



CHDMA EPC
2004 UPDATE

EPC and Healthcare Distribution: Current State of the Industry



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**HDMA EPC
2004 UPDATE**

EPC and Healthcare Distribution: Current State of the Industry

A White Paper Issued By:

**Members of the Healthcare Distribution Management Association's
(HDMA)
Collaborative Commerce Committee**

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The terms “RFID” and “EPC” are not synonymous. Unfortunately, they are commonly used interchangeably, which is causing some confusion about the state of radio frequency identification (RFID) in the healthcare and other industries. RFID is the broadest term. EPC is a subset of RFID technology.

RFID is a general term that describes wireless identification technology that communicates data by radio waves. Data is encoded in a chip, which is integrated with an antenna and packaged into a finished tag. Data is encoded and read with read/write devices, commonly called readers or interrogators. RFID technology operates at several different frequencies (e.g. 125 KHz, 13.56 MHz, 860-930 MHz, 2.45 GHz), which each have distinct performance characteristics. RFID tags offer different rewritability options, memory sizes and tag forms.

EPC stands for Electronic Product Code, which can have several meanings. EPC may refer to the EPCglobal Network™, a specific EPC system of RFID technology maintained by EPCglobal Inc. The EPCglobal Network includes a numbering system, data exchange protocols, and technical specifications for RFID technology at different frequencies and performance levels, which are designated by classes and versions (e.g. Class 1 Version 2, Class 0, etc.).

“EPC” is often commonly used to refer to an Electronic Product Code number. An EPC number is a unique ID number that is created as part of the EPC system. An EPC number provides unique serialization for an individual item, a characteristic that is highly valued in the healthcare industry to facilitate automated track-and-trace systems. Most RFID technology standards initiatives focus on technical specifications for tag and reader performance; the unique serialization capability of the EPC system truly sets it apart.

The term “EPC” is frequently used incorrectly in literature and presentations to describe broader and more general RFID technology; “RFID” is also used incorrectly to describe specific aspects of the EPC system. This white paper has been carefully written and edited to ensure references to “RFID” and “EPC” are appropriate.

– John Burnell

Recommended Utilization of Electronic Product Codes in Healthcare Distribution

The HDMA Board of Directors approved this position statement during a time when the industry was being faced with an increase in counterfeit products and increasing concerns for patient safety. The purpose of the Board position statement was to provide a goal for deployment of EPC in healthcare, to encourage active participation in industry-wide pilots, and to foster the development of a realistic industry roadmap to support a safe and effective distribution supply chain. Since the release of the Board position in November 2003, the HDMA Healthcare Foundation has completed a study entitled, "Adopting EPC/RFID in Healthcare: Costs/Benefits". Our members have continued to demonstrate their desire to address patient safety concerns by becoming vigilant in participating in industry pilots (e.g. Project Jumpstart), as will be discussed in this paper. We believe the industry is on the path to move forward with this technology, but it is important to note that original timeframes are GOAL dates for early adopters. Ongoing research into the technology indicates that industry-wide adoption likely will occur later. It is the opinion of HDMA that the industry needs to work collaboratively with all constituents of the healthcare supply chain and that several milestones will need to be met in order to achieve industry adoption. Several of these milestones are identified within the context of this paper.

Incidents of counterfeit, tampered, or adulterated product entering the healthcare supply chain is a great concern to the safety of our nation. With the development of new Electronic Product Code (EPC) technology creating the ability to track, trace, and monitor individual product units using radio frequency identification (RFID), the healthcare distribution industry has the opportunity to transform the evolving pharmaceutical supply chain.

This technology will serve as a prophylactic barrier to help prevent unsafe product from entering the supply chain by establishing a secure electronic pedigree through which every unit of medication can be authenticated. As an added safety feature for temperature sensitive medications, the RFID chip also can monitor and electronically quarantine any unit that may be damaged by heat exposure as it transitions through the supply chain. In addition, it will streamline distribution processes, revolutionize inventory management, transform critical processes for handling returns and recalls, and automate inventory rotation, resulting in a more efficient distribution system.

HDMA supports the establishment of a consistent, industry wide initiative collaborating with all members of the healthcare distribution supply chain to drive the adoption, implementation, and utilization of EPC tags. In addition, HDMA fully supports the development of appropriate infrastructures that will uniquely identify and track products and information throughout the healthcare distribution supply chain.

Therefore, it is the position of the HDMA Board of Directors that manufacturers and distributors should utilize EPC tags at the case level with a goal for deployment of December 2005.

Furthermore, pharmaceutical packagers and manufacturers should incorporate EPC tags at the selling unit level with a goal for deployment by 2007. In addition, it is recommended that healthcare distributors develop the appropriate infrastructure for tracking and tracing of products utilizing the EPC.



From nurses to legislators, and from international pharmaceutical makers to the corner drugstore, momentum is building throughout the healthcare industry for increased use of radio frequency identification (RFID) technology to track and trace products. RFID initiatives from Wal-Mart, Target, the METRO Group in Europe and other retailers may have gained the most attention, but the pharmaceutical industry may surpass retail in RFID adoption. Within 18 months, according to “RFID in the Pharmaceutical Industry,” a research report from META Group released in August 2004. In fact, more than 12 billion pharmaceutical units are candidates for item-level tagging with Electronic Product Code (EPC) RFID technology, according to “RFID Systems in the Manufacturing Supply Chain,” an ARC Advisory Group study released in July 2004. The study also predicted most pharmaceutical items will be tagged by 2007, and is one of many reports to recognize the value of EPC technology, which includes a numbering system to serialize and uniquely identify items, plus technical specifications to give users a choice of interoperable tags that may meet the specific needs of the healthcare industry.

The healthcare industry is laying groundwork to create effective, standardized systems by conducting pilot projects and driving technology development and standards adoption. The current lack of standards, lack of consensus on implementation methods, and limited availability of proven, appropriate technology represent significant challenges to adoption. The Healthcare Distribution Management Association (HDMA) and others are taking on these challenges and making progress, as will be detailed in this paper.

The HDMA's original RFID white paper, “Protecting Safety and Improving Efficiencies in the Healthcare Supply Chain—Using Electronic Product Codes,” introduced the basics of RFID technology, explained the suitability of the EPC system for meeting healthcare industry needs, and described industry applications. This white paper will help prepare readers as their organizations consider implementing RFID technology by providing an overview of the leading healthcare initiatives, presenting HDMA's goals and recommendations, summarizing results of an early adopter, and introducing additional resources.

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There are many drivers contributing to the call for EPC adoption, including the promise of improved counterfeit product detection, the ability to generate and maintain electronic pedigrees, improved supply chain visibility, more efficient return and recall processes, and improved inventory control. Numerous programs are underway to understand and verify these benefits. Creating an effective RFID strategy using EPC requires an understanding of the various specific industry initiatives, their goals and requirements, and a general understanding of how RFID can create advantage in the industry.

Fortunately, there is enough common ground among the various industry initiatives to enable all healthcare stakeholders to implement RFID strategies and systems that will position them to satisfy growing industry track-and-trace requirements, while also improving the efficiency of their business processes.

Early efforts suggest that EPC systems adopted in the healthcare industry can provide multiple benefits. For example, branded, prescription drug manufacturers who begin tagging products at the item level could realize annual benefits of more than \$10 million per \$1 billion in revenue, or 1 percent of revenue, according to a study prepared by the HDMA Healthcare Foundation. While not specifically quantified in the case studies, the HDMA Healthcare Foundation report also calculated the benefits of using EPC technology for brand protection and for avoiding the cost of generating and maintaining paper pedigrees. Based on secondary research, these benefits amounted to more than \$11 million annually for a \$1 billion drug at high risk for counterfeiting. The quantified benefits are based on improved patient safety, brand protection, increased channel visibility and regulatory compliance, improved chargeback/rebate accuracy, reduced out of stocks, improved recall/return management, reduced unsaleables, inventory reduction, and warehouse labor reductions.

The analysis assumed the hypothetical manufacturer spent \$0.25 cents per tag, decreasing 20 percent a year to bottom out at \$0.10 per tag. The \$0.25 is a reasonable reflection of what some EPC tags can be purchased for today. Earlier in the history of EPC development, some technology manufacturers and promoters boldly predicted tag costs would fall fairly quickly to \$.05. Based on current tag prices, the standards and production developments that still need to occur, and a possible short-term shortage of EPC tags, it is difficult to project with confidence that \$0.05 tags will be available in the near term. Therefore, system planning projections should not be based on this price level. Fortunately, the HDMA Healthcare Foundation study has shown \$0.05 tags are not necessary for EPC technology to provide a positive return on investment (ROI).

HDMA GOALS

HDMA strongly supports the use of EPC and RFID technology as an effective strategy to help ensure supply chain integrity and public safety. HDMA believes EPC will be a particularly effective anti-counterfeiting solution due to its ability to electronically record a product's transaction history (or pedigree) using a unique product identification number. As such, HDMA's goal is to become the most visible voice advocating a uniform, national solution for item-level EPC adoption across the entire supply chain. HDMA's goals for EPC and related activities are outlined below.

- 1. In accordance with FDA recommendations, HDMA is encouraging pharmaceutical manufacturers to begin item-level tagging of top priority drugs. Top priority drugs, as defined by HDMA, include:**

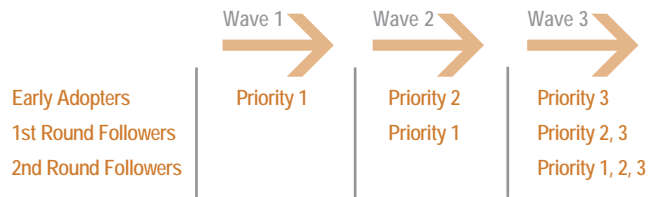
- Drugs likely to be counterfeited;
- Drugs with a high volume of chargebacks;
- Drugs with special regulatory requirements (e.g. controlled substances);
- Drugs falling under customer and/or regulatory mandates (e.g. Wal-Mart, DoD, and other supplier tagging programs);
- Drugs with high revenues and high costs per unit of sale.

- 2. Gain industry consensus for this rollout plan.** To promote consensus, HDMA is continuing to collaborate with other stakeholders in the healthcare and RFID industries, including Project Jumpstart; EPCglobal US; Auto-ID Labs; sister associations such as Biotechnology Industry Organization (BIO), National Association of Chain Drug Stores (NACDS), Pharmaceutical Research and Manufacturers of America (PhRMA); and others. By collaborating, HDMA will lead a coalition effort to identify industry and business issues impacting EPC adoption.
- 3. Establish uniform standards for electronic pedigrees.** Encourage states/federal lawmakers enacting electronic pedigree solutions to seek industry guidance and involvement prior to finalizing any pedigree requirements on industry.
- 4. Work proactively with the FDA.** When and where appropriate, HDMA will provide research and recommendations that enable the agency to resolve issues surrounding EPC, such as labeling, frequency selection, stability testing, etc.
- 5. Create and exchange research and information.** HDMA will develop (or promote studies already conducted) research reports that comprehensively outline issues such as the costs, benefits, business requirements, timelines, data standards, tag/technology requirements, and implementation needs of an EPC infrastructure, and will encourage industry wide pilot development.
- 6. Build groundswell support for EPC.** To meet this goal, HDMA will collaborate with sister associations and technology vendors/consultants, communicating the benefits of EPC to outside groups via speaking engagements, meetings, educational sessions, web resources, etc.
- 7. Actively participate in development of EPC data standards.** To ensure industry-appropriate standards and uniformity, HDMA will actively participate in groups such as the EPCglobal Healthcare & Life Sciences Action Group, to create technical and business process standards, such as tag data requirements, data sharing protocols, data access standards, technical architecture, etc.
- 8. Demonstrate the thought leadership required to give credibility to EPC adoption initiatives.** Many other organizations and individuals share similar goals for promoting EPC adoption within the industry. HDMA is actively involved in several of these industry initiatives, with the intent of advancing knowledge of EPC's potential impact and of creating the foundation for collaborative, compatible technology implementations throughout the industry.

Furthermore, the HDMA has proposed a suggested industry EPC rollout schedule, as summarized in Figure 1. The chart and recommendations were adapted from the HDMA Healthcare Foundation report "Adopting EPC in Healthcare: Cost and Benefits." See the full report, available from the HDMA Web site, www.healthcaredistribution.org for complete information.

FIGURE 1

Proposed Industry Rollout Schedule



Priority	Products To Be Tagged at Pallet, Case, and Unit-of-Sale Level
Priority 1	Prescription Drugs With a High Number of Counterfeiting Incidents
	Prescription Drugs With High Chargebacks
	Drugs With Special Regulatory Requirements (e.g., Controlled Substances)
	High-Value, Prescription Oral Solids (High Revenues and High Cost per Unit of Sale)
Priority 2	Prescription Drugs With High to Medium Value (e.g., Greater Than \$50 Million in Sales per Year)
	Drugs With Special Handling or Storage Needs (e.g., Temperature Controlled, Light Sensitivity)
	High-Value OTC Drugs
Priority 3	Drugs Mainly Used in the Hospital Environment, Which Needs to Control Medication Dispensing/Administration Errors (e.g., Chemotherapy)
	Other OTC Drugs/Generic Drugs

The following section provides an overview of some related EPC activity in the healthcare industry.

INDUSTRY INITIATIVES

The FDA has actively investigated and promoted RFID use as one key component of an overall strategy to secure product integrity and further protect patient safety. In February 2004, the FDA stated, *“Because the capabilities of counterfeiters continue to evolve rapidly, there is no single ‘magic bullet’ technology that provides any long-term assurance of drug security. However, a combination of rapidly improving ‘track and trace’ technologies and product authentication technologies should provide a much greater level of security for drug products in the years ahead.”* The FDA has been very active, supportive, and constructive in its efforts to promote RFID without issuing any mandatory requirements. The agency’s approach to RFID adoption has created an opportunity for HDMA and various other pharmaceutical, healthcare, and retail trade associations to develop their own RFID policies and programs.

There are clear regulatory and business drivers leading the industry to increased RFID/EPC use. The highlights, requirements, and strategic implications of specific leading initiatives are presented below.

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FDA Unit-of-Use Bar Code Rule

In February, 2004 the FDA issued a new rule requiring pharmaceuticals to be marked with a bar code at the unit-of-use (unit dose) packaging level. The FDA specifically ruled that RFID could not be used as a substitute for bar code identification. The background issued with the complete ruling (available at www.fda.gov/oc/initiatives/barcode-sadr) was careful to state that RFID holds tremendous potential to improve pharmaceutical tracking in the supply chain and to deter counterfeiting, but noted these considerations fell outside the scope of the rule, which was to facilitate improved accuracy in medication administration. The relative value of RFID compared to bar code for medication administration was deemed not worth the incremental cost and added implementation complexity. The FDA rule does allow unit-of-use packaging to include an RFID tag in addition to the bar code. Manufacturers and other stakeholders in the supply chain can therefore apply item-level RFID tags for counterfeit protection and supply chain applications without threatening their compliance with the FDA bar code requirement.

FDA Counterfeit Drug Task Force

The FDA Counterfeit Drug Task Force report issued in February 2004 made a strong case for rapid industry adoption of RFID. The report and related resources are available at www.hhs.gov/news/press/2004pres/20040218.html. The non-binding report made a series of recommendations that support RFID as the leading tool to protect against pharmaceutical counterfeiting and to enable convenient, secure electronic pedigrees. Some of the more significant recommendations and comments include:

- *The adoption and common use of reliable track and trace technology is feasible by 2007, and would help secure the integrity of the drug supply chain by providing an accurate drug "pedigree," which is a secure record documenting the drug was manufactured and distributed under safe and secure conditions.*
- *Radiofrequency [sic] Identification (RFID) tagging of products appears to be the most promising approach to reliable product tracking and tracing.*
- *Authentication technologies for pharmaceuticals have been sufficiently perfected that they can now serve as a critical component of any strategy to protect products against counterfeiting.*
- *At the time the PDMA [Prescription Drug Marketing Act] was enacted the only way to pass on a pedigree for drugs was to use paper, which has posed practical and administrative challenges. RFID technology, which would provide a de facto electronic pedigree, could surpass the intent of the PDMA and do so at a lower cost. In light of the rapid progress toward much more effective electronic pedigrees...the FDA intends to continue to stay its regulations regarding certain existing pedigree requirements to allow suppliers to focus on implementing modern effective pedigrees as quickly as possible.*

The task force also proposed a three-year timetable leading to wide-scale adoption of RFID for anti-counterfeit product protection and electronic pedigrees. Key industry milestones and goals of the timetable include:

- 2004** – Industry should conduct feasibility studies for RFID-enabled mass serialization of pallets, cases, and packages.
- 2005** – Implement mass serialization on some pallets, cases, and packages of pharmaceuticals most likely to be counterfeited; acquisition and use of RFID technology by some large manufacturers, large distributors, and some large drug store chains.

2006 – Mass serialization of most pallets and cases of pharmaceuticals likely to be counterfeited and some pallets and cases of other pharmaceutical products; mass serialization on most packages of pharmaceutical likely to be counterfeited; and acquisition and use of RFID technology by most manufacturers, most distributors, most chain drug stores, most hospitals, and some small retailers.

The recommendations do not specify or recommend any specific RFID standard, protocol, or frequency. Other initiatives specifically recommend the use of EPC technology, but this is neither expressed nor implied in the FDA task force report. However, the FDA did write *“The use of mass serialization to uniquely identify all drug products intended for use in the United States is the single most powerful tool available to secure the U.S. drug supply.”* Because the EPC system specifically defines RFID technology protocols and a serialization system, it seems especially well suited to meet the FDA’s goals.

The industry has responded to the FDA’s anti-counterfeiting and RFID efforts by making tremendous progress, which is highlighted below. Major retailers and purchasers of pharmaceuticals have gone further than the FDA by creating business requirements that demand RFID tagging from their suppliers. The U.S. Department of Defense and Wal-Mart headline a growing list of organizations requiring suppliers to apply EPC tags on cases, pallets, and select individual items starting in 2005, with an eye to wide-scale, item-level tagging in the following two or three years. Other initiatives are addressing how the industry can use EPC for counterfeit protection, pedigrees, recalls, returns processing, inventory management, and more.

Project Jumpstart

Project Jumpstart was formed in February 2004 to promote pilots of EPC technology in the pharmaceutical industry supply chain. HDMA is a member of Project Jumpstart, which was formed by Accenture, a leading business consulting and services firm, and also includes consumer goods and pharmaceutical manufacturers, distributors, retailers, and associations. In September 2004, some Project Jumpstart members completed a 12-month EPC pilot project that was unprecedented in its scope and pharmaceutical industry participation.

The participants spent months designing the pilot then conducted an eight-week trial that tracked 10 products from multiple manufacturers through 16 business scenarios at 15 locations. More than 13,000 products were tagged and read. HDMA participated in the project, as did Abbott Laboratories, Barr Laboratories, Cardinal Health, CVS Pharmacy, Johnson & Johnson, McKesson, National Association of Chain Drug Stores (NACDS), Pfizer, and Rite Aid, with Accenture serving as project administrator.

The project was designed as a proof of concept for using EPC technology in multiple business operations. The main focus was to determine how unit-level item serialization could improve supply chain security. Other goals included:

- Assess EPC suitability to satisfy regulatory mandates such as the Florida pedigree requirement;
- Establish processes to facilitate returns and recalls;
- Develop and execute tests to see if electromagnetic energy from radio frequency affects the efficacy, potency, and strength of solid drugs included in the trial;
- Gain knowledge and develop solutions for labeling, including tag frequency and the color, size, wording, and location of RFID labels.

Jumpstart declared the project a success and reported it demonstrated the potential of EPC technology to provide many benefits specific to the industry, including meeting regulatory transaction history requirements, returns and recall management, improved consumer safety through electronic track-and-trace and authentication capabilities, greater order

accuracy, and increased labor productivity. Several obstacles and challenges to wide-scale implementation also were identified. The project provided many insights and recommendations as to how companies can develop RFID strategies and implement the technology, and how the industry needs to collaborate to further develop EPC systems to meet specific needs.

A second Project Jumpstart pilot, with additional participants, is scheduled to conclude in December 2004. Project Jumpstart has also given assistance to the FDA Counterfeit Drug Task Force. More information about Project Jumpstart is available through Accenture or HDMA.

HDMA Patient Safety Task Force (PSTF)

HDMA created the Patient Safety Task Force, a coalition of companies and associations convened to assess technological approaches for combating the existence of counterfeit activity in the healthcare supply chain. The PSTF's report, which was issued July, 2004, concluded that electronic track-and-trace systems were the best potential solution, which led the group to its stated goal of RFID tagging with unique serialization for all products in the healthcare supply chain.

The PSTF developed an envisioned five-step implementation approach starting with case and pallet tagging and escalating to extensive item-level tagging with full industry utilization of serialization and EPC reading systems. The task force did not create a timeline because of the substantial technical development and industry collaboration that is required. The PSTF recommended the formation of a steering committee and sub-committees to guide its efforts, and expressed its hope for EPCglobal to be among the organizations providing cross-industry representation in its efforts.

Learn more about the PSTF at www.healthcaredistribution.org/about_hdma/task_product.asp. On the same page, users can also download the task force response to the FDA Counterfeit Drug Task Force and the "PSTF Business Requirements Document" white paper.

EPCglobal Healthcare and Life Sciences Business Action Group

The EPCglobal Healthcare and Life Sciences Business Action Group (HCLS BAG) is tasked with defining and developing aspects of EPC technology to meet the specific needs of the healthcare industry. Formed in July 2004, it is a formal working group of EPCglobal Inc., a not-for-profit organization entrusted to drive the global, multi-industry adoption and implementation of the EPCglobal Network. The Healthcare and Life Sciences group's membership includes pharmaceutical and medical device companies, retailers, hospitals, and regulatory bodies. There are six working groups under the Healthcare and Life Sciences group umbrella: Strategic Planning, Research and Development, Information, Technology, Process, and Policy. HDMA strongly urges the pharmaceutical industry become more involved with EPCglobal to drive the rapid development and adoption of suitable, respected RFID standards for the industry. More information about EPCglobal's action groups is available at www.epcglobalinc.org/action_groups/bag.html.

Association Initiatives

The National Association of Chain Drug Stores (NACDS), Grocery Manufacturers of America (GMA), and the Food Marketing Institute (FMI) issued a joint report (which was prepared on their behalf by A.T. Kearney and Kurt Salmon Associates) in February 2004 with multiple recommendations for implementing RFID. The report, "Connect the Dots, Harnessing Collaborative Technologies to Deliver Better Value to Consumers," endorses the EPC system and recommends that consumer packaged goods (CPG) manufacturers and retailers adopt EPC as the global standard for electronic product identification.

The report focuses heavily on data synchronization issues and concludes that global data synchronization (GDS) should be the top priority for manufacturers and retailers, ahead of any EPC initiatives, because GDS provides the foundation for EPC.

A projected technology adoption timeline was presented, showing pilots and some case and pallet tracking occurring in the short-term period after the report's release, followed by broad case and pallet tracking in two to three years, along with increased multi-company supply chain collaboration and some item-tagging pilots. Wide-scale item tagging rollouts were predicted for five to 10 years in the future. The report is available at www.fmi.org/supply/Connectthedots.pdf.

Customer-driven Tagging Programs

Wal-Mart and the U.S. Department of Defense (DoD) have announced the largest and most defined RFID shipment tagging requirements for their suppliers. Several other programs have also been announced, and many more are expected. The DoD and Wal-Mart programs are notable because they set clear, mandatory deadlines and technology specifications for their suppliers. The details vary, but the programs generally require leading suppliers to provide EPC tags on some pallets and cases shipped to select locations beginning January 1, 2005. Requirements escalate to incorporate additional suppliers and product categories, leading to full implementation in 2006, including some item-level tagging. Both organizations have stated their intent to require tags that comply with the EPC Class 1 Generation 2 (C1G2) specification. The specification is expected to be completed and ratified as an EPCglobal standard in late 2004. Wal-Mart and the DoD are allowing their suppliers to apply other types of EPC tags, including Class 0 and Class 1 Generation 1 protocols, while the C1G2 specification is being completed, and will allow a transition period before only Class 1 Generation 2 tags will be accepted.

By requiring EPC-protocol RFID tags, Wal-Mart, the DoD, and other organizations are potentially elevating EPC as the de facto standard for supply chain RFID. Many of the RFID implementation timetables predicted by industry analysts or proposed by the FDA and various industry associations correspond to the actual deadlines announced by early adopters. It is clear these user organizations have tremendous influence on how EPC technical specifications are being developed and on overall adoption of the technology.

DEVELOPING AN RFID STRATEGY

Organizations at all points in the supply chain are subject to more recommendations than requirements for implementing RFID. To date, the DoD and retailer programs represent the only true RFID implementation requirements; the other initiatives outlined above are suggestions, recommendations, and/or proposals for pilots. However, companies should not underestimate the momentum behind RFID or the expected rate of adoption. Early RFID use is expected to grow much more rapidly than bar code or EDI technologies did in the past because of the business and potential legislative/regulatory drivers behind it, and the growing recognition of the operational benefits it provides. RFID projects require extensive planning and testing before implementations can get up and running. Organizations should begin planning their RFID strategies immediately in recognition of the time required to complete RFID projects and the industry momentum behind the technology.

Step 1: Form a Team

RFID can have a far-reaching impact into the organization, so a cross-disciplinary team should be formed to plan, implement, and manage RFID systems. Finance will need

to be involved for project budgeting and for return on investment analysis. Production, warehousing, and shipping operations are directly impacted and should be well represented. Operations managers can contribute insight as to how reduced inventory levels and increased responsiveness could impact other areas of the organization. Engineering and packaging professionals might be engaged to help solve tag placement challenges and to minimize interference. Marketing could even play a role to help communicate the safety and responsive benefits RFID tagging can provide, and to help position new business processes for competitive advantage.

Step 2: Plan for EPC Serialization

The common bond among multiple industry RFID recommendations and proposals is that each advocates pharmaceutical goods be tagged with a unique, serialized identifier. Recommendations differ as to what packaging level the tag should be applied and how it should be used, but all endorse unique serialization. Therefore, organizations should commit to unique serialization in accordance with the EPC system as the foundation for all RFID programs.

Step 3: Consider Applications

Once objects (pallets, cases, cartons, or individual items) are uniquely identifiable, organizations at all points in the supply chain can take advantage of them in many ways. Unique identification (e.g. an EPC number) stored on an RFID tag can:

- Satisfy customer tagging requirements;
- Create a secure electronic pedigree;
- Provide a means for manufacturers, distributors, retailers, pharmacists, and hospitals to quickly authenticate products;
- Facilitate precise, efficient recalls and returns processing;
- Provide lot, batch, and sample tracking benefits to manufacturers and distributors; and
- Facilitate expiration date management, stock rotation, and other inventory control activities.

Step 4: Coordinate with Supply Chain Partners

These benefits are only available if all participants in the supply chain are using the same tagging technology and serialization structure. The traditional obstacles that stand between RFID tagging and the benefits it can provide are the lack of standards for tag and reader interoperability, no consensus or standards for data content or ownership, questions surrounding synchronization and sharing, RFID cost, lack of security protocols, and technology reliability questions concerning real-world applications. Fortunately, these obstacles are all gradually being removed. The rapidly changing state of RFID technology must be considered when RFID policies are investigated and developed.

The EPC system appears to meet the industry's primary needs of providing unique serialization in an open, standardized technology. However, EPC specifications support multiple, incompatible radio frequencies (e.g. 13.56 MHz high frequency and 860-930 MHz ultrahigh frequency) and memory capacities (64 bits, and 96 to 256 bits). These differences mean that using "EPC" technology will not guarantee interoperability with trading partners. There will always be a need for coordination and standardization. Momentum is behind UHF EPC technology (860-930 MHz), particularly the Class 1 Generation 2 specification that is expected to be ratified late in 2004. **Delays to standards ratification, or the commercial development and availability of compliant products, would deal a serious setback to industry implementation efforts.**

Many of the beneficial supply chain applications for EPC technology – including return and recall management, pedigree documentation, and improved inventory flow – involve sharing

data from tag readings among trading partners. There are provisions within the EPC system to facilitate convenient, timely data exchange. The availability of new types of data, in real-time, raises new questions as to how information is best exchanged and processed. Questions also exist as to who “owns” information from tag readings. While EPCglobal works to solve the technical challenges to integration, the business process questions are being explored in pilot programs and strategy sessions that HDMA and other industry leaders are involved in.

HDMA’s recommendations for prioritizing products for EPC tagging based on findings from the HDMA Healthcare Foundation report are summarized in Figure 2 below.

FIGURE 2:  **Basic Priorities of the EPC/RFID Rollout**

Basic Priorities of the EPC/RFID Rollout

Priority	Products	Rationale
Priority 1	Prescription Drugs More Likely To Be Counterfeited	<ul style="list-style-type: none"> • Technology Reduces Risk of Counterfeiting Through Improved Detection, and, Therefore, Risk for Associated Revenue Losses, Recall Costs, Liabilities, and Brand Impact • Anticipates Potential Regulatory Requirements, e.g., Electronic Pedigrees
	<ul style="list-style-type: none"> • Prescription Drugs With High Revenues or High Chargebacks • Products With a High Percentage of Contracted Volume 	<ul style="list-style-type: none"> • Increased Chargeback Accuracy Was a Major Benefit Driver in One of the Business Case Drugs (Applies to Drugs With High Chargebacks)
	Drugs With Special Regulatory Requirements (e.g., Controlled Substances)	<ul style="list-style-type: none"> • Compliance With Wal-Mart C-II Mandate • Facilitates More Secure Supply Chain
	High-Value, Prescription Oral Solids (High Revenue and High Cost per Unit of Sale)	<ul style="list-style-type: none"> • Ease of Implementation/Good Test Case; Technology Issues Such as Readability Through Liquids or Metals Can Be Avoided • Less/No Risk of Negative Effect of Electromagnetic Field on Drug
Priority 2	Prescription Drugs With a High- to Medium-Value (e.g., Greater Than \$50 Million in Annual Sales)	<ul style="list-style-type: none"> • Allows the Distributor To Capture Majority of Supply Chain Efficiency Benefits
	Drugs With Special Handling or Storage Needs (e.g., Temperature Controlled, Light Sensitivity, Biologicals)	<ul style="list-style-type: none"> • Allows for a Tighter Control of Those Products • Potentially Reduces Liability
	High-Value OTC Drugs	<ul style="list-style-type: none"> • Only if Major Retail Pharmacy Chains Have Adopted the Technology • Significant Benefits on the Retail Level (e.g., Theft, Shrinkage, Inventory Control)
Priority 3	Drugs Mainly Used in the Hospital Environment, With Need to Control Medication Dispensing/Administration (e.g., Chemotherapy)	<ul style="list-style-type: none"> • Major Hospitals Deploy When Technology Is Implemented at the Point of Dispensing • Technology May Have the Potential to Improve Medication Dispensing/Administration
	Other OTC Drugs/Generic Drugs	<ul style="list-style-type: none"> • Depending on Penetration of Technology on the Pharmacy Level



KEY MILESTONES AND PROGRESS NEEDS

The best of intentions, project plans, and resources are not enough for organizations to implement effective, efficient EPC systems because of key factors that are beyond any user organization's control. Many of the developments needed for successful EPC programs must be made at the industry level by standards bodies and technology companies. The HDMA Collaborative Commerce Committee believes all of the following progress milestones must be reached to facilitate timely, wide-scale adoption of EPC technology in the healthcare industry:

- Industry data structure issues resolved by Q2 2005;
- Appropriate EPC tag standards established by Q3 2005;
- Voluntary guidelines for data sharing, ownership, integration, and security developed by Q4 2005;

HDMA plans to convene a new Data Management Task Force in December 2004 to begin work on industry data structure issues. Many standards bodies and other organizations are also actively trying to solve the technology performance and business process challenges that surround RFID implementations in the healthcare industry. Staying informed of these efforts is an important part of RFID planning. Some organizations with initiatives specific to pharmaceuticals and allied industries were identified and profiled in the Industry Initiatives section of this paper. These organizations primarily are focused on investigating and recommending business practices to optimize the use of RFID technology in the industry and on efforts to assist implementation and integration. HDMA is committed to being the leading resource to facilitate RFID adoption in the industry, and will monitor these activities closely. Visit the HDMA Web site often to see updated material for additional resources and RFID information appropriate to the healthcare industry.

EPC IN PRACTICE: A CASE STUDY

Despite the challenges, companies are successfully piloting and implementing RFID systems and obtaining outstanding results. The following example provides insight to how strategies and processes were developed that resulted in a successful implementation.

It describes the experiences of a real pharmaceutical company that does not wish to be identified. The company became involved with RFID because it supplies Wal-Mart and is required to label individual pill bottles for Class 2 narcotics with EPC tags by January 2005. The pilot project goal was to complete unit level tagging by April, 2004, and to add case-level tags by 2006. The company has moved beyond pilot stage to integrate EPC labeling into its production operations, and it is successfully shipping tagged products to Wal-Mart today.

When the project started, the company faced the usual questions regarding readability, integration strategy, and business case development. What is particularly instructive are the unexpected challenges that arose as this early-adopter moved from investigation, to pilot, to production system, particularly in the areas of production-speed labeling, segregating tagged and untagged items in storage prior to distribution, managing the volume of RFID data, and determining how deeply to integrate the RFID labeling system with existing enterprise applications. These issues and their resolution are described more thoroughly below.

The Pilot

The company formed a project team with representation from several areas of the company, and engaged the firm's enterprise resource planning (ERP) software vendor, SAP, to assist in process planning and system development. The project team planned a pilot that was designed to test the proof of concept for RFID labeling and data integration processes. Specific pilot project goals included:

- Be able to apply EPC labels to individual bottles of pharmaceutical product on a high-speed packaging line;
- Demonstrate the ability to perform 100 percent online verification of each individual bottle for EPC readability and data accuracy at a line speed of 120 bottles per minute;
- Reject all bottles that fail the read test;
- Achieve 100 percent online verification for EPC readability and uniqueness of each tagged bottle in its final 24-count shipping case configuration, rejecting failures; and
- Provide information for internal track-and-trace processes by collecting EPC data as RFID-tagged products move from packaging to storage to shipment.

Scalability was a concern when the system was developed for production. Only one portion of one product line initially required EPC tagging. The company needed to ensure the system could meet its needs, but did not want to expand the scope of the project and make undue changes to its production systems and software applications.

For example, the company did not want to create a new SKU (stock keeping unit) number solely to identify the subset of its products that received EPC tags for Wal-Mart. While the introduction of one additional SKU could be easily integrated into business systems, the practice would not scale well when EPC tagging expanded to include more product lines, customers, and internal applications. Because tagged products would not be identified with a separate SKU, the manufacturer had to develop a process to segregate them from non-tagged goods and ensure they were shipped to Wal-Mart. The process involves adding additional characteristics to the product batch (lot) master data record and is supported by the company's SAP ERP system.

The System

The EPC encoding and labeling system was integrated into an existing packaging line that applies 120 labels per minute to bottles spaced six inches apart. A label converter integrated programmed EPC tags into the company's legacy product labels. The material was used with existing packaging machinery, so no encoding was necessary on the production line. The converter verified that each label was readable and that each contained a unique serial number before providing the material to the manufacturer. The converter also provided each product's EPC number on a diskette. RFID readers and photoelectric sensors were added to the packaging line and interfaced to a programmable logic controller (PLC) to verify the EPC tags were still readable after the application process, and to divert rejected bottles. Label placement on the bottles was adjusted several times to obtain the best possible reading performance.

Labels were verified again after bottles were packed into 24-count cases to ensure readability in the final packaging configuration. The manufacturer used RFID to collect track-and-trace information when finished products were moved from packaging to storage, and again when products were prepared for shipment.

To ensure tagged items were shipped to Wal-Mart, the labeling system was integrated with the company's SAP R/3 enterprise resource planning software applications. The EPC serial number for each bottle was associated with batch and lot information in the SAP system. In turn, batch and EPC information was integrated with the SAP Sales and Distribution module, allowing specific products to be allocated to specific customers. Integrating data at this level facilitated convenient and accurate product handling through storage and distribution operations. The processes were developed to ensure tagged product was delivered to the right customer, but also created an accurate traceability record that associated customer shipments with specific batches, which is valuable information for a variety of applications.

The Future

The system was designed to meet Wal-Mart compliance needs, but the experience it provided has led the manufacturer to consider new ways RFID product tagging can be used to improve internal operations. For example, RFID could be used for inventory monitoring and reporting. In the case of controlled substances, RFID could be used to reconcile inventory differences to minimize the amount of manual time spent on these activities. This data could be compiled into a report made available any time.

The company also is considering how rewritable RFID tags could interface with temperature sensors to monitor and record ambient temperatures for cold storage products on the tag. Such a system would allow temperatures to be accurately tracked and recorded without labor. The data then could be used to issue warnings when the exposure time nears the acceptable limit. Lot and shelf life data for specific batches could also be adjusted as part of an electronic batch record (EBR). These are just a few examples of how RFID can provide advantages when integrated with enterprise applications and new business processes.

Integration Recommendations

This successful solution verifies EPC labels at several points in the production and distribution processes and utilizes item-level EPC data to create batch traceability and ensure proper product distribution. The company and its solution providers carefully considered how this data could best be collected, processed, and integrated. It is important to prevent all data collected by a RFID system from flowing through the ERP system, as the volume of data could overwhelm the software. In this example, the company had several options to filter reader data, including infrastructure integration and RFID event management and middleware software from SAP. Determining what data is needed for business processes and when it needs to be communicated will help optimize the degree of integration and information flow between RFID and ERP systems.

The value proposition around the RFID application is that it would close the loop between acquiring data, converting it to meaningful information and automating all associated transactions to improve business processes. The big question is: How to get started? The recommendation is to quickly organize a team of individuals to look into how this technology can be applied to the business. This can be done in a phased manner, as outlined below.

Phase 1 – Achieve a rapid low cost compliance with customer requirements (if necessary). This involves the following:

- Determine the project objective – this should include meeting the mandate (if applicable) and deploying a scalable RFID solution that integrates business processes in order to drive a positive ROI.
- Determine the process – this involves pallet, case, or item tagging for the outbound delivery process.
- Plan a basic outbound delivery solution to meet the mandate, if applicable.
- Integration with enterprise systems, with basic reporting.
- Determine the minimum hardware requirements. Consider the following: RFID readers, printer/encoders, applicators, photoelectric eyes or other packaging sensors, buzzers or alert lights, power supplies, and programmable logic controllers.
- Determine the software needs, including: integration and event management software at the ERP level, RFID-capable label design software, RFID infrastructure software and middleware.
- Consider the services part of this project. This includes: initial analysis, design, and deployment, solution testing, and training.

Phase 2 – Scale to achieve supply chain optimization, which includes:

- Expand the solution to include additional products and/or trading partners.
- Track and trace tagged product through event management software or integration with ERP applications.
- Integrate information with suppliers and customers.
- Integrate RFID data with advanced reporting and analytics software using reporting or business intelligence tools.
- Integrate data captured by RFID into manufacturing systems.

CALL TO ACTION

The momentum behind RFID adoption in the healthcare industry is real, widespread, and supported by the FDA and by stakeholders at all points in the supply chain. Wide-scale implementation appears to be a question of “when,” not “if.” HDMA and its member organizations have a clear choice: take an active role in driving EPC developments in the industry, or risk being run over by them.

HDMA must continue to exhibit the leadership it has provided to facilitate EPC adoption. The association also must continue to be a source of reliable information for industry-related technology and business issues, and to serve as a conduit for its members to get more involved in EPC developments. HDMA itself must play a leading role in these developments, particularly for issues involving standards, data structure, ownership, integration and security, business process changes, and implementation guidelines.

HDMA members and other user organizations should lend their voices to these developments at the industry level, while preparing at the company level for the impact of EPC. Organizations should begin prioritizing products for EPC serialization and labeling, and start developing a phased implementation strategy for pallet-, case- and item-level tagging. Organizations should share the questions, concerns, and experiences from these efforts with HDMA so the development of standards and business processes are user-based and meet the specific needs of the healthcare industry.

Business drivers may compel organizations to undertake RFID activities long before any regulatory requirements are enacted. There are also questions about how the technology will be adopted and in what form, although EPC is emerging from pilots and other activities as the leading form of RFID for the industry. To prepare for the impending impact of RFID on the industry, organizations should form a project team with representation from multiple functional areas, get involved with HDMA and other industry initiatives to learn more about EPC technology and applications, and plan on conducting a pilot program in the near future. It is also important to create an educational plan to prepare the organization and its key trading partners about relevant RFID activity. It can be difficult to keep track of the fast-changing RFID program and technology developments that are impacting the industry. These challenges are shared by organizations throughout the industry. Collaboration and communication can make the task easier. HDMA provides a forum for organizations to work together to improve their own businesses and to advance RFID-enabled safety and efficiency improvements throughout the industry.

A large, stylized graphic on the left side of the page. It features the text "HDMA EPC" in a large, bold, sans-serif font, with "2004 UPDATE" below it in a smaller font. The text is set against a background of concentric, glowing orange and yellow circles that create a sense of depth and movement, resembling a stylized globe or a series of overlapping rings.

HDMA EPC
2004 UPDATE

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HDMA Collaborative Commerce Committee is a strategically focused, industry wide committee whose mission is to provide thought leadership across the realms of healthcare collaborative commerce best practices, processes, and technologies.

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The Committee achieves its mission by creating comparative analysis studies between industry opportunities and challenges and researching the latest Collaborative Commerce advances within and outside of health care. The Committee offers the healthcare supply system a forum for the exchange and exploration of emerging business processes, technology strategies and solutions, and high-level tactics.

Burnell Reports is a strategic communications company that provides consulting and editorial services to the RFID, bar code, mobile computing and select other industries. For more information, contact the author, John Burnell, at john@burnell.com or visit www.burnellreports.com.

Zebra Technologies, an HDMA member, delivers innovative and reliable on-demand printing solutions for business improvement and security applications in 90 countries around the world. More than 90 percent of Fortune 500 companies use Zebra-brand printers. A broad range of applications benefit from Zebra-brand thermal bar code, "smart" label, receipt, and card printers, resulting in enhanced security, increased productivity, improved quality, lower costs, and better customer service. The company has sold more than three million printers, including RFID printer/encoders and wireless mobile solutions, and also offers software, connectivity solutions, and printing supplies. Information about Zebra Technologies can be found at www.zebra.com.

SAP is the world's leading provider of business software solutions. SAP® solutions are designed to meet the demands of companies of all sizes — from small and midsize businesses to global enterprises. Powered by the SAP NetWeaver™ open integration and application platform to reduce complexity and total cost of ownership and empower business change and innovation, mySAP™ Business Suite solutions are helping enterprises around the world improve customer relationships, enhance partner collaboration and create efficiencies across their supply chains and business operations. The unique core processes of various industries, from aerospace to utilities, are supported by more than 25 SAP industry solutions. Today, more than 23,400 customers in over 120 countries run more than 79,800 installations of SAP® software. With subsidiaries in more than 50 countries, the company is listed on several exchanges, including the Frankfurt stock exchange and NYSE under the symbol "SAP." Additional information is available at www.sap.com.

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ADDITIONAL RESOURCES

Following is an overview of several key organizations and their role in RFID development.

AIM Global is a trade association for the automatic identification and data capture (AIDC) industry, whose members include many leading RFID manufacturers and integrators. AIM frequently collaborates with industry groups and standards bodies to provide technical expertise, user education, and other resources. The organization's Web site (www.aimglobal.org) is a good resource for RFID information and educational opportunities and provides links to publications and events.

Auto-ID Labs is a worldwide federation of universities who are conducting advanced research into EPC technology. The EPC system was originally developed at the Auto-ID Center at the Massachusetts Institute of Technology (MIT), before responsibility for commercializing the system was transferred to EAN and the UCC. MIT is now one of six universities with Auto-ID Labs. The others are University of Adelaide (Australia), University of Cambridge (England), Fudan University (China), Keio University (Japan) and University of St. Gallen (Switzerland). Research topics include RFID packaging, sensor systems, software, markup languages, RFID performance, smart products, potential business impact, and more. For more information visit www.autoidlabs.org.

EPCglobal is responsible for developing, maintaining, and promoting the EPC system. It develops and maintains technical specifications, manages work groups to advance the technology in various business sectors, and sponsors additional research into the uses and benefits of the technology. Visit www.epcglobalinc.org for more information.

The **ISO** (the recognized acronym for the **International Organization for Standardization**) is the world's leading standards organization. Though better known for its ISO 9000 quality certification, the ISO is very active in RFID standards work. The organization has developed and ratified several internationally-recognized RFID standards (ISO 15693, ISO 18000 series, and ISO 17363 through 17368 standards are particularly relevant), and has many more in development. ISO has no official affiliation with EPCglobal, but the organizations are working together to coordinate efforts and to minimize redundant development. Visit www.iso.org for more information.

RFID Journal produces a Web site (www.rfidjournal.com), magazine, and conferences that offer news and insight into RFID technology and standards, pilots, implementations, and other developments.

The **Uniform Code Council (UCC)** and **EAN International (EAN)** are the parent organizations to EPCglobal. They maintain the EAN.UCC system of business standards, which includes the U.P.C. and EAN numbers used globally to identify individual products. The UCC and EAN closely coordinate EPC developments to complement existing standards and business processes. Visit www.uc-council.org or www.ean-int.org for more information.

The following organizations were previously referenced and described in the white paper. Their contact information is listed here as a convenience:

Healthcare Distribution Management Association (HDMA)

Biotechnology Industry Organization (BIO) www.bio.org

EPCglobal Inc. www.epcglobalinc.org

Food Marketing Institute (FMI) www.fmi.org

Grocery Manufacturers of America (GMA) www.gmabrands.com

National Association of Chain Drug Stores (NACDS) www.nacds.org

Pharmaceutical Research and Manufacturers of America (PhRMA) www.phrma.org

Project Jumpstart for more information about Project Jumpstart, contact HDMA.

U.S. Food and Drug Administration (FDA) www.fda.gov



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