Securing the Pharmaceutical Supply Chain

RFID Workshop, Rutgers University

Edmund W. Schuster, Research Affiliate – MIT Auto-ID Labs

A Special Word of Thanks to my Colleagues

- Stuart J. Allen - **Professor Emeritus, Penn State**
- David L. Brock - **Principal Research Scientist, MIT**
- Pinaki Kar - **Independent Consultant, NYC**
- Mark Dinning- **RFID Project Leader, Dell.**
- Tom Scharfeld - **Research Manager, Auto-ID Labs**
- Robin Koh **– Director of Applications Research, Auto-ID Labs**

A Special Word of Thanks to my Colleagues (continued)

- Nhat-So Lam – **Family Retail Business, Toronto**
- Attilio Bellman – **Manager of Consulting, Bearing Point**
- Elaine Lai, **graduate student UC Berkeley**
- Daniel Engels – **Research Director, Auto-ID Labs**
- Ming Li – **Supply Chain Analyst, Analog Devices**
- Indy Chackrabarti and Nhat-So Lam - **Former Graduate Students of the MLOG Program at MIT now employed i industry**
- Tatsuya Inaba **– Research Affiliate, Auto-ID Labs**

AUTO-ID LABS

A Number of Articles on Auto-ID are Available at my Personal Web Site

www.ed-w.info

AUTO-ID LABS

Research Projects – Seven Major Categories

- **Auto-ID Technology**
- **The Data Center**
- **Harvest Analytics**
- The Comparative Logistics Project
- MODS Scheduling Lab
- Achieve for Process Manufacturing
- **Healthcare Research Initiative**

The Data Center

- Entrepreneurial, research-oriented, non profit, bigger than Auto-ID
- Develop better methods to use data gathered through Auto-ID
  - The Web of Information
  - The Web of Things
  - The Web of Abstractions (models)
- Assemble mathematical models quickly, become the Henry Ford of Modeling.
- Idea to link models and other abstractions similar to the way Auto-ID links physical objects to the Internet

The Data Center (continued)

- **"An Introduction to Semantic Modeling for Logistical Systems,"** D.L. Brock, E.W. Schuster, S.J. Allen and P. Kar.
- Winner of the 2004 **E. Grosvenor Plowman Award** given by the Council of Logistics Management for best contribution to the study of logistics.

Harvest Analytics (Supply Chain Risk)

- Understand how harvest operations can be optimized
- Establish a new discipline of study within INFORMS based on practical research
- Looking to apply thinking across all areas of agriculture
- Extensions to other areas, such as fashion industry
- **"Controlling the Risk for an Agricultural Harvest"** by *S.J. Allen and E.W. Schuster*.
- **"Managing Risk for the Grape Harvest at Welch's"** by *S.J. Allen and E.W. Schuster*.

MIT Healthcare Research Initiative (Mission)

The mission of the HRI is to provide an objective, coordinated and comprehensive body of research for the application of automatic identification, mass serialization, networking and sensing technology to healthcare.

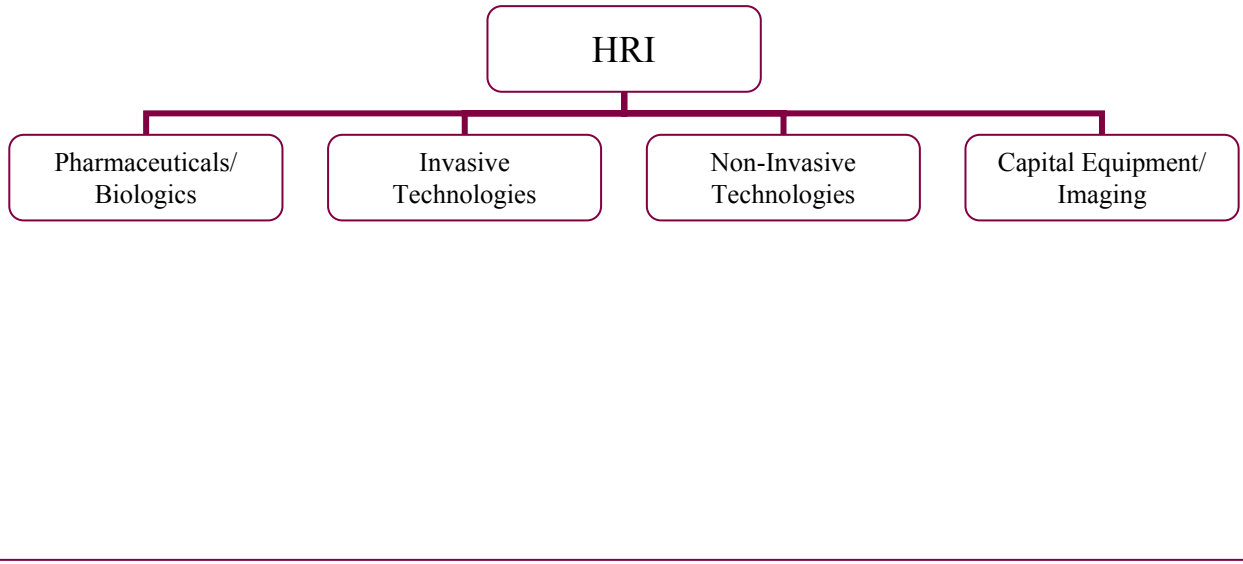
Chair of the Department of Mechanical Engineering is the Principal Investigator

Interest in Auto-ID

"The pilot is…an industry effort to fight counterfeit drugs and theft, which is a **$30 billion** problem for the pharmaceutical industry."

RFID Tests Are Positive For CVS And Pharmaceuticals
Elena Malykhina
Informationweek (Sept. 30, 2004)

HRI Research Structure



Basic Research

- Radio Frequency ID
  - The effect of RF on Product
  - The effect of RF on Environment
  - Guidelines on frequencies for different packaging levels
- Study the special requirements of Cold Chain Logistics
- Active/Semi-Passive tags
- Research the integration of telemetric and sensor technology into the pharmaceutical supply chain

Basic Research

- The IT Network
  - Security & Privacy
  - 21 CFR Part 11
  - HIPAA
  - Prime
  - PML
  - Aggregations & Associations
  - Product Catalogs
  - Business Dictionaries
  - Technical Dictionaries
  - Redundancy

Applications Research

- Efficient Receiving, Picking, Shipping Operations
- Shrinkage
  - Shelf Life Management
  - Perpetual/Physical Inventory Reconciliation
  - Warehouse Operation Errors
  - Internal & External Theft Control

Tactical Applications Research

- Inventory Management
  - Product Availability
  - Demand/Supply Synchronization
- Diversion Control
- Returns
- Recalls
- Sample Administration
- Kitting/Consolidation

Strategic Applications

- Inventory Parking
- Brand Protection
- Additional Services
  - VMI Programs
- Complexity Management
  - Individualized Drugs
  - SKU Proliferation
  - Distributed Manufacturing Infrastructure
  - Virtual Inventory

Product Integrity

- False Product
- Tampered Product
  - Adulteration
  - Substitution
  - Re Labeling
- Unacceptable Status of Product
  - Expired
  - Discarded
  - Samples
  - Returned
  - Recalled

Patient Safety

Our Discussion Today

- How did I get interested?
- Issues in the Pharmaceutical Industry
- Auto-ID Technology
- Recent news of importance

- **FEEL FREE TO ASK QUESTIONS DURING THE PRESENTATION**

References

- **"Creating an Intelligent Infrastructure for ERP: The Role of Auto-ID Technology"** by E.W. Schuster and D.L. Brock. This is a working paper for *APICS* (April 2004).
- **"Enabling ERP through Auto-ID Technology"** by E.W. Schuster, D.L. Brock, S.J. Allen, P. Kar and M. Dinning. Book chapter to be published by *Stanford University Press* (Fall 2004).
- **"The Prospects for Improving ERP Data Quality Using Auto-ID"** by E.W. Schuster, T.A. Scharfeld, P. Kar, D.L. Brock and S.J. Allen. *Cutter IT Journal* (Sept, 2004).

AUTO-ID LABS

These files can be downloaded from:

http://ed-w.info/Auto-ID%20Articles.htm

This is a non commercial web site

(In total, there are 20 published articles and presentations about Auto-ID posted)

AUTO-ID LABS

Temporal and Spatial Utility

Time and Place

Logistics versus Data

Re-Code.com

- “name your own price”
- Re-code.com offered Internet users a large number of downloadable barcodes that could be printed at home, and applied to merchandise in stores
- The bar codes (with implied prices) were copied from existing sale and promotional merchandise at Wal-Mart Stores
- The company took quick legal action to shut the site down

Fake-Jewelry Lawsuit Shakes Big Discounters, Customers

Amy Merrick and Ann Zimmerman
The Wall Street Journal (May 11, 2004)

"The suit, filed by Liz Claiborne in U.S. District Court in Dallas, alleges that a distributor named **Consumer Product Recovery** of suburban Chicago slapped a Claiborne-owned logo on millions of dollars of cheap jewelry that it then sold to **Tuesday Morning**."

AUTO-ID LABS

"For **Tuesday Morning**, what's at stake is priceless: its credibility with its millions of customers. Tuesday Morning denied any wrongdoing and lamented in a court filing last week that this issue could cause customers to 'question...the quality of merchandise in Tuesday Morning stores.'"

From the WSJ

The Future

Control of the Supply Chain!!!

Counterfeit

Theft

Marketing Analytics

Emphasis on the Pharmaceutical Industry

"The pharmaceutical industry is going to move faster than other industries in RFID adoption," agreed James Hintlian, who oversees Accenture's health and life-sciences supply-chain practice."

"He said the major application for RFID will be preventing the introduction of counterfeit drugs into the supply chain, which he said can make up **2%** to **7%** of all drugs in the United States and as much as **80%** in some Third World countries."

RFID Could Be Boon To Small Businesses
Rick Whiting
Informationweek (May 19, 2004)

The Challenge

- Between 5 to 8 percent of the worldwide trade in pharmaceuticals is counterfeit
- Procrit, Epogen,Serostim, Zyprexa, Diflucan, Combivir and Retrovir have been counterfeited
- A recent counterfeit incident involving Lipitor

  "posed a potentially significant health hazard" according to the FDA.
- The US pharmaceutical market equals $192 billion per year

  "I have been in this business for 40 years…I have less confidence in the integrity of the supply chain today than ever before. It scares me."

  (Pharmacist Lowell Anderson of Bel-Aire Pharmacy in White Bear Lake, MN)
- The mapping of the human genome, and an explosion of new drugs – **PHARMA BEGINING TO RESEMBLE CPG**

An Assessment

"the Meta report says RFID's potential return on investment for pharmaceutical companies is significant through improved **inventory management** and **product-recall capability**, enhanced **patient safety**, and as a guard against drug **counterfeiting**."

"Given those potential benefits, Meta predicts the use of RFID by drugmakers will **surpass** that of consumer packaged-goods companies within 18 months."

RFID to Flourish in Pharmaceutical Industry
Rick Whiting
Informationweek (Aug. 23, 2004)

The Causes of Counterfeit

- Improved computer technology
  - Nearly any label can be counterfeited
- Small secondary wholesalers
  - An active “gray market exists for pharmaceuticals
- An increase in expensive drug therapies

GENUINE

COUNTERFEIT

The Changing Regulatory Environment

- Increased awareness of counterfeit by the FDA and States
- The Florida “pedigree” law
    1. Drug Name
    2. Dosage
    3. Container size
    4. Number of containers
    5. Drugs Lot or Control numbers
    6. Business Name and Address of ALL parties to each prior transaction, starting w/the manufacturer
    7. The date of each previous transaction

- California “ePedigree Law” 2006

- Other countries

    The EU, Italy and the “Bollini Law”

AUTO-ID LABS

Auto-ID as a Solution

Auto-ID Center – Historical Overview

- Auto-ID Center Founded
  - 1 October 1999 at M.I.T.
  - UCC, Gillette, and Procter and Gamble
- Global, Industry Sponsored Research Program
  - 103 Sponsors by 31 October 2003
  - $25 million raised for research
- Deliverables
  - IP Free or Freely Licensable IP
  - Recommended Standards
  - Reference Implementations
- Vision
  - Networked Physical World

Adapted from D.W. Engels

The Auto-ID Center's Technology

- The EPC System is comprised of a set of building blocks

  EPC – Electronic Product Code provides unique identifier

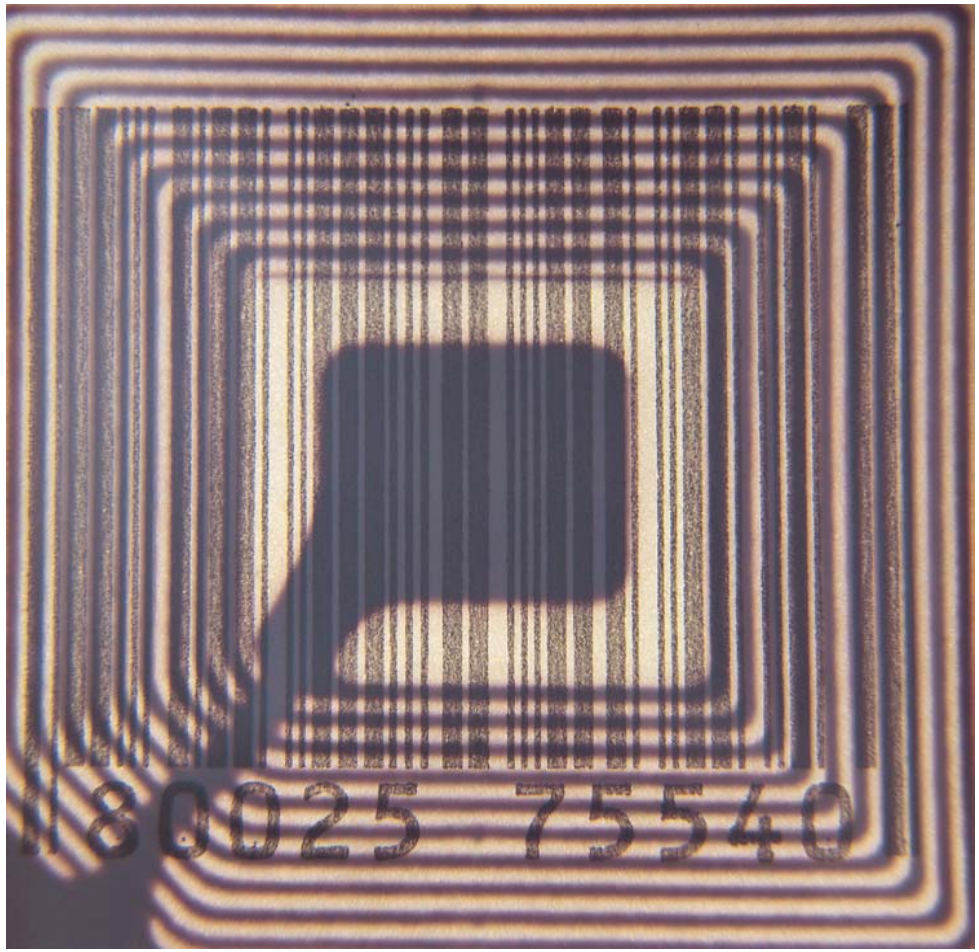
  ONS – Object Name Service locates information server

  Savant – Scalable data collection and system management system building block

  PML – Describes objects and captured information

  eTags – On item electronic tags and readers (enable smart objects)

  RFID HAS BEEN IN EXISTANCE FOR AT LEAST 60 YEARS



AUTO-ID LABS

Types of RFID Tags

Passive - passive communication, no on-tag power source
(Wal-Mart Mandate)

Semi-Passive - passive communication, on-tag power source

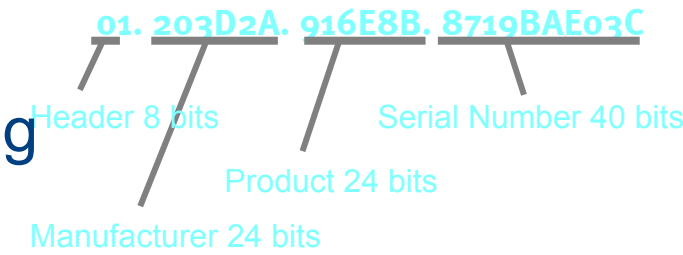
Active - active communication, on-tag power source

Adapted from D.W. Engels

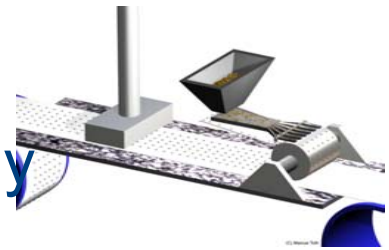

RFID
ThingMagic

The Hypothesis Put Forth by Prof. Sarma

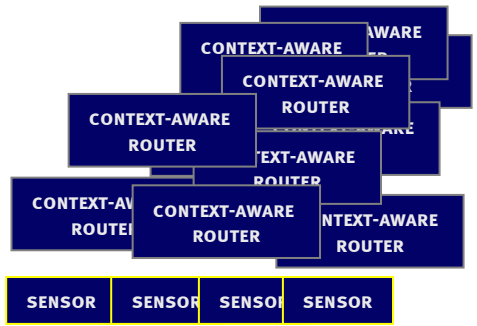
- Place unique number on tag
  - Electronic Product Code, EPC
  - 64 bit, 96 bit, and upwards



- Develop manufacturing technology for small chips and tags



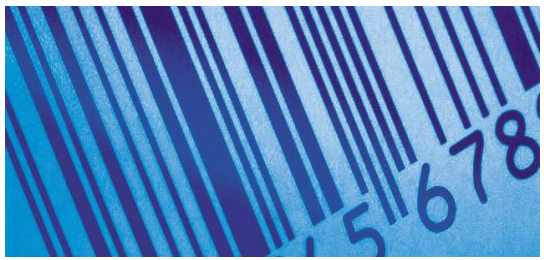
- Move data on the network
  - Network service for resolving EPC
  - Network architecture for gathering and routing data



What's wrong with bar-codes?

Bar Codes

- Line-of-sight
- One-at-a-time
- Manual handling
- Limited range
- Limited data



Auto-ID

- Non-line-of-sight
- 100(s) at a time
- Automatic handling
- ~1 meter
- 50 bits vs. Kbits

Adapted from material initially presented by Sanjay Sarma

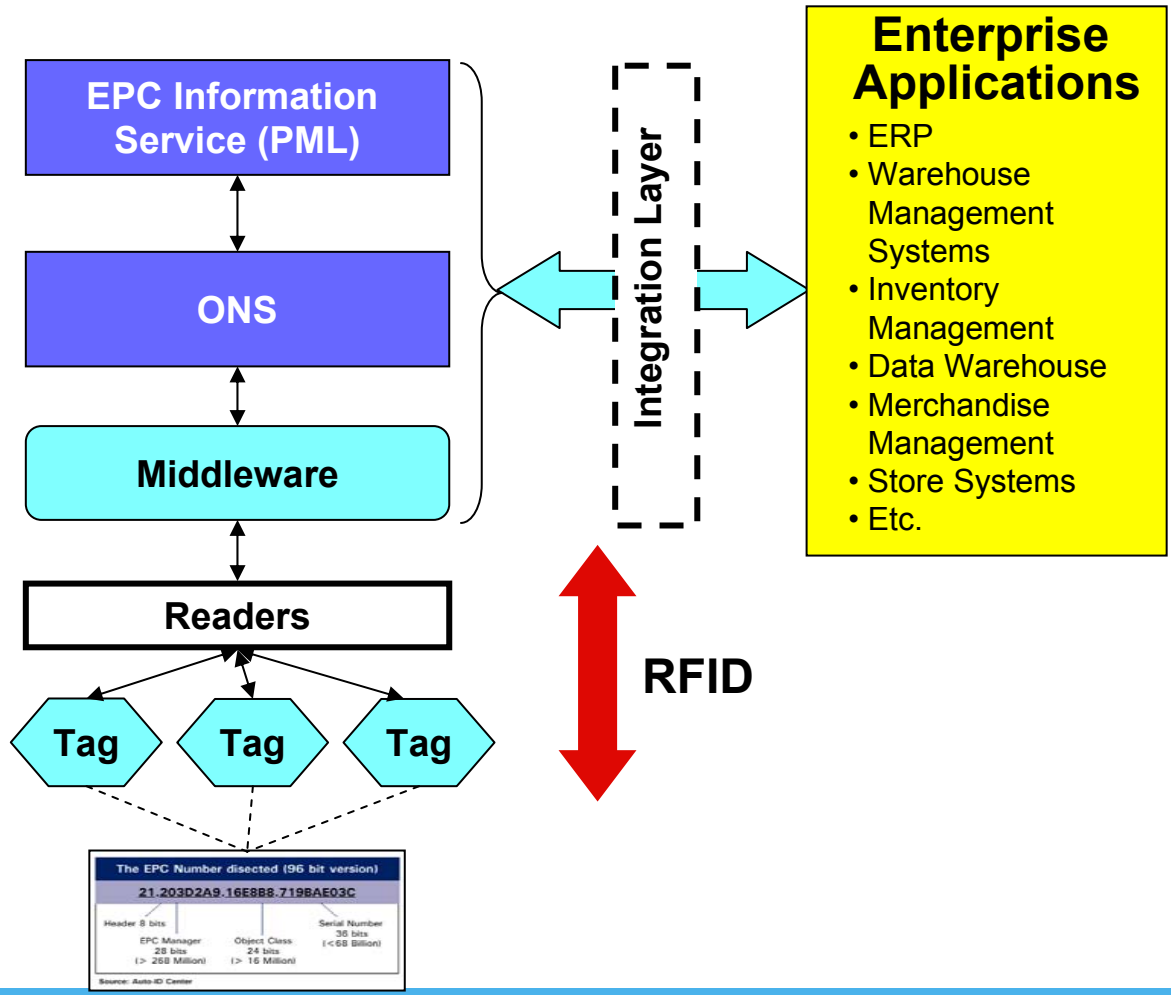
A Network that is…

- Always “on”
- Everywhere
- Facilitates interconnectivity
- Allows data sharing

The Web of Things

The EPCglobal Network

- Inexpensive tags
- Minimum data on the tag
- Middleware between readers and information systems
- Information stored on EPC Information Services, and accessed through Object Name Service



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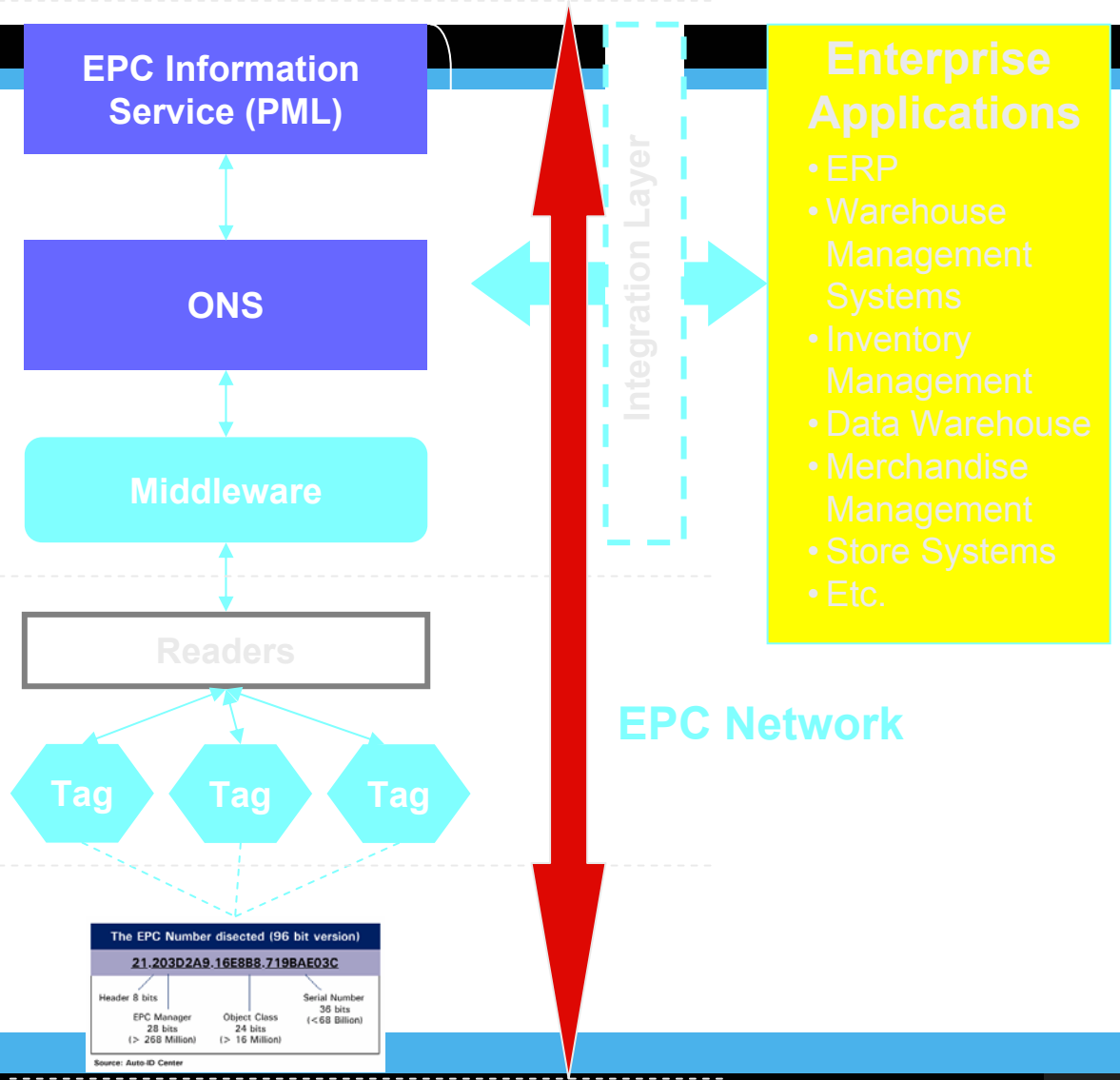


READ RATES

Technical Aspects of Passive Tags

	LF 125KHz	HF 13.56MHz	UHF 868-915MHz	Microwave 2.45 GHz
Data Rate	slower			faster
Scanning near Metal/Liquid	better			worse
Size	larger			smaller

source: SAMSys

Packaging and RFID SIG (MIT)

Investigate the impact of materials on the performance of RFID systems

- Field Probe

  Develop a physical tool to aid in the analysis of RFID systems.

  Tool will measure power levels, simulate an RFID tag, and monitor important system parameters.

- Simulator

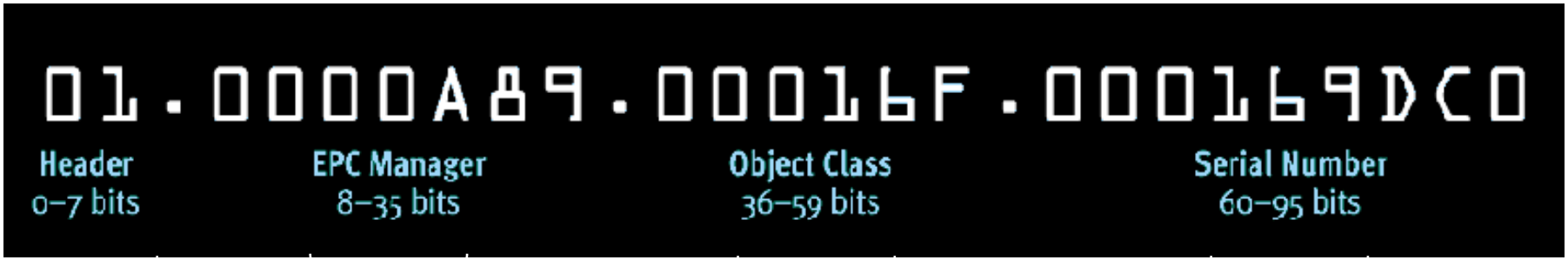
  Develop a simulator tool of RFID electromagnetic energy in the presence of physical objects.

  Tool will provide first order simulation on the capabilities of RFID systems in the presence of physical objects.

- Antenna

  Develop RFID tag antenna (for cases) that work well in the presence of metallic contents.

Electronic Product Code (EPC)



Version 8 bits

Manufacturer 28 bits
(> 268 Million)

Product 24 bits
(> 16 million)

Serial Number 36 bits
(> 68 billion)

Read Event

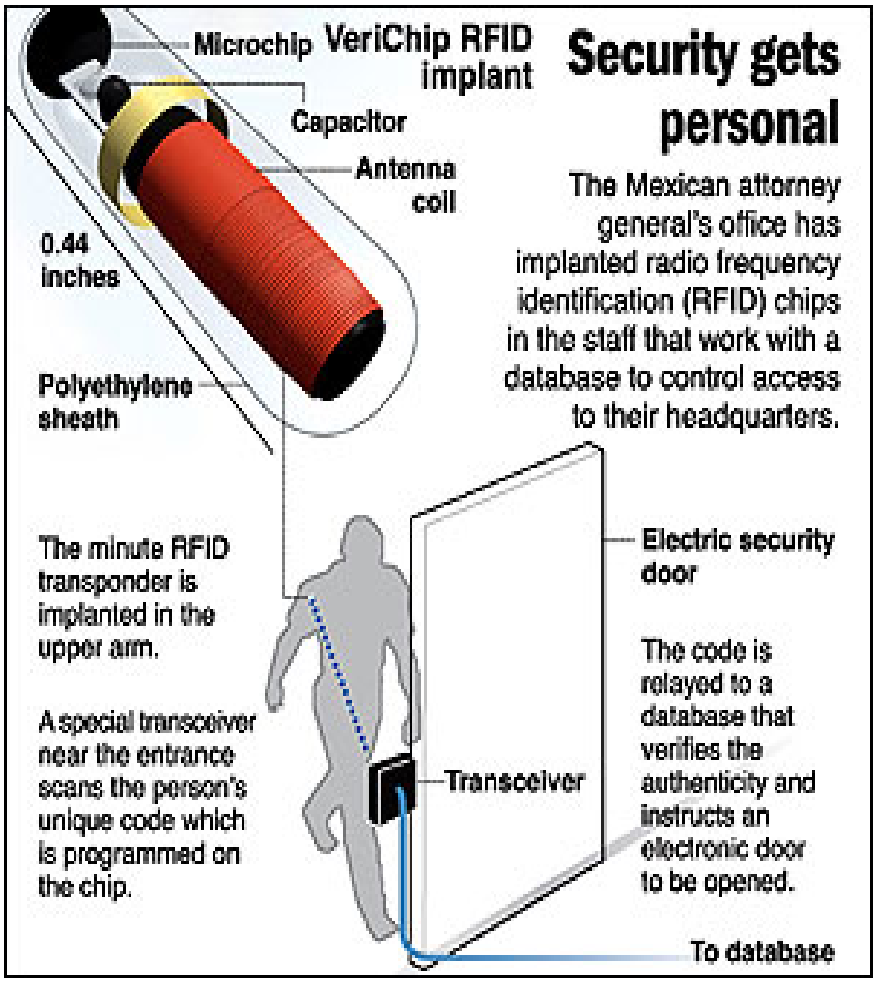
- What
- When
- Where

Packets of data

What is Next for Auto-ID

- Reduce cost, improve quality and read rates
- Gaining critical mass
- Build vendor base
- Slow build-out, over 3 – 8 years
- Changes to ERP systems
  - Transactional Bill of Material
  - Intelligent infrastructure
  - Smart products
- Making sense of the data?

“Mexican Officials Implanted With Microchips: Getting 'Tagged' Permits Special Access to Secure Areas”



Will Weissert, AP (July 15, 2004)


Johnson's
bedtime
bath
1 DOZEN (2-6)'s
15 FL. OZ. (444 ml)
01
003211
V-80
1 03 8137 003211 0
080 2


2 LITERS
Enjoy
Coca-Cola
CLASSIC
EASY TO USE
DISPENSER
The Stain Lifter


Coca-Cola
CROWN

AUTO-ID LABS

"Once you cover the cost of the infrastructure,
The cost of the information is free."

Kevin Ashton, VP Marketing – Thing Magic
Frontline 2004 (Chicago)

FDA

"According to Mark B. McClellan, commissioner of food and drugs at the Food and Drug Administration (FDA) in Washington, D.C., there's a '**significant and growing problem of counterfeit drugs**.'"

"The FDA estimates that up to **40 percent of pharmaceuticals** shipped from countries such as Argentina, Colombia, and Mexico may be counterfeit."

"The goal, he says, is to build a **'21st century system that can better protect consumers against this emerging public health threat.'**"

RFID: Cure for Counterfeit Drugs?
Samuel Greengard
RFID Journal (Oct. 15, 2003)

ANTI-COUNTERFEIT MEASURE	COVERT	OVERT	REPLICATION
Intra-Formulation			
Immunoassay	✓		Low
Unique Flavoring		✓	Low
Package Level			
Design		✓	High
Watermarks	✓	✓	High
Digital Watermarks	✓	✓	New
Fibers and Threads	✓	✓	Medium
Reactive Inks	✓	✓	Medium
Holograms, OVD	✓	✓	High
Bar Code		✓	High

The Auto-ID Approach to Combat Counterfeit

Tracking involves knowing the physical location of a particular drug
within the supply chain at all times.

Tracing (pedigree) is the ability to know the historical locations, the time spent at each location, record of ownership, packaging configurations and environmental storage conditions for a particular drug.

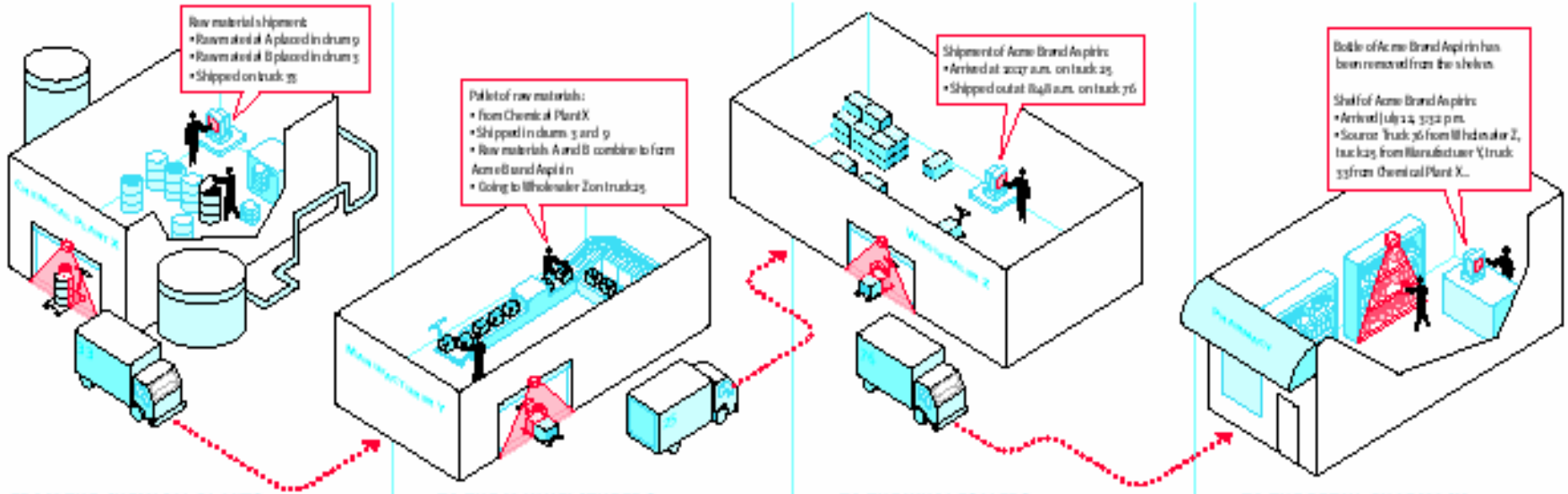
Complexity Associated with Track and Trace

- The form of the physical goods can change during each step of the pharmaceutical manufacturing and distribution process.
- Difficulties exist in tracking products through the supply chain
- The package becomes the vehicle for carrying the information needed for track and trace.
- THE PACKAGE CAN BE EASILY COUNTERFEITED

AN ACCOUNTABLE SUPPLY CHAIN: PHARMACEUTICAL PEDIGREE

XPLANATIONS® by XPLANE®

The pharmaceutical supply chain is a complex one. Not knowing the process by which pharmaceuticals make their way to pharmacy shelves can lead to risk in counterfeit products. Auto-ID technology helps manage this risk and maintain pedigree by tagging pharmaceuticals and product packaging with radio frequency identification (RFID) tags each possessing a unique EPC™. This allows products to be tracked, traced and recalled if necessary.



1. FROM THE CHEMICAL PLANTS

Chemical plants create raw materials and place them into drums. Each drum is uniquely numbered and tagged with RFID tags so the EPC™ Network can track them to the manufacturer. From this point on, the history of all raw materials is recorded in the EPC™ Network.

2. TO THE MANUFACTURERS

Raw materials are tracked and shipped from the chemical plant to the manufacturer. The manufacturer takes the tagged drums and combines raw materials to make pharmaceuticals (e.g. pills and liquids). Next, the pills or liquids are placed into tamperproof bottles and tagged with RFID tags. The EPC™ Network can easily account for the raw materials that go into each and every bottle. The tagged bottles are then shipped to wholesalers.

3. TO THE WHOLESALERS

Each bottle is tracked to the wholesaler. Product safety requires detailed records and an audit trail. The EPC™ Network puts that information at your fingertips. If necessary, product recalls are easily targeted and executed in a timely manner.

4. TO THE RETAIL PHARMACY

Pharmaceuticals are tracked into and out of the pharmacy. Auto-ID technology tells the Pharmacists where all the pharmaceuticals are, how many bottles have been sold and when. Bottles tagged with RFID tags hold each party in the pharmaceutical supply chain accountable for their actions, ensuring the pedigree of each product.

THE EPC™ NETWORK: HOW DOES IT WORK?

With the new EPC™ network, manufacturers, distributors and retailers will be able to track and trace items automatically throughout the supply chain. Here's how it works:

THE RFID TAGS

An Electronic Product Code (EPC™) is embedded into microscopic "smart tags" and attached to an item's packaging (e.g. drums or bottles). These tags allow the items to be tracked in a completely automated, cost-effective fashion.

THE READERS

Radio Frequency Identification (RFID) readers can scan each smart tag and send the item's EPC™ to a computer running Savant™.

SAVANT™

Savant™, middleware that connects the Auto-ID Network, queries an Object Name Service (ONS) database.

ONS SERVER

The ONS maps the EPC™ to a URL where all of the item's information is stored using Physical Markup Language (PML).

PML SERVER

The PML server contains information about the item itself, its manufacturing, shipping and other related data.

Aggregation and Inheritance

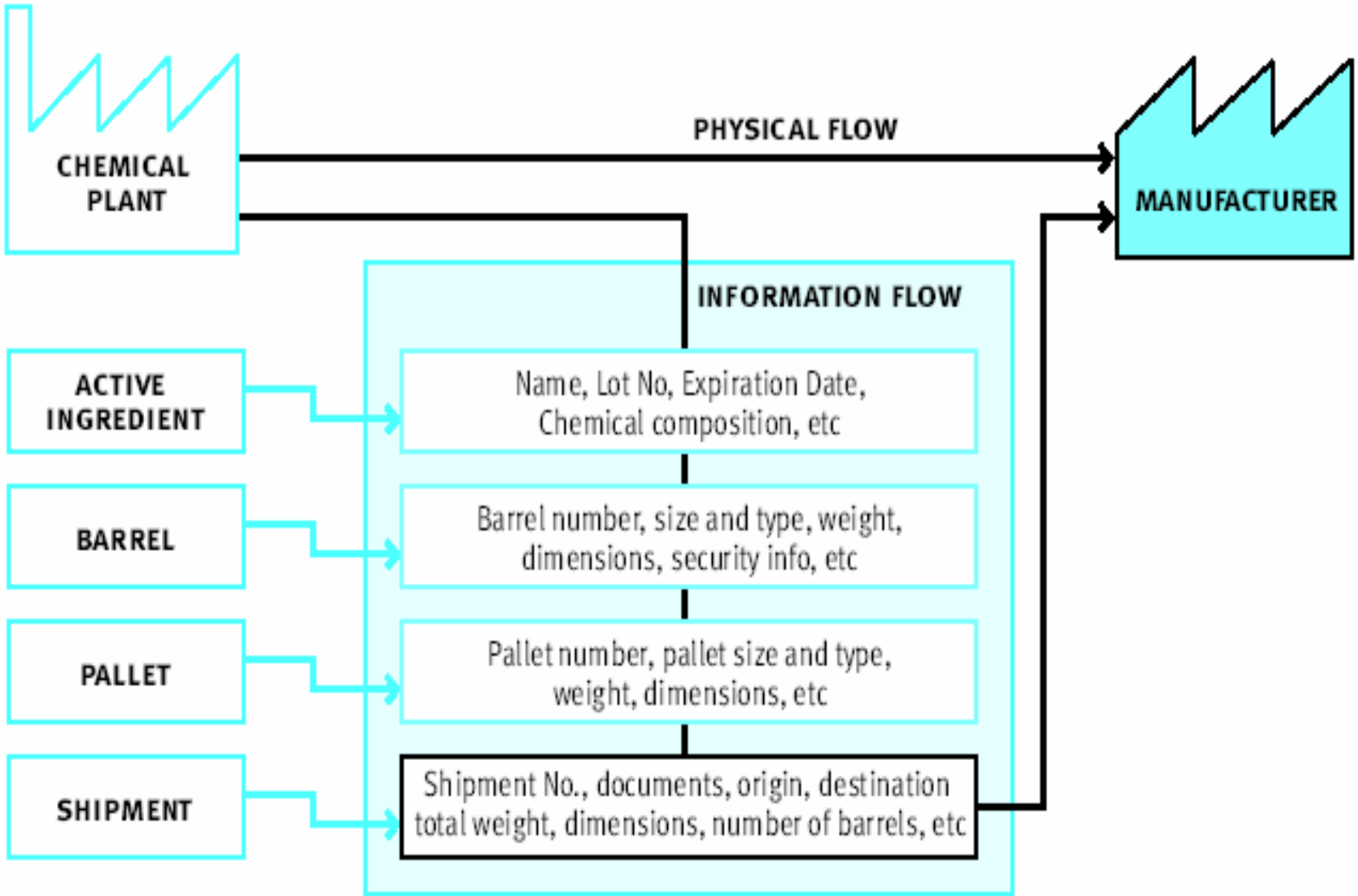
- In spite of a changes in form, a link still exists
- For any track and trace effort, organization of data becomes very important

Data Aggregation is the logical equivalent of item aggregation or assembly. By viewing data within a supply chain as a series of parent – child relationships, track and trace becomes possible.

Data Inheritance is the history of the parent data. To reconstruct the history of an item, each change in form must transfer from parent to child.

An example from practice

EXAMPLE OF INFORMATION AGGREGATION



An Auto-ID Based Solution

- Track and trace
  - track and trace requires detailed information
- Drug verification
  - verification is binary, requiring minimal information
- Information flow within the supply chain
  - Data pre positioning, serial movement of information (track)
  - Central Repository, write select information to a third party (trace)
- Thick file versus thin file
  - Transfer PML files containing large amounts of information (thick file)
  - Transfer just ePC (thin files)

Three Classes of Databases

- Manufacturer database
  - Detailed information about a drug, pack size, weight, ect.
  - Potential link to product registries such as Red Book or First Interstate catalogs

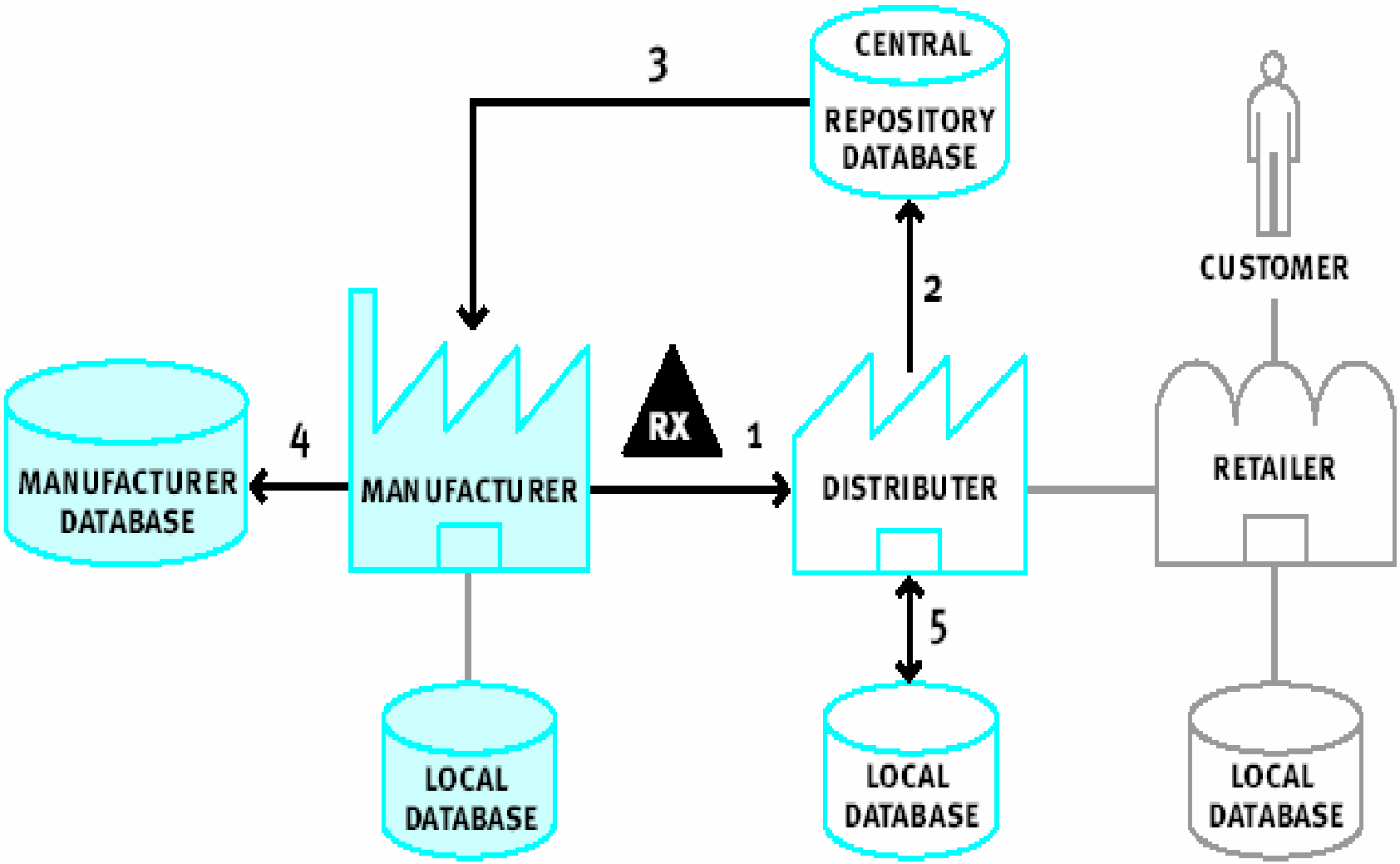
Central Repository Database

- Contains information from all firms that handled the drug

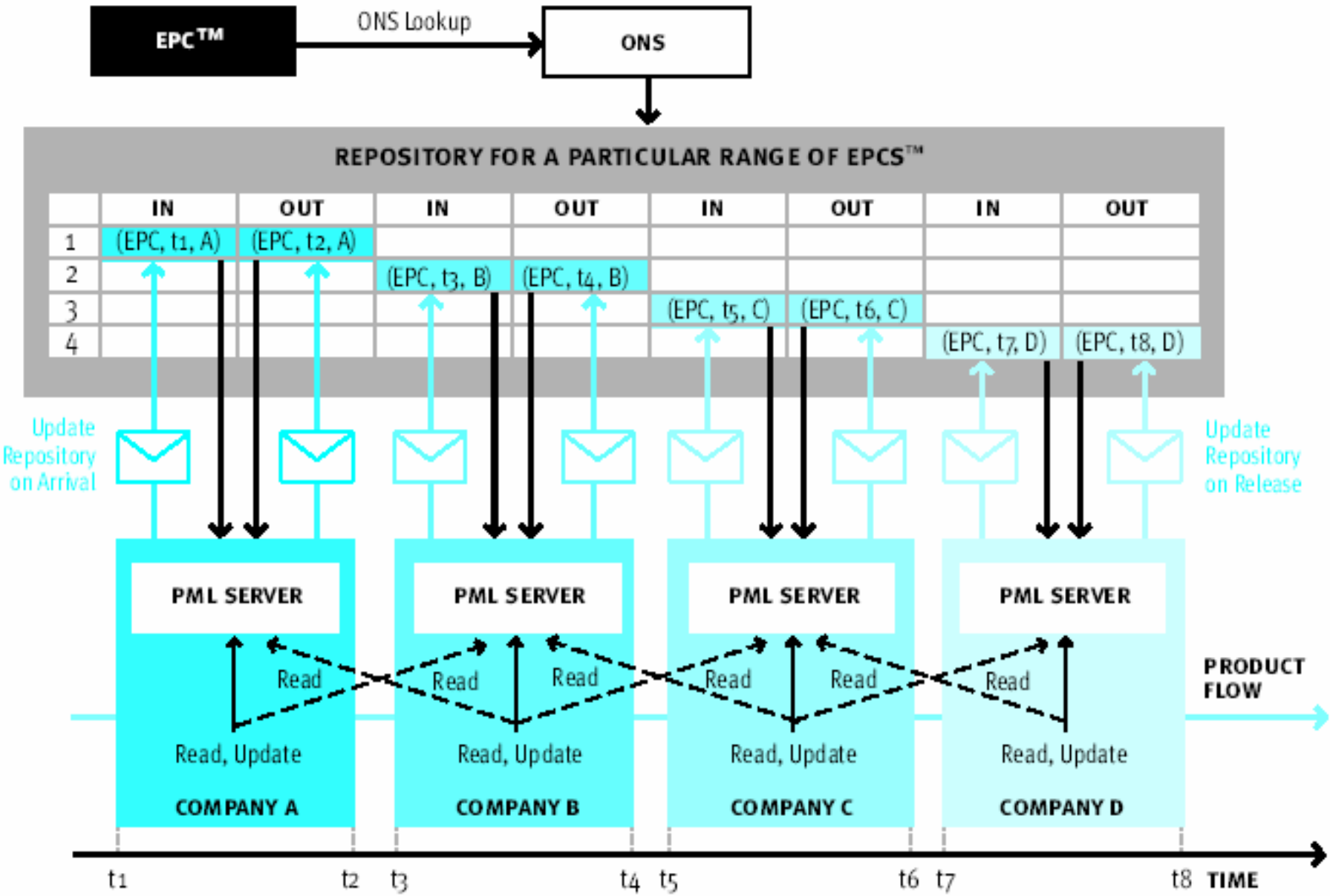
Local Database

- Warehouse location or management signatures

DIAGRAM OF RF-ENABLED SUPPLY CHAIN



CO-ORDINATING PML SERVICES ACROSS A SUPPLY CHAIN USING A REPOSITORY



A Realistic Approach to Implementation

"All three technologies--active RFID tags, passive RFID tags, and two-dimensional bar codes--will complement each other..."

Bar Codes Expected To Have A Long Life
Elena Malykhina
Informationweek (Oct. 21, 2004)

Transition Plan

2D Bar Code

To

Auto-ID?

Redundancy

"Our hand-held readers will have a bar-code capability and every RFID label will have a readable bar code in the back of it. So, if an RFID tag fails, we will have a bar code to fall back on…"

Bar Codes Expected To Have A Long Life
Elena Malykhina
Informationweek (Oct. 21, 2004)

Hospital

"'Hospitals aren't ready to adopt RFID from a financial perspective and because of the hospital IT infrastructure. They're barely ready for bar-coding,' said Braun. 'I see in 10 to 20 years bar-coding still being used at hospitals, as opposed to RFID.'"

Attributed to Steven Braun, marketing manager at Hospira

Bar Codes Expected To Have A Long Life
Elena Malykhina
Informationweek (Oct. 21, 2004)

Business Re-engineering and Auto-ID

"Making the business case for RFID, such as identifying operations that could be more efficient with its use, is proving difficult, particularly in distribution centers that already leverage state-of-the-art bar-code systems and well-ordered processes."

"'People are asking what an RFID-centric picking process should look like and how it will save them money, but it's a really difficult thing because bar coding is so good,' Woods says.

RFID Kick-Start
By Beth Bacheldor
Informationweek (May 24, 2004)

Sensing and the Cold Chain

"Uwe Weigel, a spokesperson for KSW, says the TempSens smart label costs US$10 for samples, but customers buying in bulk can get the labels for under US$3. That compares with upwards of US$25 for some RFID temperature sensors on the market today."

New Low-cost Temperature Sensor
RFID Journal (July 19, 2002)

Web Services WAN SIG (MIT)

Investigate the Wide Area Network networking requirements for secure, real-time web services

- SOAP

  Develop SOAP messaging system to enable secure, real-time communication.

- Sensor Networks

  Develop description and communication framework compatible with the SOAP Project that enables real-time data captured by a sensor network to be communicated over the WAN.

Cost (Price of Tags)

"Although sales of passive UHF RFID tags to manufacturing companies will rise dramatically during the next four years, resulting in lower tag prices, the average unit price for passive UHF RFID tags will not reach the 5-cent level by 2008, according to ARC Advisory Group, a research firm based in Dedham, Mass."

5-Cent Tag Unlikely in 4 Years
Diane Marie Ward
RFID Journal (Aug. 26, 2004)

Cost (continued)

"Instead of dipping to a nickel, as some industry observers predict, the average price of a passive UHF RFID tags will drop to only 16 cents, according to recently issued ARC report…"

5-Cent Tag Unlikely in 4 Years
Diane Marie Ward
RFID Journal (Aug. 26, 2004)

AUTO-ID LABS

"ARC found that in 2003, the average unit price of tag was 91 cents for a passive HF tag and 57 cents for a passive UHF tag."

"The firm expects that by 2008, the unit price will drop to an average of 16 cents for passive UHF tags, which vary by form factor, and to nearly 30 cents each for passive HF tags, although some tag manufacturers with high-volume contracts may be able to offer passive UHF tags for as low as 5 cents each."

5-Cent Tag Unlikely in 4 Years
Diane Marie Ward
RFID Journal (Aug. 26, 2004)

Track and Trace Software

- SAP
  - Auto-ID Infrastructure
- Unisys
  - Operation Safe Commerce
- MIT
  - Hong Kong Harbor
- Certifi
  - Warranty management, distributor management
  - marketing analytics

What is Needed to Implement Auto-ID in Pharma?

Research

- Global Issues
- Security
- Privacy
- Redundancy
- Product stability
- Technical Migration Plan

Evaluation

- Pilots
- Trials
- Proof of Concept
- Business case
- JumpStart I & II
- DSN

Standards

- EPCGlobal
- HDMA
- Others

Auto-ID Labs: Member Labs

- Current Member Laboratories
  - Massachusetts Institute of Technology
    - Research Director: Dr. Daniel W. Engels
  - University of Cambridge (manufacturing, EPCIS)
    - Research Director: Dr. Duncan McFarlane
  - University of Adelaide (RFID systems)
    - Research Director: Prof. Peter H. Cole
  - Keio University (ubiquitous computing)
    - Research Director: Prof. Jun Murai
  - Fudan University (microelectronics, VLSI design)
    - Research Director: Prof. Hao Min
  - University of St. Gallen (supply chain, PML)
    - Research Director: Prof. Elgar Fleisch

Important Question…

Where does drug security end in Terms of the pharmaceutical supply chain?

The Value of Technology

- Authentication
- Authentication + Tracing (ePedigree)
- Authentication + Tracing + Tracking

AUTO-ID LABS

Conclusion