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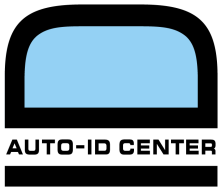

Economic Benefits of EPC™ in Pharmaceuticals

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ABSTRACT

The pharmaceutical industry is an area where there is significant activity around EPC and understanding how best to apply the technology to improve efficiency and reduce losses. Cap Gemini Ernst & Young (CGE&Y) in collaboration with the Auto-ID Center has developed a business case for the adoption of Auto-ID in the pharmaceutical industry. This case, based on CGE&Y's extensive experience with the world's leading pharmaceutical companies, distributors and hospitals, reflects the opportunities available to these companies from Auto-ID applications.

This white paper identifies not only the opportunities available within the supply chain, it also includes benefits within the drug development and clinical trials process, as well as improvements to patient safety and effects on gray market activities. Companies who read this document should note that the benefits of Auto-ID do not always require multi-company collaboration, many are realizable within the company's internal operations and direct control.

Cap Gemini Ernst & Young (**www.cgey.com**) is one of the world's largest providers of Consulting, Technology and Outsourcing services with offices around the world. CGE&Y provides a full set of services to help clients transform their operations and technologies as well as operates business processes and information technologies for many of the world's leading companies.

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BUSINESS CASE

Economic Benefits of EPC™ in Pharmaceuticals

Biography

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Colin J. Towner is a Senior Manager in Transformation Consulting in the Life Sciences Sector. He specializes in strategic analysis, operational excellence and supply chain strategy and effectiveness. He has worked with numerous pharmaceutical, medical products and biotechnology companies on issue ranging from inventory management effectiveness to operations efficiency to supply chain strategy and transformation to customer relationship management strategies. He has also worked with several companies on establishing new business models. He has authored whitepapers on Commercial Transformation in Pharmaceuticals, the future of the Medical Devices supply chain, and the application of RFID technology in the pharmaceutical value chain. Mr. Towner holds a MBA from the Ohio State University.

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Stephen Zujkowski is the Auto-ID Practice lead for CGE&Y in the Americas. He is a seasoned Supply Chain executive with over 18 years of consulting experience, backed by 11 years of industrial experience in strategy, operations and IT management. Steve has developed innovative methods in e-Synchronized Supply Chains, Marginal Supply-Chain Economics, Auto-ID Technologies, Optimization Modeling, and applications of Statistical Process Control to Supply Chain Applications. He was an early innovator in developing concepts of operation for applying RFID technology to America's Homeland Security challenges. Before joining CGE&Y was CEO and President of a global Supply Chain Software company, Regional Managing Partner of a Big 5 Supply Chain Management Practice, and VP of business Development for Savi Technology.

BUSINESS CASE

Economic Benefits of EPC™ in Pharmaceuticals

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1. INTRODUCTION

There has been a rapidly growing interest in applying EPC™ in pharmaceuticals. Previous work done to date has focused on the technical architectures, the structure of the EPC™ network, and how EPC™ can facilitate reducing counterfeit materials in the pharmaceutical supply chain. In response to significant interest from the US Food and Drug Administration (FDA), and other industry participants, this research was commissioned by the Auto-ID Center to develop a net value estimate of applying EPC™ to pharmaceuticals. The Auto-ID Center has, in collaboration with other member firms, developed business cases around distribution management, logistics, distribution centers, etc. These are, in some ways applicable to the pharmaceutical industry. But pharmaceuticals have specific applications and nuances, which this paper is intended to address.

2. WHERE ARE THE OPPORTUNITIES IN THE END

To begin a comprehensive analysis of Auto-ID application in the pharmaceuticals industry, a good starting point is a revisit of the pharmaceutical value chain. This is simply a look at each of the major stages in pharmaceutical discovery, development, marketing, sales and delivery. Within the pharmaceutical industry, each stage has its unique challenges, specific regulatory requirements, and opportunities.

The pharmaceutical value chain starts at Research and Development (R&D) and continues until the product is administered to a patient.

Figure 1

THE PHARMACEUTICAL VALUE CHAIN

Along the value chain, there are regulatory business requirements to capture information about the product, its constituents, its location, its shelf life, and its administration, much of which is laboriously written down in voluminous paper records today. Additionally, there is a significant concern from regulatory bodies (e.g. the FDA) about the diversion and counterfeiting of pharmaceuticals.

Many of the existing issues in the pharmaceutical industry relate to capturing data about discrete product units, be they barrels of active ingredient, pharmaceutical product inventories, finished goods or the distribution and administration of pharmaceuticals to patients.

Recognizing the mounting frustration with existing processes, and the substantial opportunities that a breakthrough solution would present, many have proposed solutions to address this data capture issue.

Table: Current Technology Solutions Deployed in Routine Data Capture Applications

FUNCTIONAL AREA	TECHNOLOGY SOLUTIONS DEPLOYED
R&D (e.g. Clinical Trials)	PDAs/Handhelds
Manufacturing	Barcodes, Manufacturing Execution Systems (e.g. POMS), PLCs
Distribution	Barcodes and Readers
Sales and Marketing	Barcodes, Scanners, PDAs

There are two challenges with most of these systems that introduce data errors. First, people are essential to capturing the information. They must operate a reader, write a note, enter information into a computer system and the like. In manufacturing, this information must be entered by specific qualified personnel, and attested to for accuracy. Second, the granularity of the information is limited by the capture technology. One-dimensional barcodes can hold long strings of data. The information contained on the barcode is often limited to product identification, with supplemental data such as lot and batch number being represented as separate printing on the box, tote or carton. This restriction is a result of the available space on the package, and the need to make the barcode long enough to contain all the necessary data. Two-dimensional barcodes can address the space issue, however, hardware upgrades will be required in many cases (at the manufacturer, the distributor and the hospital), as one-dimensional readers and software are not readily converted to read two-dimensional barcodes.

Application of EPC™ and RFID allows automated capture of data with a method that is much less reliant upon people to execute successfully.

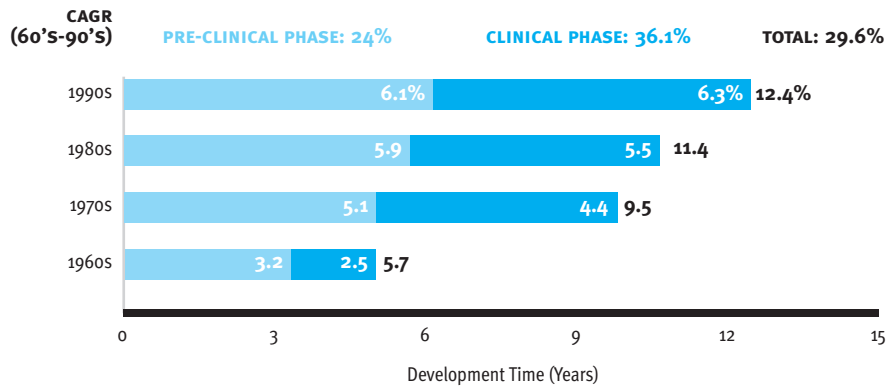
2.1. Research and Development Processes

Research and development is an expensive and lengthy process for a pharmaceutical company. Research indicates that approximately $800 million is spent over a period of 12+ years, and the clinical phase alone has increased to over 6 years.[1]

[1] "Pharmaceutical Industry Profile, PhRMA, 2001; "Healthcare: Pharmaceuticals", S&P, 12/27/01

Figure 2:

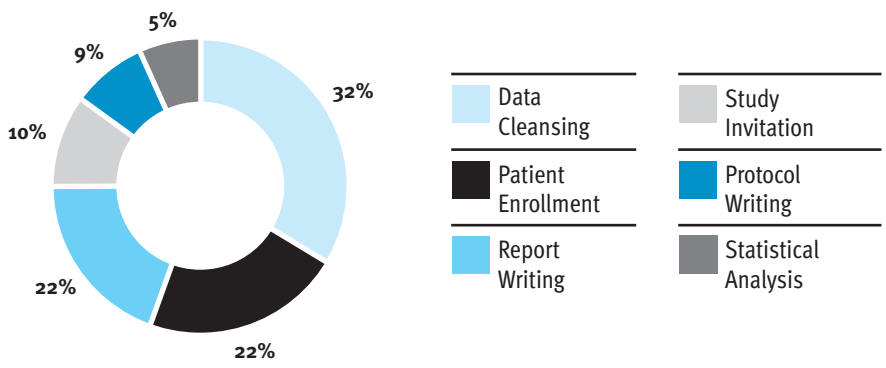
DEVELOPMENT TIMEFRAME (PRE-CLINICAL AND CLINICAL) 1960S–1990S



In the clinical phase alone (which encompasses the actual drug trials), Our own research indicates that a significant amount of the time is spent ensuring data quality.

Figure 3

BREAKDOWN OF CLINICAL TRIAL CYCLE TIME BY ACTIVITY



In an effort to reduce the time involved in monitoring and resolving data quality in the clinical phase, a multitude of electronic data capture technologies have been developed (specialized PCs, PDA applications, specialized patient monitoring equipment). These technologies are in use in a growing number of trials. EPC™ can have limited impact on this type of data capture on a stand alone basis, however, EPC™ can provide a convenient reference point for the aggregation of trial data at the individual patient and physician level. Where a full electronic suite of data capture equipment is utilized (also known as Electronic Data Capture [EDC]), EPC™ is an obvious choice as the method to connect trial information.

EPC™ can add value to the data quality process as well. A critical part of the trial is making sure the correct patient, the correct dose (either active drug or placebo) and the correct clinician are all in the right place at the right time. In a double-blind trial situation, the clinician and the patient are unaware if a placebo or the active drug is being administered. The pharmaceutical company sponsoring the trial (or its agent, a contract research organization) is responsible for providing the correct material to the clinician, and each dose is labeled with a unique serial number to attempt to ensure correct capture of information for future statistical analysis.

Utilizing EPC™, there are two primary categories of benefits in clinical trials. First, supply chain accuracy benefits. These are the Track and Trace benefits discussed by Koh & Harrison (The EPC™-enabled safe, secure supply chain (2003)) and others in the Auto-ID Center literature. Current clinical trial dose supply chain activities are often manually based, and are a small shipment distraction to the traditional shipment of cases and pallets of product. It is also often handled through a completely separate organization within the pharmaceutical company, often a subset of the R&D organization. The ability to track clinical trial doses through the supply chain from manufacturer to clinician facilitates generating necessary alerts when doses are being delayed, thereby providing sufficient time to correct the situation before a potential data inaccuracy is introduced into the system, i.e. the dose did not arrive at the correct time and under the correct environmental conditions.

Second, applying EPC™ to the individual trial dosages allows not only tracking of the appropriate dose through the clinical trial supply chain, but also facilitates verification at the point of administration that the correct dose (active or placebo) is being delivered to the correct patient. If EPC™ was to be utilized by the clinician and the patient (perhaps through EPC™-enabled smart cards or wristbands) an additional level of verification would be easily obtained by comparing the EPC™ on the dose against the clinician and patient's EPC™s.

This positive identification and verification would eliminate a portion of the data errors that consume 32% of the 6+ year clinical trial process; even without the other electronic data capture technologies being in use. Our estimate is that these errors, combined with the supply chain benefits in the clinical trial materials could reduce the duration of the clinical trial by 2–5%, with the majority of that benefit arising from the reduction in data errors and associated work to resolve the error or eliminate the affected data from the trial.

The complete list of opportunities evaluated for EPC™ application in clinical trials is shown in Table 0, along with the cost categories evaluated.

Table 0

SOURCES OF BENEFIT		
AREA	**TIMING**	**DESCRIPTION**
Clinical Trials	Shorter Trials	– Time spent fixing data entry errors will be reduced, improves the time to market – Time spent cleansing data during clinical trials will be reduced, which improves the time to market – Time spent waiting for supplies during clinical trials will be reduced, which improves the time to market
	Lower Development	– Fewer resources will be required to cleanse data Costs for database lock

COSTS REQUIRED TO IMPLEMENT AND OPERATE EPC™ AND RFID		
AREA	**TIMING**	**DESCRIPTION**
Hardware Clinical Trials	Upfront Ongoing	– Acquisition of EPC/RFID hardware for clinical trial sites – Annual maintenance of EPC/RFID hardware at the clinical sites
Installation Clinical Trial Sites	Upfront	– Installation of clinical trial readers and connection of readers to network
Software Clinical Trials	Upfront Ongoing	– Initial customizations & licensing for EPC/RFID clinical trial software – Annual maintenance (upgrades) to EPC/RFID clinical trial software
Remote Software Monitoring Clinical Trial Sites	Upfront Ongoing	– Allows IT to centrally manage distribution and maintenance of EPC/RFID clinical trial applications – Allows IT to centrally manage distribution and maintenance of EPC/RFID clinical trial applications
Integration	Upfront	– Integrating ERP and EPC/RFID software
Tags Clinical Trials	Ongoing	– Tags have to be purchased, updated with the correct information and attached (via wristbands)
Training	Upfront	– IT maintenance personnel and users need to be trained on EPC/RFID technology
Help Desk	Ongoing	– Support users (e.g. answer questions, remote fixes, etc…)
Consulting	Integration	– R&D – Professional fees required to prepare the organization for EPC/RFID from a people, process and technology perspective

The calculation of the benefits and costs are shown in Table 1.

Table 1

Assumption
- 13% discount rate
- One new drug introduced to market every 2 years
- 3 drugs in Phase 3 clinical trials annually
- 30% tax rate

THE CALCULATION OF THE BENEFITS AND COSTS

COST	YEAR 0	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
Shorter Trial		$44,900,000	$44,900,000	$44,900,000	$44,900,000	$44,900,000
Lower Development Costs		$8,100,000	$8,100,000	$8,100,000	$8,100,000	$8,100,000
Shorter Release Times		$3,400,000	$0	$3,400,000	$0	$3,400,000
Total Clinical Trial Benefits		**$56,400,000**	**$53,000,000**	**$56,400,000**	**$53,000,000**	**$56,400,000**
Installation & Integration	$8,746,000					
Ongoing Maintenance, Training & Support		$176,900	$176,900	$176,900	$176,900	$176,900
Total Costs	**$8,746,000**	**$176,900**	**$176,900**	**$176,900**	**$176,900**	**$176,900**
Total Gross Benefit	($8,746,000)	$56,223,100	$52,823,100	$56,223,100	$52,823,100	$56,223,100
Taxes	($2,600,000)	$16,900,000	$15,800,000	$16,900,000	$15,800,000	$16,900,000
Net Benefit	($8,746,000)	$39,323,100	$37,023,100	$39,323,100	$37,023,100	$39,323,100
5-Year NPV	**$126,400,000**					

The value of speeding the clinical trial completion is significant. The oft-stated rule of thumb is $1 million in profit for every day earlier a drug is in the market. Our assessment utilized a value of $675,000, to account for non-blockbuster drugs and 3rd and later entries into a therapeutic category.

Other benefits in the clinical trial area arising from the application of EPC™ include:
- Reduced patient rejection from trial due to dose administration errors
- More accurate audit records
- Improved therapeutic responses from getting new drugs to patients more quickly

These benefits are not included in the financial estimates above and are additional sources of value to the clinical trials process.

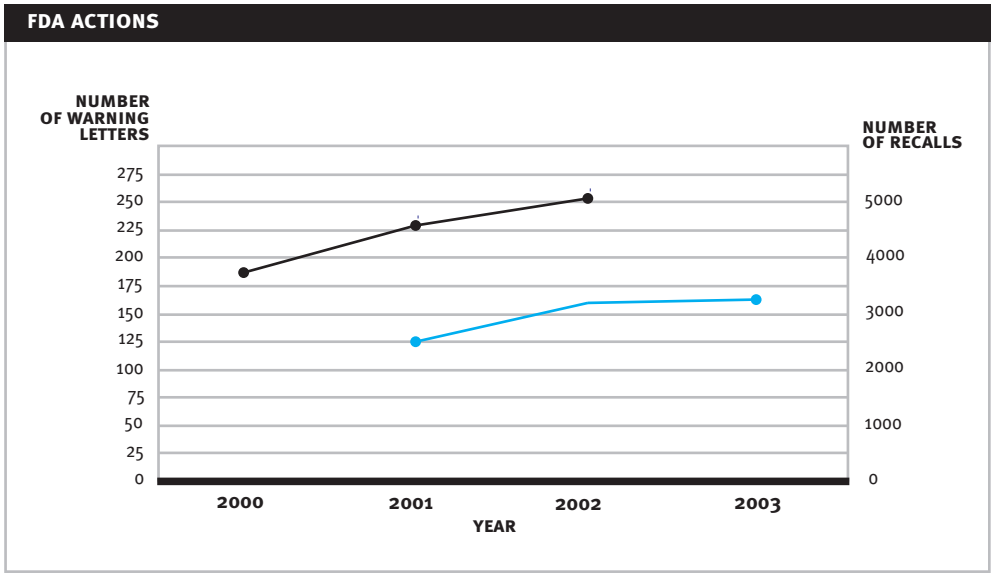
2.2. Manufacturing

Pharmaceutical manufacturing is a highly regulated and documentation intensive process. In the US, the FDA publishes Good Manufacturing Practices (GMP) practices, which define the standards by which pharmaceuticals will be manufactured. There are two areas where the unique serialization of the EPC™ can add value. The first utilizes the aggregation and association capabilities of the EPC™ network. In this situation, the pedigree of materials can be tracked from original material manufacture through procurement and throughout the manufacturing process. Koh and Harrison (The EPC™-enabled safe, secure supply chain (2003)) have previously discussed this concept. The second is the ability to apply unique identifiers to manufacturing equipment, thereby allowing verification of equipment status and location in accordance with manufacturing requirements. The manufacturing process is documented in a batch record, which, in paper form, can be 12 to 18 inches thick and require 6-12 weeks to review for compliance after the manufacturing process is complete. During that review time, product availability, planning and manufacturing capacity decisions are evaluated based upon an estimate of the accuracy of the batch record and its probability of being approved by Quality Assurance staff. Utilizing EPC™ to establish pedigree and to trigger alerts when manufacturing operating procedures are not being followed can speed batch record review and improve the data used in manufacturing decisions.

In the US, the FDA appears to be taking a more aggressive stance in inspecting pharmaceutical companies, as evidenced by the increasing trend in warning letters. (See Figure 4 _ FDA Actions)

Figure 4:

Warning letters
Recalls

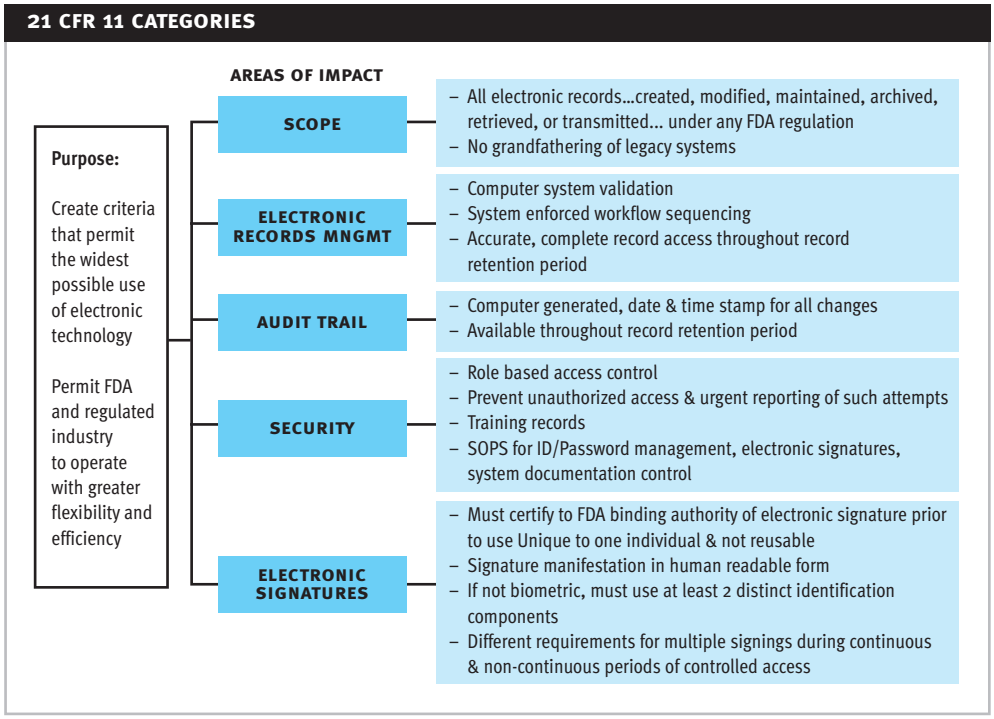


In 2002, the FDA issued 159 warning letters, 80% of the warning letters issued by the FDA involved production systems. The top 10 reasons for GMP citations by the FDA are shown in Figure 4a, Figure 4a here many of which can be improved through the use of EPC™ and RFID. Each of these warning letters requires analysis and specific written response by the pharmaceutical company, which is a time consuming process. In addition to GMP, the FDA also administers 21 CFR 11, which provides guidance on the use of electronic technology such as EPC™/RFID in the pharmaceutical industry.

21 CFR 11 has five areas of impact on technologies, as shown in Figure 5 – 21 CFR 11 Categories. Highlighted within each of the impact areas are specific aspects where EPC™ can improve compliance with the regulation.

Figure 5:

Source: FDA 21 CFR Part 11
Note: 21 CFR Part 11 = Chapter 1 (Food and Drug Administration, Dept of Health and Human Services) Title 21 Code of Federal Regulations Part 11 (Electronic Records; Electronic Signatures)



2.2.1. System Enforced Workflow Sequencing

Where EPC™ codes are associated with vessels or product carrying totes, the location and association of the product and tote can be tracked and verified to ensure manufacturing workflow is conducted according to the approved operating procedure.

2.2.2. Computer Generated, Date and Time Stamp for all Changes

EPC™ readings can be simply associated with the date and time stamp of the reading. This can include having EPC™-enabled identification tags worn by manufacturing personnel, and a reader at the data input station that matches data input to EPC™ and stamps a time and date with that record. This application can also be extended to equipment, and capturing the date and time a specific piece of equipment has completed a cleaning process, or has been moved from a staging area into a cleaning or production area.

2.2.3. Workplace Security

One of the key directives in 21 CFR 11 regards password and access control. Issuing each production employee a unique EPC™ at the beginning of the work shift, and securing the tag to the employee (similar to a hospital patient's ID wristband) provides a simple means to issue a new, unique password to each production employee on a daily basis. Associating the tag with the employee's qualification records also provides a mechanism to ensure that only the appropriate employee documents their performance of manufacturing operations. Attempts by an unauthorized employee would be captured as well and can generate alerts to supervisors and others as appropriate.

2.2.4. Electronic Signatures

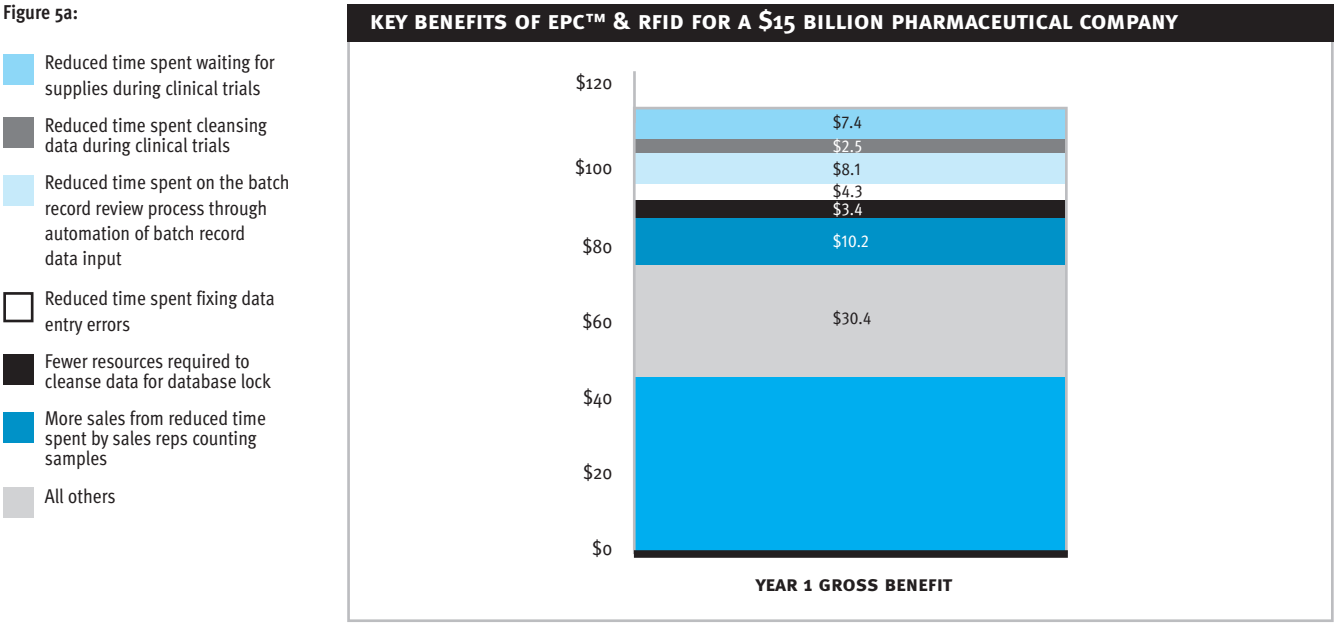
Issuing each production employee a unique EPC™ code for the day meets the 21 CFR Part 11 standard of the signature being unique to one person. Having the tags either secured to the employee via a method that must be removed at the end of the day (e.g. ID wristband), supported through inactivation of the code at the end of the workday, ensures the code is not reusable.

In the manufacturing operation, EPC™ enabled equipment can also be used to enforce manufacturing operating requirements. For example, when portable equipment is employed in the manufacturing process, EPC™s on each piece of equipment can be verified against the allowed equipment for the process, and with telemetry, also verified as to the proper arrangement. Additional equipment tracking can be employed to verify that equipment has been cleaned, is in the correct area, or contains product that is allowed to move into another production area. Each of these events can be easily captured, date and time stamped, and associated with authorized manufacturing personnel to create the electronic batch record.

Our estimate is that the application of EPC™ in the manufacturing plant can reduce batch record review by as much as 2–4 weeks. Effective use of EPC™ can also improve documentation of the manufacturing process in accordance with GMP and 21 CFR 11 and reduce effort required to address FDA inspection findings.

As indicated, for a manufacturer, there are many sources of value. Utilizing an "average" $15 billion in sales company, Figure 5a indicates where the economic value is generated.

Figure 5a:



Although there has been a significant emphasis on the role of EPC™ in improving distribution functions, there is considerable value in applying EPC™ to other areas of the pharmaceutical manufacturer's operations.

For this analysis, the impact addresses the areas shown in Table 2. Benefits from improved compliance are not factored into this analysis, but could be significant.

Table 2: Benefits and Costs Estimated for Manufacturers

SOURCES OF BENEFIT IN MANUFACTURING

AREA	TIMING	DESCRIPTION
Manufacturing	Shorter Release Times	– Automation of batch record data input (e.g. electronic signatures) will reduce time spent on the batch record review process
Supply Chain Inbound	Improved People Efficiency	– FTE time spent tracking the location of a product to see if will indeed be late will be reduced using exception based management that timely and accurate RFID data provides.
Supply Chain Within Warehouse	Improved Receiving	– FTE time for the receiving function will be reduced by RFID's ability to scan and disseminate information.
	Improved Putaway	– FTE time for the putaway function will be reduced by RFID's ability to scan and disseminate information.
	Reduced Claims	– Accurate shipping and receiving quantities will reduce claims. – Improved claims processes will improve the time for receiving payment. – FTE time for the claims function will be reduced by RFID.
	Improved Expiration Processes	– FTE time spent tracking the expiration dates of a product. – Knowing when product will expire will lead to more timely and efficient removal of prodcut.

Continuation of Table 2

SOURCES OF BENEFIT IN MANUFACTURING		
Supply Chain Outbound	Improved People Efficiency	– FTE time spent tracking the location of a product to see if will indeed be late will be reduced through timely and accurate information of exceptions.
	Reduce Expedites	– RFID will provide the data to know where product is and where it should be. Knowing exactly where a product is in the pipeline will reduce unnecessary expedited shipment. It will allow product to be moved on a more economical mode.
	Reduce DC Safety Stock	– RFID will provide accurate lead times. Reduced lead-time variability will reduce safety stock.
	Reduce Lead Time	– More accurate information will reduce the lead-time into the DC.
Supply Chain Sales Force	Improved Sample Tracking	– Reduction in time spent by sales reps counting samples will lead to increased sales.
Grey Market	Reduce Gray Market	– Improved verification and authentication of drug manufacturer, pricing correctness and general product loss will reduce the gray market

COST AREAS NEEDED TO IMPLEMENT AND OPERATE EPC™ AND RFID IN MANUFACTURING		
AREA	**TIMING**	**DESCRIPTION**
Hardware Plant	Upfront Ongoing	– Acquisition of RFID hardware for the plant – Annual maintenance of RFID hardware at the plant
Hardware Warehouse	Upfront Ongoing	– Acquisition of RFID hardware for the warehouse – Annual maintenance of RFID hardware at the warehouse
Hardware Sales Force	Upfront Ongoing	– Acquisition of RFID hardware for sales force – Annual maintenance of RFID hardware for sales force
Installation Plant	Upfront	– Installation of plant readers and connection of readers to network
Installation Warehouse	Upfront	– Installation of warehouse readers and connection of readers to network
General Hardware Plan	Upfront	– RFID implementation requires ability to process and store newly - generated plant data
General Hardware Warehouse	Upfront	– RFID implementation requires ability to process and store newly generated warehouse data
Software Plant	Upfront Ongoing	– Initial customizations and licensing for RFID plant software – Annual maintenance (upgrades) to RFID plant software
Software Supply Chain (warehouse & sales force)	Upfront	– Initial customizations and licensing for RFID warehouse software
Software Warehouse	Ongoing	– Annual maintenance (upgrades) to RFID warehouse software

Continuation of Table 2

COST AREAS NEEDED TO IMPLEMENT AND OPERATE EPC™ AND RFID IN MANUFACTURING		
Remote Software Monitoring Plant	Upfront	– Allows IT to centrally manage distribution and maintenance of RFID plant applications
	Ongoing	– Allows IT to centrally manage distribution and maintenance of RFID plant applications
Remote Software Monitoring Warehouse	Upfront	– Allows IT to centrally manage distribution and maintenance of RFID warehouse applications
	Ongoing	– Allows IT to centrally manage distribution and maintenance of RFID warehouse applications
Integration	Upfront	– Integrating ERP and RFID software
Tags Bottles	Ongoing	– Tags have to be purchased, updated with the correct information and attached to bottles
Tags Plant	Ongoing	– Tags have to be purchased, updated with the correct information and attached to machines and workers (via wristbands)
Training	Upfront	– IT maintenance personnel and users need to be trained on RFID technology
Maintenance	Ongoing	– New systems and hardware require resource support
Compliance	Ongoing	– Ensure acceptance of technology among users, generate exception reports, train new users
Help Desk	Ongoing	– Support users (e.g. answer questions, remote fixes, etc...)
Consulting	Upfront	– Professional fees required to prepare the organization for RFID from a people, process and technology perspective

Table 2a

Assumptions:
- 5 plants
- 3 distribution centers
- 13% discount rate
- 30% tax rate
- Company assumed to have $15 billion in revenue

ESTIMATED MANUFACTURING AND SUPPLY CHAIN BENEFITS						
BENEFITS	**YEAR 0**	**YEAR 1**	**YEAR 2**	**YEAR 3**	**YEAR 4**	**YEAR 5**
Total Manufacturing Process Benefits		$156,250	$156,250	$156,250	$156,250	$156,250
Inbound		$280,000	$8,100,000	$8,100,000	$8,100,000	$8,100,000
Within Plant/DC		$3,670,000	$3,370,000	$3,250,000	$3,160,000	$3,130,000
Outbound		$3,450,000	$2,760,000	$2,480,000	$2,340,000	$2,280,000
Sales Force		$2,500,000	$1,300,000	$600,000	$300,000	$200,000
Total Supply Chain Benefits		$9,900,000	$15,530,000	$14,430,000	$13,900,000	$13,710,000
Total Gray Market Reduction Benefits		$47,900,000	$47,900,000	$47,900,000	$47,900,000	$47,900,000
Total Benefits		**$67,856,250**	**$79,116,250**	**$76,916,250**	**$75,856,250**	**$75,476,250**
COSTS						
Installation and Integration	$17,504,500					
Ongoing Maintenance, Training &Support		$39,694,300	$39,694,300	$39,694,300	$39,694,300	$39,694,300
Total Costs	**$17,504,500**	**$39,694,300**	**$39,694,300**	**$39,694,300**	**$39,694,300**	**$39,694,300**
Total Gross Benefit	($17,504,500)	$28,161,950	$39,421,950	$37,221,950	$36,161,950	$35,781,950
Taxes	($5,300,000)	$8,400,000	$11,800,000	$11,200,000	$10,800,000	$10,700,000
Net Benefit	($17,504,500)	$19,761,950	$27,621,950	$26,021,950	$25,361,950	$25,081,950
5-Year NPV	**$68,800,000**					

2.3. Distribution

The application of EPC™ in distribution has been extensively discussed. Koh et al (September 2003) reviews the subject of pharmaceutical security. In the US, there is a strong effort underway at the distribution level (i.e. manufacturer to wholesaler to retailer) to complete a pilot utilizing EPC™ and RFID technology, although it is not expected to be operational until late 2004. Additionally, in the US, the Health Distribution Manufacturers Association (HDMA) has proposed taking a lead role in the verification of pharmaceutical products, as over 80% of pharmaceuticals are distributed in the US through HDMA members. In Europe, the DRIVE initiative (Drug In Virtual Enterprise) as well as the Bollini law in Italy are also pointing to the value of the EPC™ network in pharmaceutical distribution. This value is in the widely available, rapidly accesible, secure capture of information about uniquely serialized products, which is gathered at a lower cost than bar codes and without having to open boxes to verify the individual contents.

EPC™ has the potential to add significant efficiencies to distributor's operations. These benefits include:
- Reducing the number of people involved in the receiving process
- Authentication of product
- Reduction of losses due to theft and misplacement
- Simplified tracking of controlled substances
- Improved cash flow from customers (e.g. hospitals and retailers) due to more accurate shipment records,
- Increased accuracy in the returns process
- Reductions in expired product

We have estimated the potential benefit of these activities in this paper, and the potential costs associated with implementing the EPC™ network (tags and readers), as shown in Table 3.

Table 3: Benefits and Costs estimated for Distributors

SOURCES OF BENEFIT IN DISTRIBUTION		
AREA	**TIMING**	**DESCRIPTION**
Inbound	Improved People Efficiency	– FTE time spent tracking the location of a product to see if will indeed be late will be reduced through timely and accurate information of exceptions.
	Reduce DC Safety Stock	– RFID will provide accurate lead times. Reduced lead-time variability will reduce safety stock.
	Reduce Lead Time	– More accurate information will reduce the lead-time into the DC.
Within DC	Improved Receiving	– FTE time for the receiving function will be reduced by RFID's ability to scan and disseminate information.
	Improved Putaway	– FTE time for the putaway function will be reduced by RFID's ability to scan and disseminate information.
	Reduced Lost Product	– Knowing locations of each product will reduce the quantity that is lost or misplaced. – FTE time for the inventory tracking function will be reduced by RFID's ability to scan and disseminate information.
	Improved Expiration Processes	– FTE time spent tracking the expiration dates of a product. – Knowing when product will expire will lead to more timely and efficient removal of product.

Continuation of Table 3

SOURCES OF BENEFIT IN DISTRIBUTION		
Within DC	Improved Mngmt of Controlled Substances Reduce Stolen product	– RFID automates the process of tracking and managing controlled substances – The ability to track where a product is and when a tag has been tampered with will deter people from stealing product.
Outbound	Improved People Efficiency Reduce Expedites	– FTE time spent tracking the location of a product to see if will indeed be late will be reduced through timely and accurate information of exceptions. – RFID will provide the data to know where product is and where it should be. Knowing exactly where a product is in the pipeline will reduce unnecessary expedited shipment. It will allow product to be moved on a more economical mode.

COST AREAS NEEDED TO IMPLEMENT AND OPERATE EPC™ AND RFID IN DISTRIBUTION		
AREA	**TIMING**	**DESCRIPTION**
Hardware Warehouse	Upfront	– Acquisition of RFID hardware for the warehouse
Hardware Warehouse	Ongoing	– Annual maintenance of RFID hardware at the warehouse
Installation Warehouse	Upfront	– Installation of warehouse readers and connection of readers to network
Hardware General	Upfront	– RFID implementation requires ability to process and store newly generated warehouse data
Software Warehouse	Upfront	– Initial customizations and licensing for RFID warehouse software
Software Warehouse	Ongoing	– Annual maintenance (upgrades) to RFID warehouse software
Remote Software Monitoring Warehouse	Upfront	– Allows IT to centrally manage distribution and maintenance of RFID warehouse applications
Remote Software Monitoring Warehouse	Ongoing	– Allows IT to centrally manage distribution and maintenance of RFID warehouse applications
Integration	Upfront	– Integrating ERP and RFID software
Training	Upfront	– IT maintenance personnel and users need to be trained on RFID technology
Maintenance	Ongoing	– New systems and hardware require resource support
Compliance	Ongoing	– Ensure acceptance of technology among users, generate exception reports, train new users
Help Desk	Ongoing	– Support users (e.g. answer questions, remote fixes, etc...)
Consulting	Upfront	– Professional fees required to prepare the organization for RFID from a people, process and technology perspective

We have assumed a large distributor, with 30 warehouse locations. Table 3a shows the benefit and cost summary for a single large wholesaler.

Table 3a:

Assumptions
- $50 billion in revenue
- 30 distribution centers
- 15% discount rate

ESTIMATED BENEFIT TO A LARGE WHOLESALER

BENEFITS	YEAR 0	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
Inbound		$33,500,000	$30,900,000	$29,700,000	$29,000,000	$28,700,000
Within DC		$59,850,000	$53,050,000	$49,450,000	$47,850,000	$47,050,000
Outbound		$17,800,000	$7,500,000	$3,100,000	$1,300,000	$600,000
Total Distributor Benefits		**$111,150,000**	**$91,450,000**	**$82,250,000**	**$78,150,000**	**$76,350,000**
COSTS						
Installation & Integration	$23,626,000					
Ongoing Maintenance, Training and Support		$3,170,000	$3,170,000	$3,170,000	$3,170,000	$3,170,000
Total Costs	**$23,626,000**	**$3,170,000**	**$3,170,000**	**$3,170,000**	**$3,170,000**	**$3,170,000**
Total Gross Benefit	($23,626,000)	$107,980,000	$88,280,000	$79,080,000	$74,980,000	$73,180,000
Taxes	($7,100,000)	$30,300,000	$26,500,000	$23,700,000	$22,500,000	$22,000,000
Net Benefit	($23,626,000)	$77,680,000	$61,780,000	$55,380,000	$52,480,000	$51,180,000
5-Year NPV	**$182,500,000**					

Other potential benefits exist. These include the retail value of the information captured about each manufacturers shipment to each customer (along with lot and expiration date), reduced sales force time at major customers counting product (much quicker with EPC™ and RFID) or compliance benefits from improved controlled substance tracking.

2.4. Hospital

[2] Inst of Medicine 1999 report; To Err is Human. Page 1 of Ch 2

One of a hospital's primary concerns is to improve its quality of care by reducing medical errors. The 1999 Institute of Medicine (IOM) study concluded that as many as 98,000 preventable medical errors resulted in death per year.[2] There are additional errors that result in other injuries as well. Hospitals are also subject to frequent accreditation reviews, which have an impact on their ability to participate in various government programs (e.g. Medicare) and have a bearing on insurance rates and the ability of hospitals to attract patients and healthcare payors (i.e. health plans). Hospitals can utilize EPC™ to address many of these issues. One of the most significant issues in the hospital relates to compliance with documentation procedures. Hospitals have tried many different solutions: in-room computer terminals, bar codes and paper forms. Each of these solutions requires action from the physician or nurse, and all associated data entry can be deferred to meet concerns from the patient or other activity. Technologies that require active input from the physician or nurse during the process can also slow the provision of care to patients. EPC™ operates automatically and if configured appropriately, can provide real-time verification of correct therapy administration, potential drug interactions and other critical medical information.

EPC™ in the hospital is not only applicable to pharmaceuticals. Hospitals have significant amounts of mobile assets, which are difficult to track (including pumps, monitoring equipment and beds). Certain high value medical supplies are also candidates for EPC™ enabled tracking (e.g. stents, pacemakers and orthopedic implants). As technology prices continue to drop, EPC™ can be applied to physical patient records, to facilitate locating and assembling a complete record expeditiously.

Implementing a patient-centric EPC™ approach can also facilitate the capture of accurate billing information, and immediate notification of changes in therapy regimen. Each patient could have an EPC™ enabled wristband applied at admission, and this code linked to their appropriate medical information. In the US, implementation of this approach will require a careful review of information security and transmission in order to satisfy US Health Insurance Portability and Accountability Act (HIPAA) requirements. These EPC™ applications reduce errors and make the operation of a hospital more efficient, which is a significant concern with the current nursing shortage in the US.

The hospital requires an additional level of granularity in applying EPC™ to its operations. Whereas at the manufacturer and distributor levels, EPC™ identification of an individual bottle of a drug is sufficient, at the hospital level, the value is in tracking at the unit dose level, that is, at the individual pill administered to the patient. Many times, the medication is repackaged at the hospital, and the application of an EPC™/RFID to the individual package supports rapid checking for drug interactions, documentation of dosage administration time, and when matched to an EPC™ code on the patient and the administering clinician, provides a simple method to ensure patient safety. This approach can also be utilized to control theft and to proactively monitor drug expiration dates.

Supply chain issues are also applicable in the hospital setting. Matching receipts to orders, facilitating the dispensing of products from the central pharmacy to satellite pharmacies, tracking specially compounded drugs and verifying products to be returned are as applicable to the hospital as to the distributor are all applications where EPC™ can add value, increase efficiency and reduce costs. The Johns Hopkins hospital is actively pursuing an RFID solution to tracking intravenous fluids, to ensure the correct fluids are delivered to the right patient. [3]

[3] Radio RX: Schoenberger, Christina; Forbes.com; 09.15.2003

For the purposes of this paper, we have assumed a 400-bed hospital as the base unit. The cost of readers and tags is also based upon this assumption. Table 4 shows the sources of benefits and costs considered in this analysis for such a hospital.

Table 4: Benefits and Costs Estimated for Hospitals

SOURCES OF BENEFIT IN HOSPITALS		
AREA	**TIMING**	**DESCRIPTION**
Inbound	Improved People Efficiency	– FTE time spent tracking the location of a product to see if it will indeed be late will be reduced through timely and accurate information of exceptions.
	Reduce Central Pharmacy Safety Stock	– RFID will provide accurate lead times. Reduced lead-time variability will reduce safety stock.
	Reduce Lead Time	– More accurate information will reduce the lead-time into the hospital.
Within Central Pharmacy	Improved Receiving	– FTE time for the receiving function will be reduced by RFID's ability to scan and disseminate information.
	Reduced Lost Product	– Knowing locations of each product will reduce the quantity that is lost or misplaced. – FTE time for the inventory tracking function will be reduced by RFID's ability to scan and disseminate information.
	Improved Expiration Processes	– FTE time spent tracking the expiration dates of a product. – Knowing when product will expire will lead to more timely and efficient removal of prodcut.
	Reduce Stolen product	– The ability to track where a product is and when a tag has been tampered with will deter people from stealing product.

Continuation of Table 4

SOURCES OF BENEFIT IN HOSPITALS		
Care Quality Fewer Adverse Drug Events	Incorrect Drug Administration Remove chemically ineffective/ altered drugs	– RFID reduces the likelihood that a patient takes the wrong drug or incorrect amount. – RFID tracks whether medicine falls outside of temperature and/or humidity requirements, thus preventing inadverent damage to the efficacy of the drug

COST AREAS NEEDED TO IMPLEMENT AND OPERATE EPC™ AND RFID IN HOSPITALS		
AREA	**TIMING**	**DESCRIPTION**
Hardware Inventory	Upfront Ongoing	– Acquisition of RFID hardware for hospital inventory – Annual maintenance of RFID hardware for hospital inventory
Hardware Patient Care	Upfront Ongoing	– Acquisition of RFID hardware for patient care – Annual maintenance of RFID hardware for patient care
Installation Inventory	Upfront	– Installation of hospital inventory readers and connection of readers to network
Installation Patient Care	Upfront	– Installation of patient care readers and connection of readers to network
General Hardware Inventory	Upfront	– RFID implementation requires ability to process and store newly generated inventory data
General Hardware Patient Care	Upfront	– RFID implementation requires ability to process and store newly generated patient data
Software Inventory	Upfront Ongoing	– Initial customizations and licensing for RFID inventory software – Annual maintenance (upgrades) to RFID inventory software
Software Patient Care	Upfront Ongoing	– Initial customizations and licensing for RFID patient care software – Annual maintenance (upgrades) to RFID patient care software
Remote Software Monitoring Inventory	Upfront Ongoing	– Allows IT to centrally manage distribution and maintenance of RFID inventory applications – Allows IT to centrally manage distribution and maintenance of RFID inventory applications
Remote Software Monitoring Patient Care	Upfront Ongoing	– Allows IT to centrally manage distribution and maintenance of RFID patient care applications – Allows IT to centrally manage distribution and maintenance of RFID patient care applications
Integration	Upfront	– Integrating ERP and RFID software
Tags Hospital Workers	Ongoing	– Tags have to be purchased, updated with the correct information and attached to hospital workers (via wristbands/id cards
Tags **Patients**	Ongoing	– Tags have to be purchased, updated with the correct information and attached to the patients (via wristbands)
Training	Upfront	– IT maintenance personnel and users need to be trained on RFID technology
Maintenance	Ongoing	– New systems and hardware require resource support

Continuation of Table 4

COST AREAS NEEDED TO IMPLEMENT AND OPERATE EPC™ AND RFID IN HOSPITALS

AREA	TIMING	DESCRIPTION
Compliance	Ongoing	– Ensure acceptance of technology among users, generate exception reports, train new users
Help Desk	Ongoing	– Support users (e.g. answer questions, remote fixes, etc…)
Consulting	Upfront	– Professional fees required to prepare the organization for RFID from a people, process and technology perspective

The value associated with the hospital utilizing EPC™ is meaningful. The magnitude of the improvement is smaller than the manufacturer or distributor values, however, that is consistent with the relative size of a 400-bed hospital compared to a major manufacturer or distributor.

Table 4a

Assumptions;
– 50% reduction in adverse events
– 400 bed hospital
– 15% discount rate

ESTIMATED BENEFIT TO A HOSPITAL

BENEFITS	YEAR 0	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
Inbound Material		$18,200	$10,200	$6,200	$4,200	$3,200
Within Central Pharmacy		$86,800	$58,800	$44,800	$37,800	$34,300
Care Quality		$7,000,000	$7,000,000	$7,000,000	$7,000,000	$7,000,000
Total Benefits		**$7,105,000**	**$7,069,000**	**$7,051,000**	**$7,042,000**	**$7,037,500**
Installation & Integration	$11,444,000					
Ongoing Maintenance, Support and Training		$1,166,250	$1,166,250	$1,166,250	$1,166,250	$1,166,250
COST						
Total Costs	**$11,444,000**	**$1,166,250**	**$1,166,250**	**$1,166,250**	**$1,166,250**	**$1,166,250**
Total Gross Benefit	$(11,444,000)	$5,938,750	$5,902,750	$5,884,750	$5,875,750	$5,871,250
Taxes	$(3,430,000)	$750,000	$1,770,000	$1,770,000	$1,760,000	$1,760,000
Net Benefit	$(11,444,000)	$5,188,750	$4,132,750	$4,114,750	$4,115,750	$4,111,250
5-Year NPV	**$3,300,000**					

The benefits associated from increased patient safety associated with reduced litigation expenses and settlements have not been included in this estimate, nor has any potential benefits from the application of EPC™ to medical devices and supplies. Considering the average hospital spends 25% to 75% more on medical devices and supplies compared to pharmaceuticals, there are significant additional cost saving opportunities through the application of EPC™ to those areas.

2.5. Diversion and Counterfeit

Diversion and counterfeit are growing concerns in the US market. Diversion, as parallel trade, is widespread in Europe and can be a significant source of lost revenue to pharmaceutical companies. IMS has estimated the amount of parallel trade, as shown in Figure 6 – Proportion of Market Sales Resulting from Parallel Import

Figure 6: Source: IMS

Japanese market: USD46.5bn + 3.6%

PROPORTION OF MARKET SALES RESULTING FROM PARALLEL IMPORTS

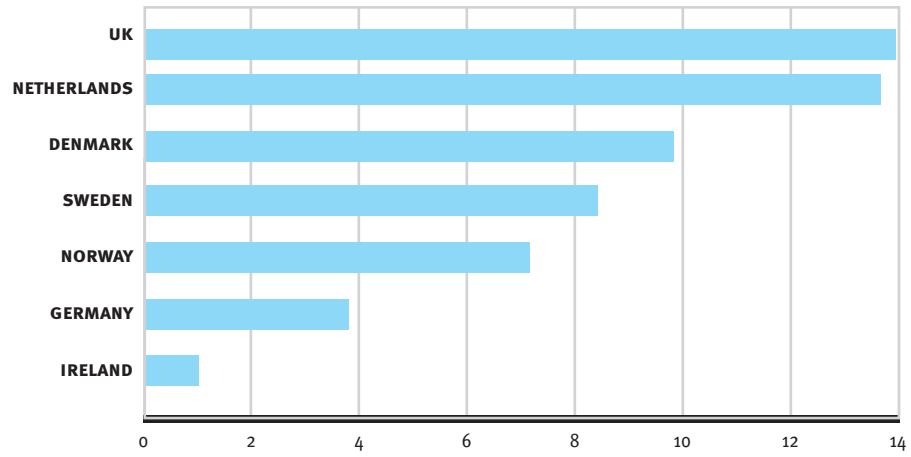


Figure 7 indicates the economic case in Europe for these issues is much more the concern of the manufacturer than others in the channel.

Figure 7

- Manufacturer's margin
- Wholesaler's margin
- Pharmacy margin
- VAT

a. British Association for Pharmaceutical Wholesalers
b. National Pharmaceutical Associations
c. Oppenheim Research, "Pharmagroßhandel. Chancen für die Großen", 2000

MARGINS FOR PHARMACEUTICAL PRODUCTS

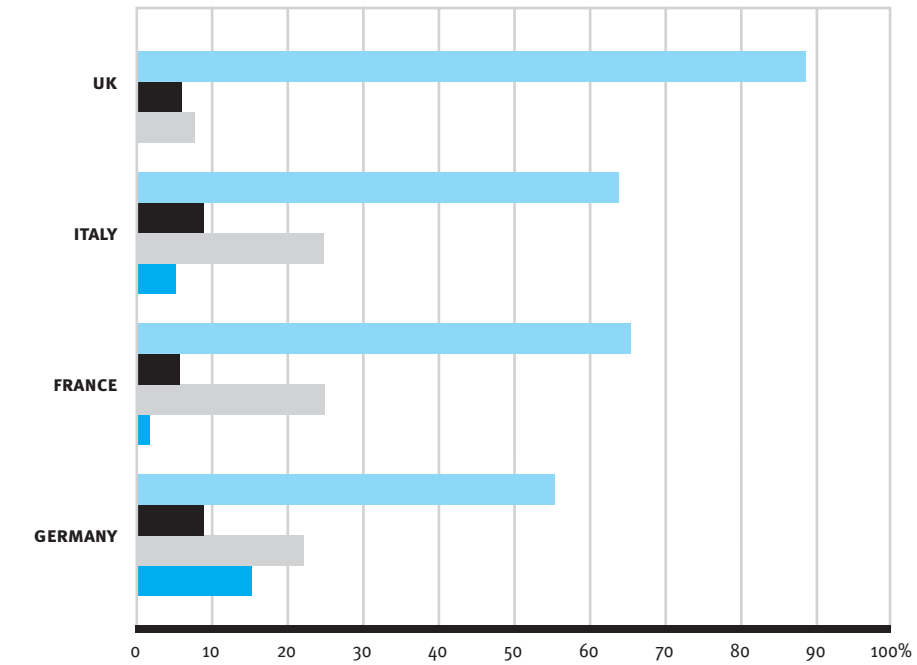
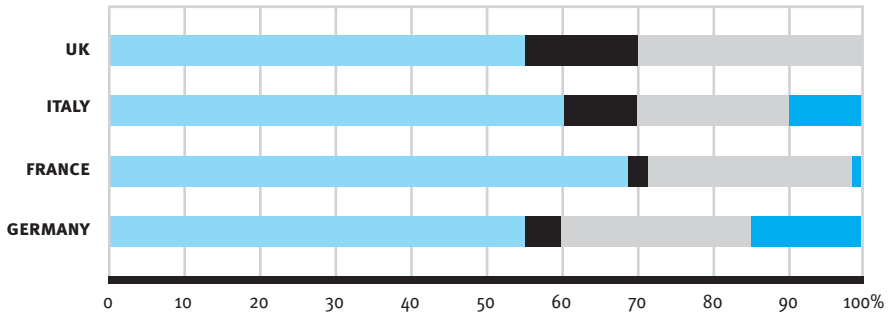


Figure 7

Manufacturer's margin
Wholesaler's margin
Pharmacy margin
VAT

MARGINS FOR PHARMACEUTICAL PRODUCTS



Normal business practice results in the manufacturer bearing the cost of replacing counterfeit product, thereby losing the margin that could have been realized if the product was sold normally. For the US market, CGEY has estimated the amount of impact to selected manufacturers from counterfeit and parallel trade (aka reimportation) in Table 5.

Table 5

* $ in bn
** Parallel Trade & Reimportation

Assumptions
- The large manufacturers sell equally in most geographic markets
- The large manufacturers are affected equally by the losses incurred by Counterfeit, Shrinkage and parellel trade
- For Counterfeit drugs – loss is assumed to be 100% of the profit.
- For Shrinkage loss – loss is assumed to be 100% of the revenue
- For parellel trade – loss is assumed to be 50% of the profit due to differential pricing.

Citations
[1] S&P Pharma Ind. Survey report, June 26th 2003.

GREY MARKET ESTIMATION

Leading Firms	Rev.*	% Intl. Rev.1	US Rev*	US Profit*	Counterfeit	Shrinkage	P.T. & R.**	Total	% of Rev.
Pfizer	$40.83	40%	$24.50	$12.25	0.24	0.12	0.12	0.48	1.98%
GSK	$28.20	30%	**$19.74**	**$8.46**	**0.17**	**0.09**	**0.08**	**0.35**	1.76%
Merck	$21.63	18%	$17.74	$6.49	0.13	0.08	0.06	0.28	1.57%
AstraZeneca	$17.84	30%	**$12.49**	**$5.35**	**0.11**	**0.06**	**0.05**	**0.22**	1.76%
Aventis	$17.25	30%	**$12.08**	**$5.18**	**0.10**	**0.06**	**0.05**	**0.21**	1.76%
JNJ	$17.20	41%	$10.15	$5.16	0.10	0.05	0.05	0.20	2.00%
Novartis	$15.36	30%	**$10.75**	**$4.61**	**0.09**	**0.05**	**0.05**	**0.19**	1.76%
Bristol Myers Squibb	$14.70	35%	$9.56	$4.41	0.09	0.05	0.04	0.18	1.86%
Wyeth	$11.70	40%	7.02	3.51	0.07	0.03	0.04	0.14	1.98%
Total			124.01	55.41	1.11	0.59	0.55	2.25	1.82%
							Loss % On Average		**1.83%**

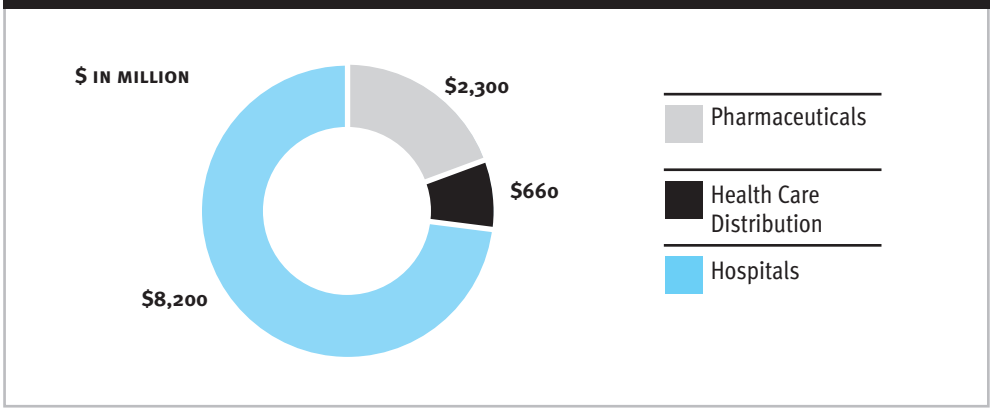
Where not a significant amount as a percentage of total sales, it is nonetheless a significant total dollar amount. This amount does not include the costs associated with a recall of such product (if counterfeit), nor the potential litigation costs associated with the possible administration of a counterfeit drug to a patient.

3. BUSINESS CASE SUMMARY

The application of EPC™ has a significant net benefit in the pharmaceutical supply chain, to the manufacturer, the distributor and the wholesaler, and there are additional benefits from improved compliance and reduced risk to patients that have not been quantified in this analysis. We have also estimated the total potential net benefit to the US healthcare industry from EPC, and the distribution of that benefit is shown in Figure 8.

Figure 8

ESTIMATED NET VALUE FROM APPLYING EPC™ IN PHARMACEUTICALS IN THE US



Note that a significant amount of the value accrues to hospitals. This is a function of the large number of hospitals in the US. It is also likely understated for all parties as the costs of litigation and settlements arising from incorrect administration of pharmaceuticals, costs of recalls, and avoided compliance costs are not included in these estimates.

In our view, there is significant value in applying EPC™ and RFID to the pharmaceutical value chain. It is not only cost effective, it addresses issues of regulatory and safety risks at all levels of the value chain, and can have a positive revenue impact through accelerating processes. Large elements of the value do not require multi-company or industry group cooperation; there are many valuable applications that are within a company's individual control. It is time for the participants in the pharmaceutical industry to seize this opportunity and apply EPC™ and RFID to the value chain.

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