PHARMACEUTICAL SERIALIZATION & AUTHENTICATION

Includes:

Key Challenges for Pedigree Authentication and Serialization
Andy Dé and Mandar Paralkar, SAP

Serialization, Pedigree Tracking and Tracing, and Standards—State of the Industry
Michelle Grayson, Touch Medical Communications, and Steve Winkler, SAP

Ensuring Patient Safety with RFID Solutions
Brian Brown, Cephalon, Inc

Track and Trace from the Plant to the Patient Bedside
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PHARMACEUTICAL SERIALIZATION & AUTHENTICATION

Executive Summary

SAP

Key Challenges for Pedigree Authentication and Serialization—Business Drivers, US Food and Drug Administration Mandates, and Regulations

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Serialization, Pedigree Tracking and Tracing, and Standards—State of the Industry

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Ensuring Patient Safety with Radiofrequency Identification Solutions

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Serialization as a Bridge Between Life Sciences and Healthcare—Track and Trace from the Plant to the Patient Bedside

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As medical science has advanced, so too have the number, type, and complexity of drugs and devices available. In order to carry this burgeoning product portfolio, the life sciences supply chain network has also enlarged and grown in complexity, and there are now more intermediaries than ever before between the manufacturer and the patient. It is a major challenge to account for the movement of all products within the supply network—and moreover to prevent diversions and counterfeits. However, in this networked, globalized world, where information travels fast, it is of critical importance to be able to secure the supply chain to ensure patient safety and maintain an unblemished reputation.

Counterfeits risk harming human life by containing incorrect active ingredients—or even no active ingredients at all. If allowed to flourish in the life sciences supply chain, these sub-standard products can damage the brand and reputation of the authentic manufacturer. Moreover, money from the sale of counterfeits will not go towards supporting the research and development (R&D) infrastructure of pharmaceutical and device manufacturers and may well be used to support illegal or harmful activities. The issue of diversions can be equally damaging as certain markets are denied their medications, while middlemen and traders enjoy profit by selling them on. It is impossible to do more than guessestimate the full impact of counterfeits and diversions (which run well into tens of billions of dollars a year), but they are undoubtedly a growing concern. As the Internet becomes ever more prevalent, it is easier and easier to hide the provenance of pharmaceutical products on sale.

The world is waking up to these problems. Certain countries, including the US and many in Europe and Asia, are developing legislation to help protect the life sciences supply network. By enhancing the ability of stakeholders within the network to be able to track and trace the products, it becomes harder to divert or insert items, and easier to ensure high levels of quality and safety. As the life sciences industry operates on a global scale, these mandates need to fit within a wider framework, which is provided by global standards such as those from GS1 and Electronic Product Code Information Services (EPCIS). With guaranteed interoperability, it is possible to achieve accurate, reliable drug tracking and authentication at each node of the drug supply chain.

For life sciences executives concerned with ensuring the highest levels of patient safety and brand protection, the solution will be to adopt an enterprise-wide approach to addressing these issues. This will include considering how to proactively comply with emerging serialization mandates across the world, while at the same time balancing the costs and benefits of serialization and authentication and determining which products and brands to prioritize.

This publication explores some of these key challenges facing life sciences companies today from the insiders’ perspective. There is an overview of the problems of counterfeits and diversions and the role that serialization and authentication plays. It also addresses the critical role of industry standards and best practices in business process enablement using advanced IT solutions, and there is a case study of Cephalon’s success in addressing these challenges. In addition to addressing the tactical needs for compliance and supply chain visibility, the publication closes with an analysis of the strategic benefits of extending serialization to the patient bedside, including the potential benefits in terms of fewer medication errors and adverse events culminating in higher patient safety.

We hope you enjoy the articles and find them useful in helping to further your understanding of the potential strengths of the life sciences supply chain environment and to derive strategic plans to realize them.
The life sciences supply network is steadily growing in complexity, and it is not unusual for pharmaceutical products to pass through least four to six intermediaries before reaching the patient. In addition, life sciences companies, especially pharmaceutical and biotechnology firms, face an ever-increasing incidence of counterfeit drugs and diversions as their product passes along the supply chain from the manufacturer to the patient. Counterfeiting and diversions have life-threatening implications, and can also jeopardize a company's reputation, brand equity, growth, and profitability; it is thus imperative for manufacturers to address these issues.

Counterfeit drugs are those not made by the manufacturer or its licensee, and may be contaminated, contain inaccurate amounts of active ingredient(s), or indeed contain no active ingredients at all. Diversions are genuine drugs that have been intercepted on their way to the intended market and sold into new—often unauthorized—markets, taking advantage of differential pricing in different territories (price arbitrage) and/or drug shortages. Often, diversions will be repackaged to better align with the new territory's language and typical product appearance. As diversions use complicated channels with many middlemen, they are hard to track. This invites additional substitutions and insertions of products made by spurious manufacturers that are clandestinely substituted for real products in the supply chain. Again, if these make their way to the patient's bedside, there can be a debilitating impact on health.

The Scale of the Problem
The problems of diversions and counterfeits are acute in the pharmaceuticals industry. It is estimated that 7–8% of drugs worldwide are counterfeit. In developed countries the figure is roughly 1% of sales, while in some less stringently regulated countries this figure can exceed 30%. Furthermore, the proportion of counterfeits sold from Internet sites that do not disclose their physical address can reach 50% of the total drugs sold from such sites. It is impossible to accurately determine the extent of the counterfeit problem. High-end estimates include the oft-quoted prediction from the US-based Center for Medicine in the Public Interest, which predicts that worldwide counterfeit drug sales will reach $75 billion in 2010—an increase of more than 90% over 2005 figures. Whatever the true figure, given that the rate of counterfeits is estimated to be growing at 6–8% annually, this is a big problem for manufacturers both in the US and worldwide.

A number of European countries have adopted serialization initiatives for pharmaceuticals, and there is a drive to establish a common standard across Europe. In December 2008, the European Commission tabled a package consisting of pathways to various initiatives, including proposals to tackle the growing issues of counterfeiting and illegal distribution of medicines, enable citizens to have access to high-quality information on prescription-only medicines, and improve patient protection by strengthening the European system of pharmacovigilance. In the US, current and nascent laws and regulations, both at the state level and across the whole of the country from the US Food and Drug Administration (FDA), demand that stakeholders capture and document the entire chain of custody of each drug product from the point of manufacture to the point of dispensing, thereby ensuring a safe and secure drug supply that can be authenticated if needed. Impending legislation from the state of California, now scheduled to be enacted in January 2015, requires biopharmaceutical manufacturers to label prescription drugs with unique serial numbers (electronic product codes [EPCs]) and transmit pedigrees with products as they move through the supply network from manufacturers to wholesale distributors and, eventually, to dispensing pharmacies and hospitals.

These laws and regulations also stipulate that each product’s pedigree documents must refer to its unique serial number, which can therefore...
The key to ensuring a safe and secure supply chain with full product authentication and pedigree validation across the entire life-cycle of the drug product—from point of manufacture to point of dispensing—is to ensure that serialization and traceability are built into the supply chain, manufacturing, and distribution processes. There are different ways to achieve serial identification, with 2D barcodes being a relatively cheap option that require little sophisticated technology to track and trace (although without authentication), but in terms of scope and range, radiofrequency identification (RFID) has emerged as one of the leading technologies. RFID allows organizations to read a large number of tags simultaneously without line of sight or individual scanning of tags. In addition to the use of serialized information to support pedigree and authentication, the unique tracking of objects (with RFID or other methods such as a barcode) is also useful for supply chain management, asset-tracking applications, and a host of other business processes.

RFID is being deployed in many industries, including fast-moving consumer goods and on chips within animals (pets and cattle), and has been demonstrated to support track-and-trace applications and processes. Within the life sciences industry, GS1 Healthcare US and EPCglobal are co-ordinating the development of a series of standards to facilitate the RFID tagging, capture, and exchange of serialized product information. These include the Drug Pedigree Messaging Standard (DPMS) and the EPC Information Service (EPCIS) standard.

### Issues and Objectives

For executives within the pharmaceutical industry, the top issues will be ensuring the highest levels of both patient safety and brand protection. Life sciences manufacturers need to adopt an enterprise-wide approach to addressing these issues, since any incidence of counterfeiting—particularly when it concerns life-saving drugs or devices—can reflect poorly on the company. Thus, executives need to consider how to proactively comply with emerging serialization mandates in the US and Europe while balancing the costs and benefits of serialization and authentication for the company and determining which products and brands to prioritize.

Different stakeholders have different issues and objectives concerning supply chain traceability. For example, a Chief Operating Officer will need to manage company-wide risk caused by emerging mandates and consider compliance, customer satisfaction, brand protection, and financial risk. In product manufacturing, the main issues are linking a finished product with all the component parts and raw materials used during manufacturing, as well as taking account of upstream traceability, accuracy of recall, global visibility, and regulatory compliance. Within the supply chain, it is vital to ensure secure distribution of products, prevent and detect counterfeiting, and address reverse logistics, at the lowest cost. In sales, track and trace will have an impact on product quality, safety, and compliance issues, and ensure customer satisfaction.

### The Insider’s View

Many industries have already adopted RFID tagging as the standard way to ensure pedigree authentication and serialization. An overview of the state of adoption of serialization strategies and RFID technologies within the pharmaceutical industry is provided in the paper by Michelle Grayson and Steve Winkler (see pages 6–8).

The technology and capabilities to achieve a safe and secure supply chain are available today.

In order to best understand the process of serialization and pedigree authentication within the life sciences industries, it is useful to examine the experiences of Cephalon, an early adopter of RFID technology, as told by Brian Brown (see pages 9–11).

Finally, the major messages from these papers are examined in a final round-up by Mandar Paralkar and Andy Dé that will help pharmaceutical and
medical device companies to leverage technologies and best practices to address the challenges present within the industry (see pages 12–15).

Counterfeiting and diversions are among the many problems that the life sciences industries face, and it may appear that there are many obstacles to overcome before these issues can be solved, but the technology and capabilities to achieve a safe and secure supply chain are available today. If they are properly deployed across the whole of the supply chain, they can prove to be invaluable tools in the ongoing mission to ensure patient safety.

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2. Projections by Center for Medicine in the Public Interest, based on 2008 estimates by the World Health Organization (WHO).
Serialization, Pedigree Tracking and Tracing, and Standards—State of the Industry

a report by
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Serialization is the process of uniquely identifying an object so that not only are its product type, expiration date, best-before date, lot number, etc. associated with the item, but any one item can also be distinguished from other items of the same type from the same batch. This can be done with both true serialization—where objects are sequentially numbered—or with a randomized series of unique numbers. A product’s pedigree, on the other hand, documents its chain of ownership or possession. Combined with serialization, pedigree permits tracking of individual items throughout the supply chain.

Importance of Standards
Introducing systems such as pedigree and serialization for international goods requires careful planning, which is where standards can help. The total cost of ownership (TCO) and overall integration costs for new hardware and software can be kept to a minimum if all elements of the supply chain have a commonality, provided by standards. Similarly, in a dynamic supply chain that regularly introduces new stakeholders—such as new suppliers, partners, or customers—the exchange of information across different systems will be facilitated by use of common standards. The amount of data that modern systems have to cope with has grown exponentially. Pedigree laws demand that the unique identifiers for items packaged together in a case or pallet are readable in order to be able to associate the case with the items inside all the way through the supply chain. As current practice is to identify only the batch, the onus falls on the associate the case with the item s inside all the way through the supply chain. As current practice is to identify only the batch, the onus falls on

Standards Organizations
The largest standards organization working in this field is GS1, a global federation of 108 member organizations representing companies interested in implementing standardized technology to address real business problems. Established more than 30 years ago, GS1 welcomes direct contribution and participation from a spectrum of interested companies, including manufacturers, retailers, healthcare providers, transportation and logistics providers, aerospace and defense companies, and the technology developers themselves. There are other organizations working on creating standards in healthcare, including Health Level 7 (HL7), the International Health Terminology Standards Development Organisation (IHTSDO), developing and promoting Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT), and the International Council for Commonality in Blood Banking Automation, Inc. (ICCBBA), which manages the International Society of Blood Transfusion (ISBT)’s 128 standards for transfusion medicine and transplantation. All international standards must conform to those developed by the International Organization for Standardization (ISO).

Across the globe, each country has its own set of regulations regarding serialization that may differ from the FDA’s, depending on their perspective and maturity level. Nevertheless, pharmaceutical supply chains are global and any one chain will need to be able to comply with multiple national standards. Therefore, it is important to have internationally

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accepted standards mandated by an international, independent body. GS1 has developed a basic identifier, the Global Trade Item Number (GTIN), which is known as the sGTIN when serialized. Sixty-five countries already accept the base GTIN for pharmaceuticals, but only a few of them are in the process of actually having the items serialized. GS1 interacts with most of the major governments around the world. The FDA has already stated that its sNDC is compatible with sGTIN. Global standards, particularly in the healthcare industry, are a major challenge as all countries are concerned about ensuring the health of their own citizens through their own regulated healthcare systems.

**Serialization Technology**

Linear barcodes are not suitable for serialization processes owing to the limited amount of data they can contain; the nearest technology is 2D barcoding. Some countries are mandating serialization in 2D barcodes on pharmaceuticals; for example, Italy and Belgium already require serialization for pharmaceuticals at a country-specific level. Turkey is preparing to implement true serialization laws by taking a global approach. Other countries require identification only at the lot level; for example, France will require a vignette in the form of a 2D barcode including lot number and expiration date by the end of December 2010. An alternative to barcode technology is radiofrequency identification (RFID). RFID tags are programmable and can be validated and read without line of sight. One of the main advantages of RFID technology is that when the tag is commissioned, the product is identified and read in a matter of seconds. This is a much more complex procedure than with a 2D barcode. When it was first introduced there was a great deal of interest in RFID, particularly in the US. However, at that point the technology was still at an early stage; the cost of the tags was fairly high, as was the infrastructure investment required. Although this has changed and prices have come down, the common view of RFID as added cost remains—yet there are many advantages over barcodes. For example, unlike 2D barcodes, RFID-labeled items can be associated with a pallet in real-time (a process of inference) and checked in situ. It is not possible to verify a barcoded item once it has been put into the case without unpacking it. Another challenge is simply concerning the quantity of data and the size of the barcode or tag. Many medical products offer only a very small amount of real estate, which is a challenge in terms of both ability to mark and speed. RFID technology is continually improving; these days it is possible to buy a larger-capacity RFID tag for not much more than the smaller one, and the larger tag can easily contain an entire serial number. At the same time as technology costs are coming down, the reliability of the technology is increasing.

**Radiofrequency Identification Issues**

There is some concern that using RFID technology around biological products could inadvertently cause damage, particularly with active tags that operate at a high frequency. However, the evidence is equivocal. The University of Wisconsin-Madison RFID Laboratory has been conducting a three-year project in partnership with three national blood centers concerning RFID (passive 13.56MHz technology) and delivery of blood products. So far, they have found no evidence of electromagnetic interference, even with zero distance between RFID emitter and medical device. Nevertheless, the FDA has urged caution regarding use of RFID tags with biological products, and noted that there is some evidence that this technology may interfere with pacemakers and implantable cardioverter defibrillators. There are political aspects of the RFID technology as well: namely, there must be spare RF bandwidth in each country for it to work. Some countries, particularly in Europe, already have a lot of RF bands allocated. National governments understandably feel strongly about allocation of RFs for various purposes, and gaining agreement for bandwidth in each country is no easy task. There are also practical issues to consider: many production lines run more or less continuously, or at least at full capacity with all down-time accounted for—often a year or two in advance. Finding time to shut them down in order to test or implement a new system is hugely problematic. Furthermore, no two production lines are the same; they frequently have unique configurations and are bounded by particular space limitations, thus adding RFID equipment is a challenge for manufacturers. However, such business challenges can be overcome with enough will. If manufacturers see the return on investment, these issues will prove only short-term obstacles.

**Future Perspectives**

Electronic pedigrees and serialization, whether using 2D barcodes or RFID, both offer increased visibility across the supply chain—visibility that to a degree is available today, but only at a price. Certain companies exist that track items as they are traded and shipped around, process that information, and sell it back to manufacturers. In this way, by implementing serialization technologies, there will be an adjustment to the business mechanisms in the supply chain, which will be resisted by certain stakeholders. However, on the other hand, this could enable a release of resources. Other returns on investment are possible: these technologies offer more security against counterfeits and diversions and better ability to respond to fluctuations in demand. Of course, the benefits are different for each stakeholder in the supply chain. For the FDA there is the benefit to public health offered by the ability to spot fakes and to perform product recalls. Manufacturers gain visibility over where their products end up and can verify genuine items—also benefiting public health. Wholesalers can speed up business processes and ensure shipments are received and are genuine. Pharmacies can

**Pharmaceutical supply chains are global and any one chain will need to be able to comply with multiple national standards.**
undertake better inventory management. Many manufacturers, such as Pfizer, Novartis, and Cephalon (see pages 9–11), are piloting RFID technologies for high-value products (those more likely to be copied or diverted). These companies are not yet ready for full-scale implementation. The main hindrance to universal adoption of serialization with RFID is the fact that there is not yet a critical mass of companies able to implement this technology. Nevertheless, the business benefits of an RFID-enabled serialization are estimated to outweigh the set-up costs and incremental price of RFID tags, particularly as the cost of the tags and the technology in general is falling. Companies gain the ability to authenticate product integrity across the consumption lifecycle, greater visibility and supply chain efficiencies, proactive compliance with emerging and existing government regulations and laws, patient confidence in the product, more accurate and automated receipt of goods, and more effective returns processing, to name a few. It is likely that, for the next decade, after serialization and ePedigrees have been comprehensively introduced, there will be a mixed environment of 2D barcodes and RFID. While RFID is the stronger, more versatile system, it still needs to improve in terms of cost, value, and functionality—not to mention widescale adoption. However, employing RFID is a way to future-proof a biopharmaceutical supply chain, and there are other roles these devices can potentially perform—such as being sensors to ensure a proper cold chain, for example. What is important in the short term is the serialized identification of pharmaceuticals and medical devices, and the opportunity to have visibility in a way that has not previously been achievable. As 2D barcodes and RFID will most likely co-exist for some time, this will enable supply-chain stakeholders to leverage the technology that is most appropriate for a certain application or product group and realize these specific returns on investment. Eventually, serialization will be mandated by law worldwide. Until that happens, the best course of action for a pharmaceutical firm is to start preparing the basics and working with its partners in the supply chain to understand the system and the technologies, so that when the laws are introduced it is ready and able to turn opportunity into profit.

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Ensuring Patient Safety with Radiofrequency Identification Solutions

a report by

Brian Brown

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Patient safety and wellbeing is the ultimate goal of all pharmaceutical firms; however, this can be assured only if the product being supplied is securely passed along the supply chain from manufacturer to pharmacy and then on to the patient. These products are high-value commodities that, unfortunately, are often the target for diversion and counterfeiting. The biopharmaceutical industry is stepping up to the plate to introduce technology that will make it easier to quickly and accurately track their products using radiofrequency identification (RFID) technology, and Cephalon, Inc. is one of the early adopters.

Background

Cephalon is an international biopharmaceutical company dedicated to the discovery, development, and commercialization of innovative products to treat human diseases. Currently, we operate in four core therapeutic areas: central nervous systems disorders, pain, oncology, and inflammatory disease. We generated approximately $1.9 billion in gross sales in 2008, and employ more than 3,000 people worldwide.

Cephalon has an entrepreneurial spirit, courtesy of founder Dr Frank Baldino, who is also Chief Executive Officer (CEO) and Chairman of the Board. Therefore, when we were contacted by Walmart in 2003 with a request to tag our products with RFID, it sparked interest in investigating this technology. Although we could not fulfill the mandate at the time, we recognized that RFID was a technology that we should investigate to enable us to comply with future requests and to promote a secure supply chain. We recognized the critical point was not if RFID would become a required technology, but when.

Radiofrequency Identification Partners

Although we had significant interest in exploring RFID in 2003, we recognized that we did not have sufficient knowledge in-house to implement RFID on our own. My Vice President, Randy Bradway, recognized immediately that we needed to build partnerships in our field to expand our knowledge and improve our chances of being successful in our endeavors. To this end, we have developed relationships with several leading companies.

A major partner in our program is ADT Security Services. ADT has been with us from the beginning and has provided significant support in helping us understand the physics of RFID and how we could use the technology for our benefit. In addition to performing the physical installation of our readers and antennas, ADT has performed site surveys and product-tag testing in its laboratory in Boca Raton, Florida.

In addition to ADT, we have partnerships with SysTech and OATSystems. These companies provide software that encodes our tags and captures information from them after application to products/containers. ENC, a boutique consulting firm, is our primary RFID integration specialist, and uses SAP RFID technology. We are also working with SupplyScape to implement our Electronic Drug Pedigree System.

The Auto ID Infrastructure (AII) developed by SAP is our internal electronic product code (EPC) information service, and maintains our information related to available and utilized EPCs. SAP communicates with SysTech and OATSystems to provide blocks of EPCs for encoding and tagging. When the tags are printed, they are encoded with the EPC and placed on the package. After the quality assurance process is complete, the association between the physical package and the EPC is transmitted back to SAP-AII, along with additional details related to the contents.

In addition to the hardware and software vendors focused on the RFID space, we maintain strong relationships with our trading partners, which enables us to understand their visions on the benefits and challenges as related to RFID.

Although we believe that we have a secure supply chain, we recognize that we can benefit from adding additional layers of security through the implementation of product serialization and an electronic drug pedigree system.

Brian Brown is an Associate Director of Logistics and Analytics at Cephalon, Inc. He is an experienced project manager, leading company-wide implementations of a variety of projects, such as business intelligence and radiofrequency identification (RFID). He is leading several initiatives in support of a safe and secure supply chain, which include RFID and ePedigree initiatives. An experienced speaker, Mr Brown has shared his vision of the benefits of RFID and ePedigree at industry and technical events such as RFID World, RFID Live, and Sapphire, and the Healthcare Distribution Management Association/National Association of Chain Drug Stores (HDMA/NACDS) RFID Healthcare Summit.

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It can be seen that we have built a network of companies that have enabled us to expand our knowledge of RFID and serialization. Moreover, this process of knowledge-sharing is not a one-way flow of information: we have helped our partners gain a better understanding of some of the concerns that affect the pharmaceutical supply chain so they can improve the services they offer to this industry.

Radiofrequency Identification Pilot Trials

We have successfully implemented three RFID pilot trials and are currently working on two additional programs. Each trial has been developed as a learning process, and has built upon the knowledge and insight gained from prior phases.

Our initial pilot was a ‘proof-of-concept’ study where we verified that we could capture the movement of tagged products using RFID in a warehouse belonging to our third-party logistics firm. This pilot was successful, although we were disappointed with the low read rates that generation 1 tags provided. This pilot trial was completed in December 2005.

Our second pilot phase verified that our tagged product (cases) could be read by an external trading partner. This pilot trial was successfully completed in early 2006.

Our third pilot trial tagged cases and pallets of one of our products on the manufacturing line. It was a manual ‘slap and ship’ approach, and was the first time we enjoyed the benefit of generation 2 tags. Our read rates increased significantly from those of the generation 1 tags trial, and we verified that we could perform RFID in a manufacturing environment (see Figures 1 and 2). Currently, we are working on two RFID pilot programs: first, serializing shipping containers with RFID at our third-party logistics partner premises, and second, implementing unit-level serialization using RFID and redundant 2D barcodes. In addition to these programs, we have been accepted to participate in the SAP All 7.0 Ramp Up Program and will also be integrating SAP-All with our SAP ECC System.

Radiofrequency Identification Benefits

Although we believe that we have a secure supply chain, we recognize that we can benefit from adding additional layers of security through the implementation of product serialization and an electronic drug pedigree system (ePedigree). I will describe below a few of the benefits that we see RFID enabling in the future, but the potential for process improvement is limitless.

If ePedigrees are passed through the supply chain, we can manage the recall process by contacting the known locations of our products. These capabilities will enable us to recall products more efficiently.

The combination of producing serialized product and generating ePedigrees will provide our trading partners (and their trading partners) with the knowledge that the product that they receive is authentic, manufactured by Cephalon. This layer of serialization and data-sharing ultimately allows the patient to have absolute confidence that the product they are receiving is authentic and verifiable.

An important benefit of RFID at a warehouse level is the ability to receive products more accurately with automated receipts of goods. On the outbound side, we also see internal benefits as there is less need for manual quality assurance efforts. Currently, the procedure is that a number of people review the contents of each order. If we are able to ascertain the contents of a container using RFID, we are able to designate different tasks to the personnel who would otherwise be occupied.
By serializing products, we can implement recall processes that are more focused than current standards. If necessary, we can implement recall activities at the unit level, as opposed to batch level. Additionally, if ePedigrees are passed through the supply chain, we can manage the recall process by contacting the known locations of our products. These capabilities will enable us to recall products more efficiently. Returns processing can also become more effective with the use of RFID. By capturing the EPC and referencing the data back to our ePedigree and internal systems, we can verify the path of products. This will enable us to credit our customers more accurately and efficiently, with less manual data entry.

Naturally, implementing RFID will generate significant amounts of data that by themselves will be meaningless. The difference between ‘average’ and ‘successful’ implementation of RFID will be how these data are used. If they are interpreted and utilized, they will provide meaningful business information to help streamline operations and bring innovation to the supply chain. This is one area where companies can turn their investment into RFID in a valuable resource with potential new revenue streams.

**Mandating Radiofrequency Identification**

So far, the main US legislation concerning pharmaceutical RFID implementation is California’s ePedigree mandate, which explicitly requires serialization for all drug packages coming into the state, covering the drug’s life from the point of manufacture to the point of sale. While this can basically be achieved with a 2D or a Reduced Space Symbologies (RSS) barcode, we believe that RFID is the future-proofed alternative. The Californian requirements have been delayed several times, with the implementation date currently scheduled for 2015. We have strived to comply with the requirements as they have evolved, and we believe that we will be compliant when required.

One benefit of working for a mid-sized company is that we have approximately 20 products; some manufacturers have more than 3,000 stock-keeping units to deal with, which is an exponentially greater challenge. I think that many companies will take a phased approach to ePedigree implementation, beginning with their high-value, most often diverted and most ‘dangerous’ drugs.

Nationally, there is discussion related to serialization standards and the potential federal legislation related to ensuring a safe and secure drug supply chain. At this time, it is too early to speculate on the future requirements on a national scale. One could argue that California, with a gross domestic product larger than all but the top eight economies in the world, can essentially be thought of as a de facto country in its own right. Elsewhere in the US, Nevada and Virginia have smaller, less extensive ePedigree requirements; Florida’s 2006 ePedigree legislation stipulated that information has to be manually recorded only. The US Food and Drug Administration (FDA) has a January 2010 deadline for the creation of a system to protect the pharmaceutical supply chain from “counterfeit, diverted, subpotent, substandard, adulterated, misbranded or expired drugs.”

However, this is not limited to electronic solutions; nevertheless, with the potential for 50 different mandates from each of the states, the pharmaceutical trade could rapidly become very tricky if no national legislation supersedes.

**Long-term Outlook**

In the long run, tagging products at the unit level using RFID to create fully serialized ePedigrees will enable a reduction in much of the manual effort that is currently involved in the supply chain, including unit counts and product review prior to shipping. With one scan, hundreds of tags for store-room products can be read and correlated with the inventory. The ability to check quickly and in realtime will stop shipment errors from occurring and will help identify where differences occurred en route. It may be a number of years down the line, but RFID technology will completely revamp the way in which shipping of pharmaceutical goods is conducted. At Cephalon, our view has always been that 2D barcodes do not remove the requirement for line of sight when tracking products, and therefore while they provide serialization they will not bring any great efficiency advances. One of the biggest benefits of RFID is that the contents of a case of products can be read without opening the case.

Overall, RFID will increase efficiency in receiving and shipping and managing inventories, potentially affecting the whole supply chain. Currently, we receive electronic data interchange (EDI) inventory-level data from our wholesalers, but when this new environment is fully enabled, we hope to have access to an individual-unit-level visibility. Ideally, we will reach data-sharing agreements with pharmacies to provide us with visibility on stock levels down to individual bottles on the shelves. I believe that the whole supply chain will be online in five to 10 years. At that point we will have greater visibility and less chance of counterfeit drugs entering the market.

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Serialization will enable each individual unit of a drug to be tracked and traced all along its journey from the manufacturing plant to the pharmacy. It is increasingly becoming imperative for pharmaceutical manufacturers to introduce serialization: not only is there an increasing density of emerging mandates in this arena that must be complied with, but also implementing such a strategy facilitates superior supply chain visibility and, perhaps more importantly, helps to combat counterfeiting and diversions. Like Cephalon (see pages 9–11), a number of industry leaders in the pharmaceutical and healthcare industry are seizing these opportunities and, in doing so, giving themselves the potential to realize significant returns on their information technology (IT) investments. The crucial element of any serialization strategy is to employ a holistic approach: deploying an end-to-end IT-enabled business process across not only manufacturing, distribution, and logistics arenas, but also encompassing product safety and compliance with industry standards, to track and trace drugs from the plant floor to the pharmacy.

Company-wide Challenges

There are many critical capabilities that must be addressed to enable a comprehensive solution for serialization and track and trace that is compliant with GS1/EPC Information Services (EPCIS) standards. These capabilities should be assessed in the context of the various challenges inherent in the multiple lines of businesses within a pharmaceutical company, including manufacturing, warehousing, distribution, and product safety, as shown in the end-to-end process schematic in Figure 1. Table 1 expands on these challenges. There are a number of benefits to taking a holistic approach to serialization and track and trace, and in the process enabling the different lines of businesses to address these challenges. When considering implementing an end-to-end solution, one approach is to assess the desired capabilities for the three key areas of manufacturing, supply chain distribution, and strategy. By analyzing these capabilities in the context of the expected business benefits versus the current business shortfall, a clearer picture can be derived.

Manufacturing Genealogy

The critical functions that serialization and track and trace must perform within the manufacturing arena are related to a product’s genealogy; specifically, this includes documenting and maintaining links surrounding the end product, the associated business context, and the manufacturing process and inputs. The ideal system will automatically record and maintain the genealogy of a product, associating it with the raw materials and serialized components included, labor employed, machines used, and all of the manufacturing processes involved to provide full traceability and visibility. A typical series of business problems (pain points) and the related end-points and benefits is shown in Table 2. In order to realize these business benefits, there are a number of important capabilities required:

- manufacturing traceability to track production, batches, business context, and serialization from enterprise planning to manufacturing execution;
- serialization at point of production to ensure item-level traceability across the supply chain, higher standards of quality control, and improved regulatory compliance; and
- product genealogy to fully document material and component transformation into end products by maintaining supplier’s batch or serial number information for raw materials and components and linking it with finished products and business documents, allowing for traceability across business partners.

Supply Chain Tracking and Tracing

As a product moves along the supply chain, there are several important processes that must take place: its authentication is checked at each step, information is updated on its whereabouts, and its condition status is monitored, such that if it is found to be damaged or held in inappropriate conditions, an exception can be triggered. Typical problems versus desired capabilities and expected business benefits are outlined in Table 3. Track and trace in the supply chain has several implications:

- integration of automatic identification technologies for tracking, authentication, and condition monitoring in the warehousing and logistics process;
- logistics management and monitoring enhances enterprise-level logistics processes with automatic identification-based technologies, which are integrated with the existing processes to provide an extensible platform for future process enablement;
- automatic identification technologies used for serialization enable item-level and hierarchical product tracking, authentication, and visibility across the supply chain—within and beyond company boundaries.

Strategic Problem Assessment and Response

A crucial part of any business is the ability to collect high-quality data, analyze
and assess them, create and evaluate strategies, and then implement the best solution. Often, this will necessarily be in conjunction with a partner or partners, emphasizing the need for rapid and secure collective intelligence technologies. Not all companies are able to achieve these capabilities or endpoints sufficiently; an outline of certain typical situations is shown in Table 4. Therefore, when assessing technologies to improve strategic problem assessment and response, it is important to keep in mind the need to:

- identify and list end products based on information concerning particular manufacturing inputs and determine the product whereabouts—whether that is with an immediate customer or further downstream—based on deliveries and/or pallet, case, or item information;
- implement electronic recall notifications for affected business partners, which include specific details on recalled products from batch, lot, or pallet level, or even cases or individual items if serialized; and
- manage performance, including problem assessment and analysis, to enable accurate determination of the root cause of a problem and ensure proper scope and scale of the response.

The current trend for out-sourcing, coupled with the technology and industry-specific expertise required, means that all companies are able to achieve these capabilities or endpoints sufficiently; an outline of certain typical situations is shown in Table 4. Therefore, when assessing technologies to improve strategic problem assessment and response, it is important to keep in mind the need to:

- able to deliver end-to-end solutions tailored for the life sciences industry, with implicit best practices;
- can assure lower total cost of ownership through integration with enterprise resource planning;
- broad adoption by industry leaders across the value chain in the life sciences industry;
- able to benchmark the current practices of life sciences manufacturers against best-in-class, with measurable, quantifiable value from the implementation identified as the business case for adoption; and
- operates within a large ecosystem of partners to ensure that all business-essential needs are covered, with a proven track record of success.

Bridging the Chasm

There are issues within the wider healthcare arena. Many of the leading, revenue-generating blockbuster pharmaceuticals are facing imminent patent expiry and will therefore be threatened by competition from generics firms. In order to continue creating, testing, manufacturing, and
pharmaceutical serialization and authentication

Table 2: Problems and Solutions for Manufacturing Genealogy

<table>
<thead>
<tr>
<th>Pain Points</th>
<th>Desired Business Capabilities</th>
<th>Expected Business Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inability to maintain link between serialized components, raw materials, manufacturing practices, labor, machines and finished product for bi-directional traceability</td>
<td>Maintaining link between serialized components, raw materials, other inputs, and finished product for traceability</td>
<td>Manufacturing traceability provides ability to investigate production issues all the way to the root cause, whether component/raw material batch/machine/labor</td>
</tr>
<tr>
<td>Difficulty determining root causes of quality issues owing to poor documentation of product genealogy</td>
<td>Maintenance of quality- and materials/inputs-related information during production</td>
<td>Faster and more accurate investigation of issues, more targeted containment of problems</td>
</tr>
<tr>
<td>Data inaccuracy caused by manual rather than automated standardized processes</td>
<td>Accurate recording of control and production information for every production run</td>
<td>Accurate information provides insights into business and helps in optimization</td>
</tr>
<tr>
<td>Non-compliance with manufacturing regulations and best practices</td>
<td>Easier compliance with good manufacturing practices (GMPs) and other regulations</td>
<td>Production visibility facilitates regulatory compliance during manufacturing</td>
</tr>
</tbody>
</table>

Table 3: Problems and Solutions for Supply Chain Tracking and Tracing

<table>
<thead>
<tr>
<th>Pain Points</th>
<th>Desired Business Capabilities</th>
<th>Expected Business Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalent and growing counterfeiting and diversion of products</td>
<td>Advanced product authentication woven in all along all steps in the logistic processes</td>
<td>Detect and reduce counterfeiting and diversion, protecting the brand and customers’ health</td>
</tr>
<tr>
<td>Lack of upstream/downstream visibility to stock positions and in-transit inventory along the supply chain</td>
<td>Full collaborative visibility and tracking of goods for both forward and reverse logistics through business partners</td>
<td>Faster response times and increased customer satisfaction from collaborative visibility, reduced administrative costs during recalls/returns</td>
</tr>
<tr>
<td>High discard rate of product due to spoilage, damage, and expiration</td>
<td>Realtime monitoring and supply chain visibility enable fast response times to changes in the condition of shipments</td>
<td>Reduced spoilage of product due to poor conditions while in transit, lot expiration or damage</td>
</tr>
<tr>
<td>Delays and increased response time for recalls</td>
<td>Employing a ‘balanced scorecard’ supply chain performance incentive</td>
<td>Incentives are aligned to improve overall supply chain performance</td>
</tr>
</tbody>
</table>

relationship with physicians, and ensure patients and health workers of the authenticity of their medication.

Serialization and track-and-trace technologies have the potential to significantly lower errors with medication, reduce associated adverse drug events, improve levels of patient safety, and ensure medication compliance. Specific advantages include:

- eliminating drug dispensing errors; ensuring right patient, right drug, right dose, right route, and right time;
- improving patient safety and medication compliance;
- enhancing quality control;
- improving clinical decision support;
- proactively addressing product expiration;
- improving inventory control and billing; and
- improving nurse satisfaction and productivity.

Case Study—Jena University Hospital

The Jena University Hospital in Germany is at the forefront of this innovation and a good example of this new ability to ‘bridge the chasm.’ Jena Hospital has deployed serialization capabilities from SAP, which are integrated with its electronic medical records (EMRs) system to accurately track and trace unit doses of prescribed drugs from the hospital pharmacy to the patient’s bedside. Each unit dose has a radiofrequency identification (RFID) tag, and consequently leaves an auditable trail of its progress to ensure that each patient receives the right drug in the right dosage at the right time. To eliminate human error as completely as possible, Jena Hospital uses steel containers on an automatic, robotic internal transport system, also equipped with RFID tags. The drug is administered to the patient—identified by an RFID bracelet worn by the patient—by the attendant nurse as prescribed by the physician. Furthermore, the system can record all medication automatically in the patient’s EMR, including details about type, quantity, and time of medication. Jena Hospital
has seen a significant return on investment (ROI) from the SAP solution. These returns include fewer errors of medication (including errors in ordering, prescribing, dispensing, and transcribing), lower adverse drug events (ADEs), higher levels of patient safety, and lower costs of treatment—partly as a result of fewer medication errors and ADEs. Moreover, there is the opportunity to use the new RFID and serialization capabilities to further medical expertise. As there is anonymous documentation of drugs administered to patients, it may be possible to discover correlations between disease patterns and potential drug incompatibilities, enabling medical staff to better determine effective treatments and investigate alternatives.

**Summary and Conclusions**

There are clearly potential synergies and significant benefits to be derived from ‘bridging this chasm’ between life sciences research and front-line healthcare. It can be envisioned that leading pharmaceutical companies will continue to collaborate with innovative hospitals to allow serialization of life-saving drugs for many different indications, and therefore permit track and trace from the plant to the pharmacy and even to the bedside, all the while maintaining compliance with standards from GS1 and EPCIS. While this vision has yet to be realized in its entirety, early successes anticipate that significant complementary benefits will accrue for pharmaceutical and healthcare firms intent on reaching out to each other. Such benefits include ensuring higher levels of patient safety, reducing medication errors, and restricting or even eliminating counterfeits and diversions. There is potentially a win–win–win scenario for all of the key stakeholders in the healthcare value chain, with the potential to mitigate the life-threatening risks presented by counterfeiting, diversions, and medication errors that are a harsh reality today.
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