positive environment for the user community which leads to a deeper commitment to the program. Setting short cycles and achievable milestones for the organizations is critical since successful projects have momentum.

Continuous ROI/benefits methods—A program such as this should include ongoing benchmarks and ROI measurements. At first, compliance/mandate projects are more about 'bite the bullet' motivators. But there is growing research to support the ideas that RFID uses and ROI grow over time. And although 'inference' allows for bar-coding at the item level, reducing start-up costs over time, labor-saving and other benefits increase with an all-in RFID strategy. So*, inference yet increment* might be the plan for many in the pharma chain.

Use cases grow over time. Leverage the existing investments to expand the value proposition. Increased awareness of the multi-location, multi-enterprise environment leads to further business changes and improvements. These are factors often overlooked but demonstrated in RFID projects, which by nature are very versatile. Cloud solutions really enable this, since an on-demand model is easy to get started with and therefore can ultimately provide faster time-to-benefits at lower cost.

Interoperable trading partner solution—As mentioned above, the solution for RFID in pharma is not just about serialization on the packing line, but also thinking about the data and how and when you will use it. Today, most firms have some serialization data stored in spreadsheets or a unique database. These data are beyond the reach of business applications and therefore defeat the purpose of a true traceability solution. Leverage this serialization and product information (condition, location, custody, etc.) to improve the supply chain and realize value.

Protection against evolving standards—Using third party solutions, rather than your own on-premise software, helps you keep up with evolving global standards. As global incidents have escalated in pharmaceutical crime, citizens, and therefore governments, have reacted. These have had an impact on the evolving standards. Many of the standards in the US had bipartisan support. With China's new leadership beginning to take the helm, vows for further reduction in crime and fraud have become more frequent. India's approach today is to ensure that all exports meet international standards. But as their middleclass grows—not just in wealth, but political power—more citizens will demand universal drug safety standards.

[19] Ultimately a business case should be developed. There are proof points of ROI from other pharma company implementation examples. But each firm should develop their own goals. Many of the solutions providers have been working on ensuring that these are in place as part of their implementation.

No doubt approaches like inference, the current compromise for California (which becomes the defacto US standard) will be implemented first. But over time, government and the enterprises themselves may seek more granular and accurate methods. Thus implementing a database (cloud solution) that is able to change and support these evolving issues is key.

Without the Pill the Pain Won't End

In pharmaceuticals, if we don't take the cure (the pill), then the pain won't end. It's in the adoption of solutions that the issues the industry is facing will be solved. Many conditions take time to cure, but the regimen has to be started. Treatment methods may evolve over time, but they have to begin to get the results.

Billions have been invested, by both technology providers and the end-user community, to overcome obstacles to RFID technology adoption. Thinking more broadly than a mandate—serializing with leverage of the investment—you want to select solutions that scale and protect against change with the least disruption and cost to you. Across so many application sectors and industries, organizations are thinking beyond mandates. It is time to take another look.

Bibliography: Further Reading:

- Cold Chains Are Hot
- Carton-level Temperature Tracking for Cold Chain Pharmaceuticals - Why Now?
- Zest and RFID as Data Exchange Service: The Benefits for Serialization and Track and Trace Application Solutions
- Zest Data Services information
- Reducing Risk in Global Life Sciences
- Smart and Serialized (Includes flow of Pharmaceutical Supply Chain diagram)

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