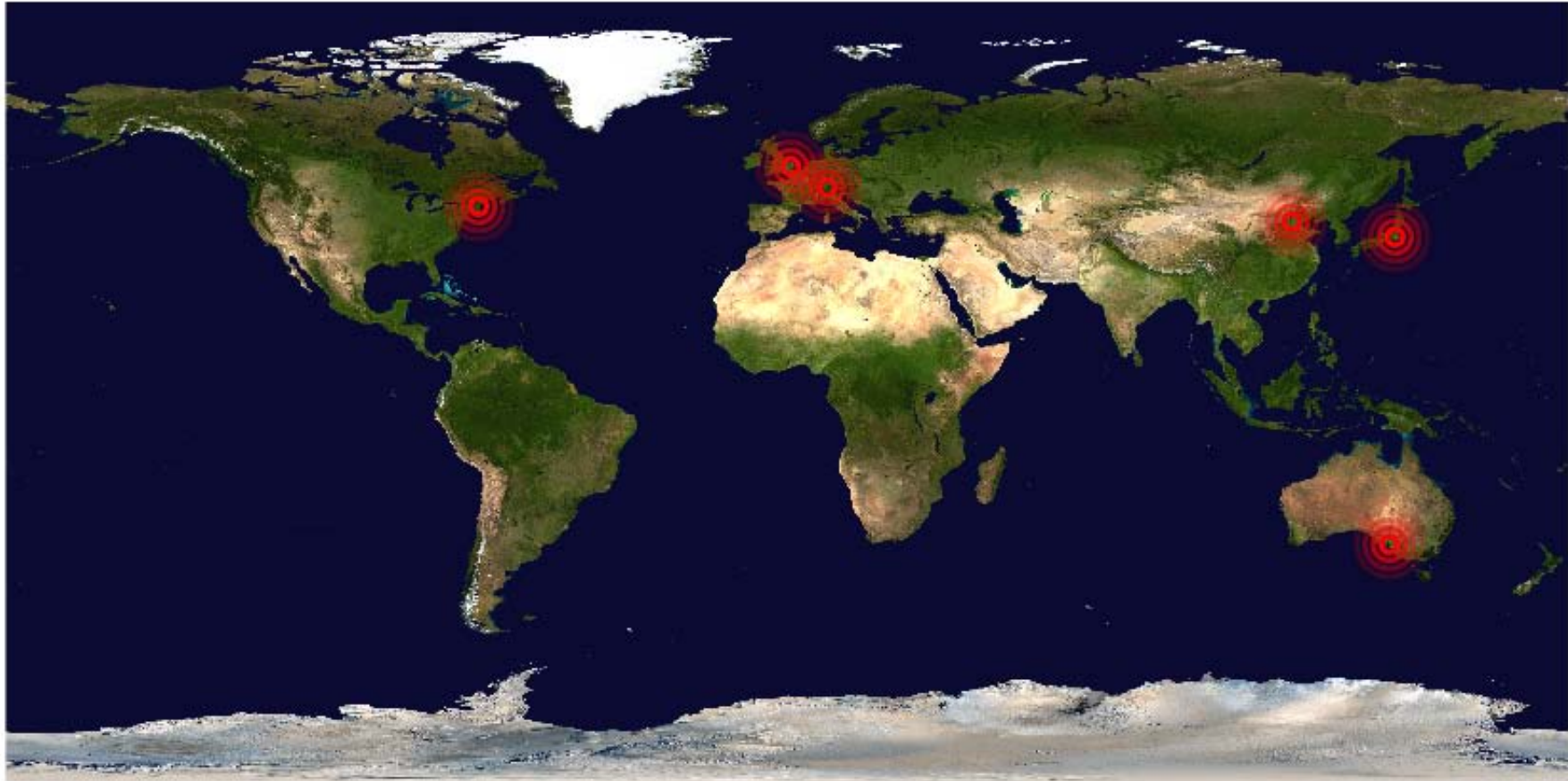

PHARMACEUTICAL TRACKING VIA THE EPC NETWORK

Dr. Mark Harrison
Associate Director
Auto-ID Labs, Cambridge, UK

<http://www.autoidlabs.org/Cambridge>



AUTO-ID LABS - A GLOBAL NETWORK

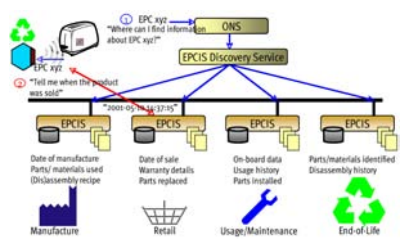
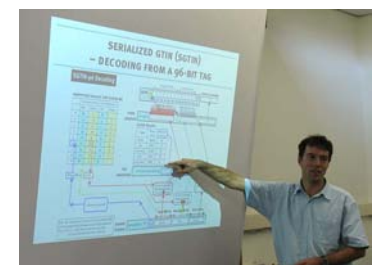
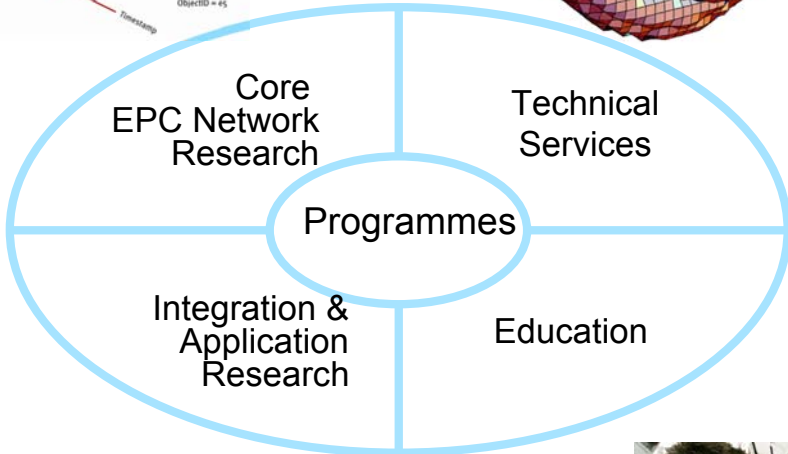
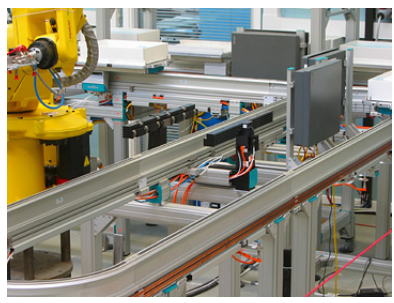
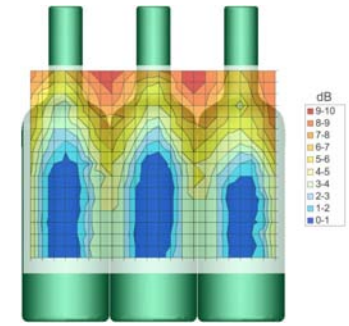
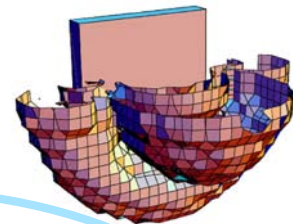
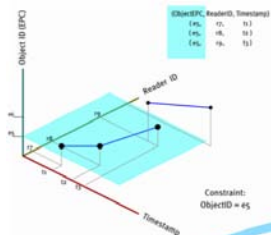
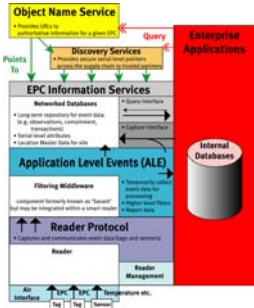


AUTO-ID LABS - DIVERSE SPECIALISATIONS

- MIT, Boston, USA
 - Core protocols
- Cambridge, UK
 - Auto-ID for industrial control and manufacturing
- M-Lab / University of St Gallen, Switzerland
 - Applications, business case studies
- University of Adelaide, Australia
 - RFID expertise - physics
- Keio University, Japan
 - Next-generation internet protocols
- Fudan University, China
 - Design of silicon microchips for RFID tags

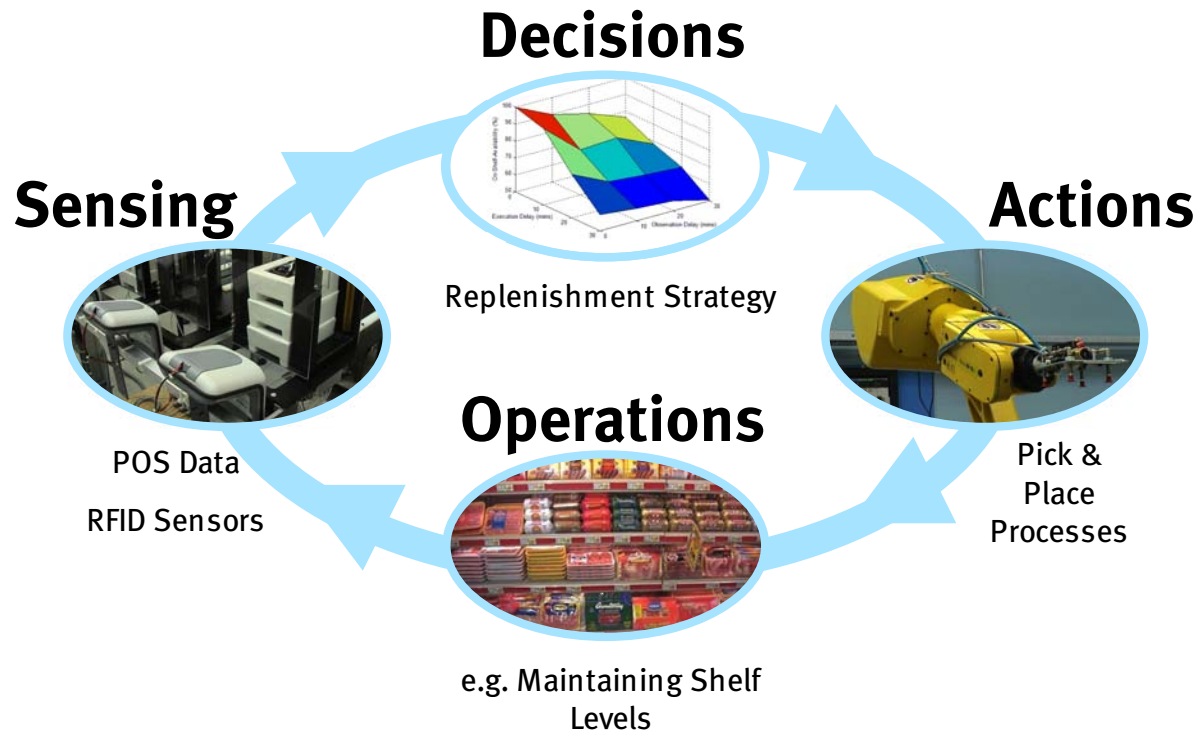


AUTO-ID LABS AT CAMBRIDGE, UK



AUTO-ID LABS AT CAMBRIDGE, UK

- ‘Closing the Loop’
 - Making Real-Time Decision and Actions using EPC Network Data



OUTLINE

1. What is the EPC Network?
2. Technology building blocks
3. Pharmaceutical traceability via the EPC Network
4. Current Activities in Healthcare & Life Sciences



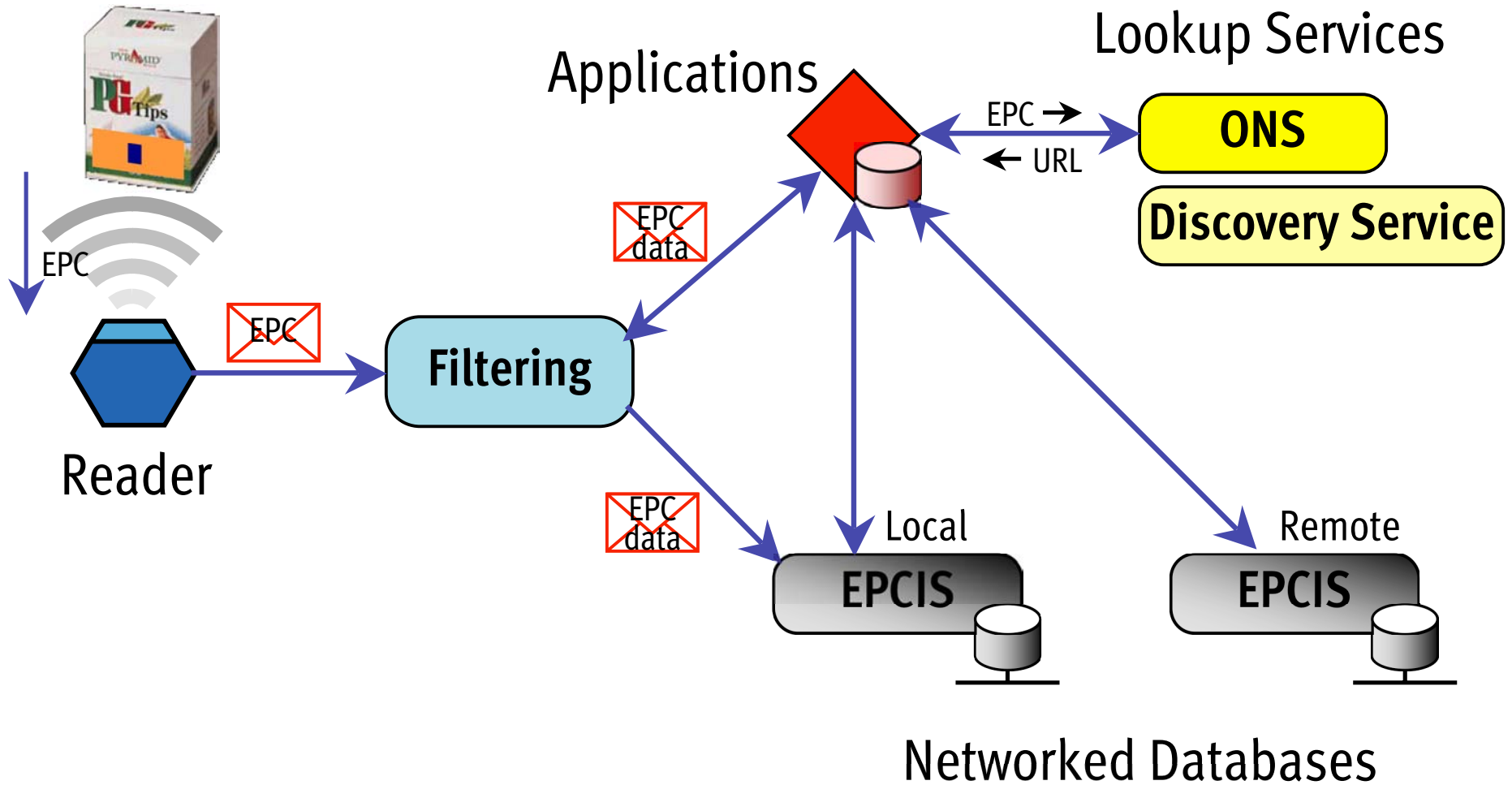
WHAT IS THE EPC NETWORK?

- More than just cheap passive RFID tags and EPC numbers
- A collection of technologies to build an ‘ Internet of Physical Objects ’
- The vision: “Identify any object anywhere automatically”

=> a global system for widespread RFID deployment based on open standards and a unique identification code for the life of the object
- The vision: “Change the world by merging bits and atoms”

=> synchronize flows of objects with flows of information about them

TECHNOLOGY BUILDING BLOCKS



TECHNOLOGY BUILDING BLOCKS

1. Uniquely identifying items
 - EPC – electronic product code
2. Detecting the presence and identity of items
 - RFID – radio frequency identification
3. Storing item characteristics and movements
 - EPCIS – EPC Information Service (networked databases)
4. Passing the information across the network
 - Filtering Layer
5. Finding information within the network
 - ONS – object name service



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EPC – ELECTRONIC PRODUCT CODE

- EPC is a naming scheme for objects
 - Unique identifier for every object – includes serial number
 - Like giving each object a unique web address
 - Designed to be scaleable & extensible
- Decouple identity from data
 - Only store the EPC on an item (via RFID tag or a barcode)
 - Additional information is held in a database and can be accessed using the EPC as a lookup key
- Global, open standard
 - Supported by GS1
(formerly Uniform Code Council and EAN International)



STRUCTURE OF THE EPC

- The EPC can be thought of as the next generation of the barcode
- The barcode usually only goes as far as identifying product type.
- The EPC goes further and gives each object a unique serial number
- **N.B. Not all EPC schemes identify product type - SSCC, GIAI do not.**



01.0000389.000162.000169740

Header	Company Code	Product Code	Serial Number
8 bits	28 bits	24 bits	36 bits



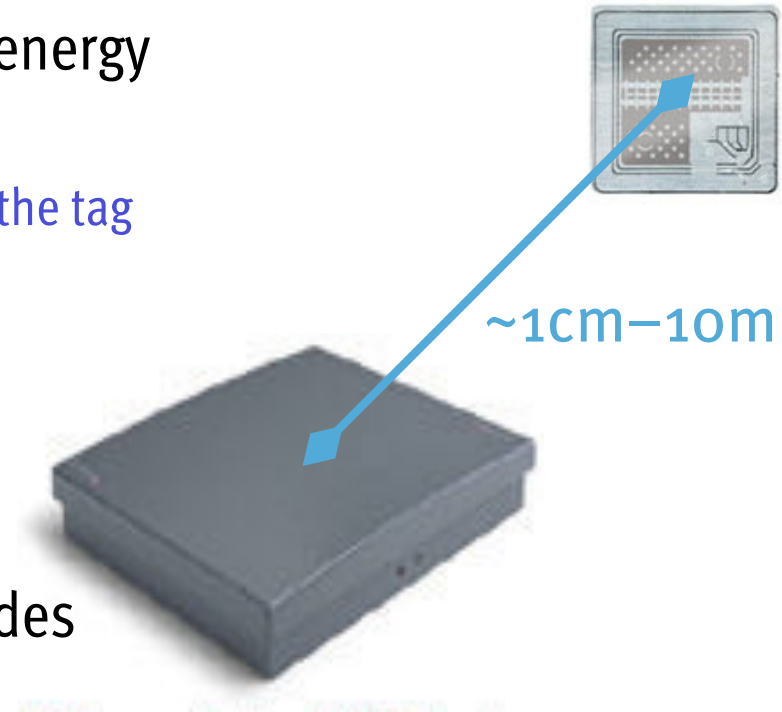
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RADIO FREQUENCY IDENTIFICATION (RFID)

- Reader transmits radio frequency energy
 - Provides power for the tag
 - Enables communication to and from the tag
- Typical operation
 - 64 bits to few kilobits of data
 - Range ~5mm to ~5m
 - 50-500 tags per second
- Significant advantages over barcodes
- Cost is the key challenge



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EPCIS – EPC INFORMATION SERVICE

- Networked databases
- Registry for event information, transactions and attribute data
- Support for updates and queries with standard defined interface

‘EPC-Related’ data	
Timestamped Event data	Attribute data (often static)
Observations (Tag readings)	Attributes defined at serial level e.g. date of manufacture, expiry
Measurements (sensor data)	
Symbolic Location/Containment	Attributes defined at product level, e.g. mass, dimensions
EPC \leftrightarrow Transaction ID	

EPCIS QUERY INTERFACE

- The EPCIS query interface
 - specifies function names, input parameters, return values for particular kinds of events / relationships, including transactions
 - will probably be specified in terms of one or more WSDL files and existing XML schema for attributes (object properties)
 - may also support bindings to AS2 mechanism currently used for EDI
- Companies will have the ability to limit the load on the EPCIS service they provide, as well as restricting access to various categories and granularities of data for different authenticated clients.
 - e.g. they might only define a number of ‘canned’ pre-determined queries to which clients may ‘subscribe’ - but disallow free-form queries



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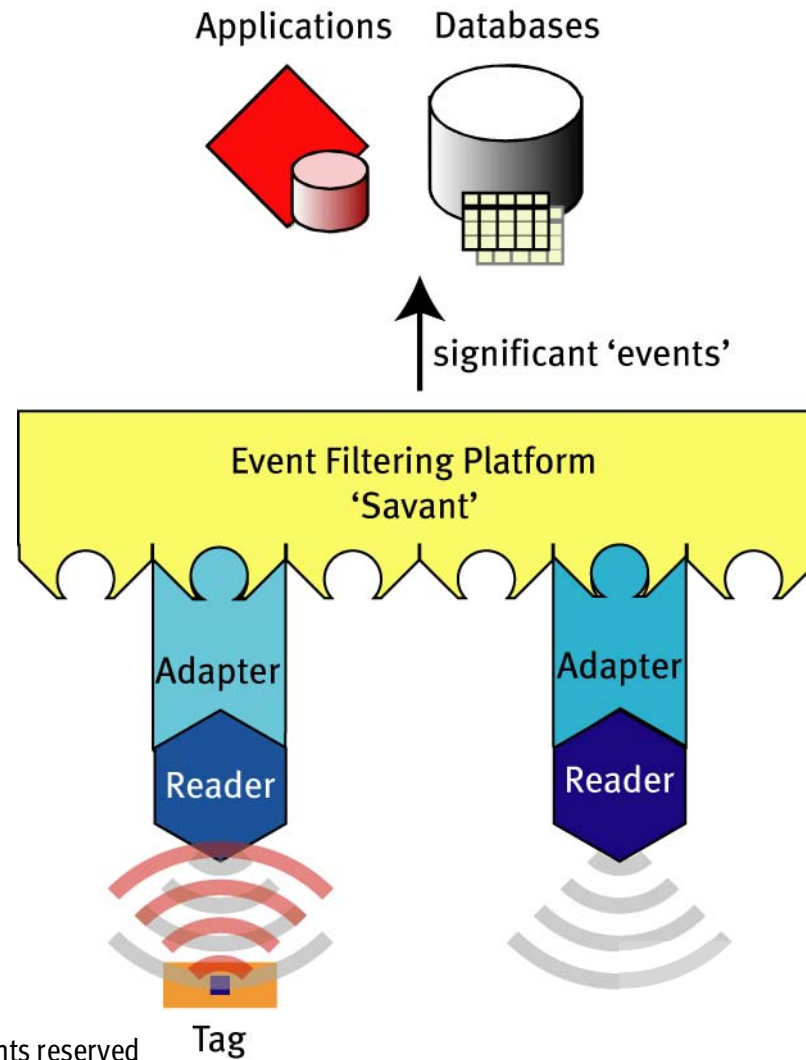


EVENT FILTERING LAYER

- Software for collecting and filtering RFID data
 - Designed to deal with copious amounts of data
 - Generates higher level “events” based on raw data
 - Supports ‘push’ of events to applications which ‘subscribe’ to them
 - OS-type platform provides common interface
 - Standardised communication formats
- Need additional middleware above filtering layer
 - More sophisticated processing
 - Interface with Business Information Systems



EVENT FILTERING PLATFORM



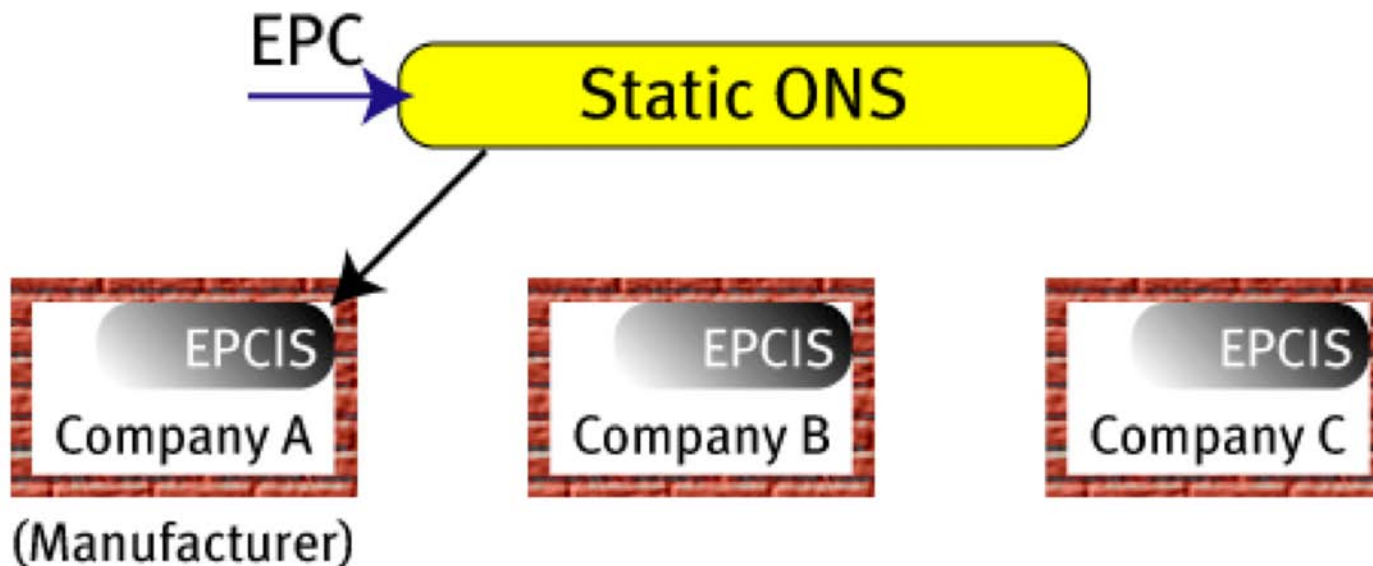
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ONS – OBJECT NAME SERVICE

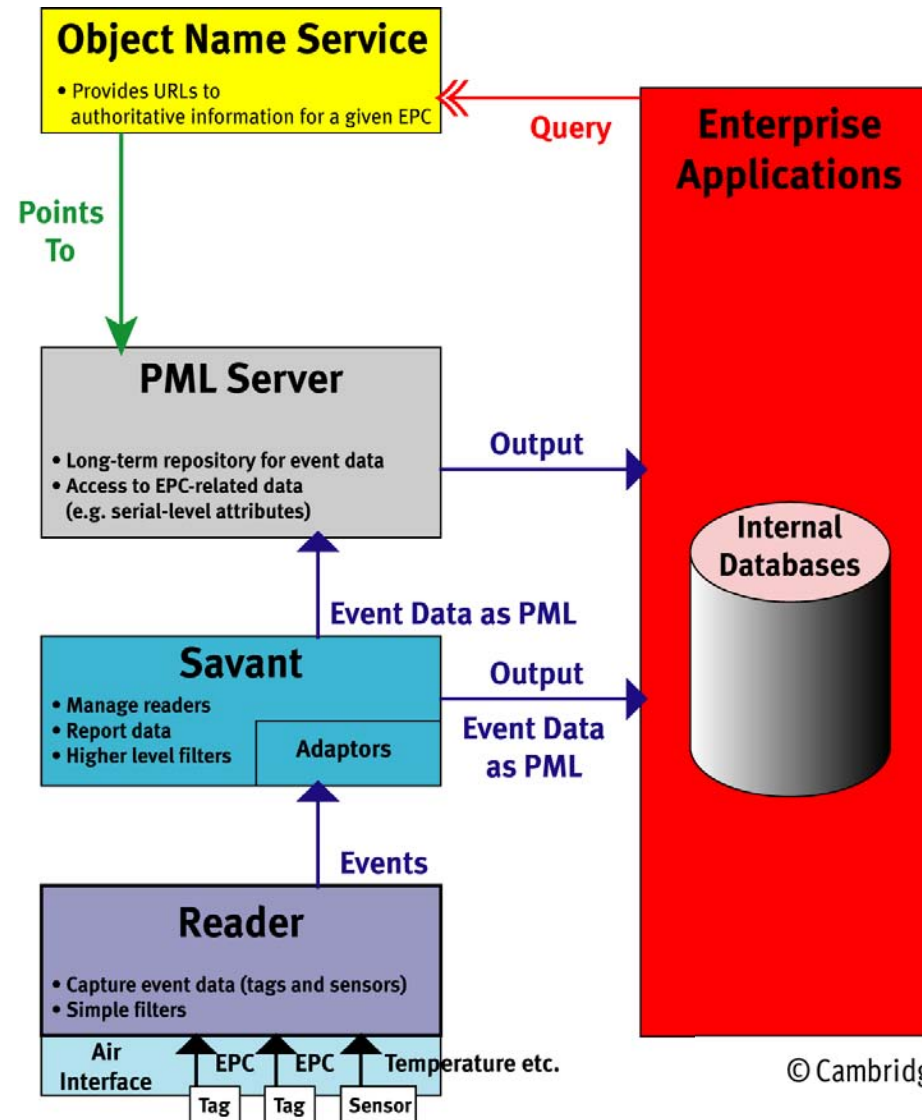
- Redirection service – telephone book
 - For finding which database relates to a given EPC
- Similar to DNS, with additions



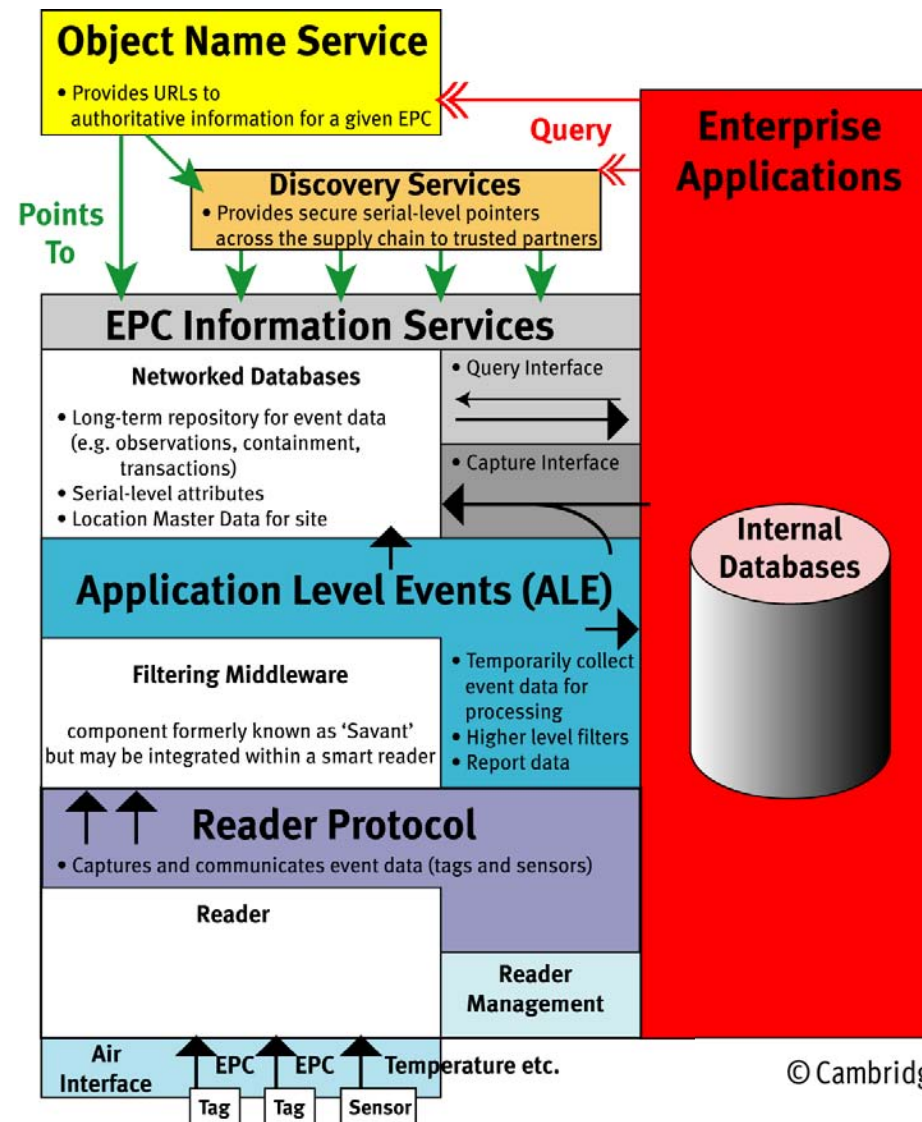
UPDATE ON STANDARDS DEVELOPMENT

- Version 1.0 specifications were released in September 2003 at the EPC Symposium in Chicago.
- Over the last year, much of the EPC Network is being redefined in terms of interfaces between components.
- This recognizes that hardware and software may fulfill more than one role - e.g. smart readers which do some filtering
- It will also be easier to certify that products comply with particular well-defined interfaces in order to guarantee interoperability
- Many of these interfaces are being defined in terms of web service descriptions (WSDL) and XML schema (XSD).
- New Specifications (ALE, EPCIS) expected to be published by Q4 of 2005.

THE EPC NETWORK - SEPTEMBER 2003



THE EPC NETWORK - 2005



PHARMACEUTICAL TRACKING USING THE EPC NETWORK

- EPC and Serialization for Pharmaceuticals
- Filtering - managing the volumes of data
- The Object Name Service (ONS) and Discovery Services
- Robust access to information
- Implementing E-Pedigrees in tandem with the EPC Network

EPC AND SERIALIZATION FOR PHARMACEUTICALS

- RFID is a different beast from barcodes.
- RFID tags can be read automatically, at a distance, without line-of-sight and potentially without the knowledge of the person carrying the object.
- Privacy concerns and HIPAA guidelines mean that we do not want to identify the product type by simply reading the RFID tag's ID code.
- We need to do mass-serialization without identifying product type - and it must all be managed in a scaleable way.
- 🖱️ RFID tag could identify the manufacturer and a unique serial number.
- Each manufacturer guarantees the uniqueness of their serial numbers.
- Machine-readable backup (e.g. 2-D barcode) is needed if the RFID tag fails / is damaged.

FILTERING

- MANAGING LARGE VOLUMES OF DATA

- EPC codes can include a ‘fast filter’ value to indicate the packaging level, e.g. to distinguish between pallet, cases and items / each.
- In UHF Generation 2 tags, filtering can even be done at the air interface (reader - tag RF protocol) - via the Select command.
 - Only tags which match a particular pattern (e.g. header + filter value) would respond. All other tags would know to remain silent.
- Filtering can also be done in software / smart readers. ALE interface standardizes this.
- Filtering avoids overloading your network and applications/databases with every ‘blip’ from an RFID reader.
- Instead you just transmit and record significant events, e.g. when a tagged object first appears at a particular location - and when it is removed



ONS AND THE DISCOVERY SERVICE

- The Object Name Service provides pointers to authoritative information about an object.
 - e.g. given an EPC code, the ONS usually points to the address of the manufacturer's information service
- ONS v1.0 is built on the Domain Name Service (DNS) which powers the internet.

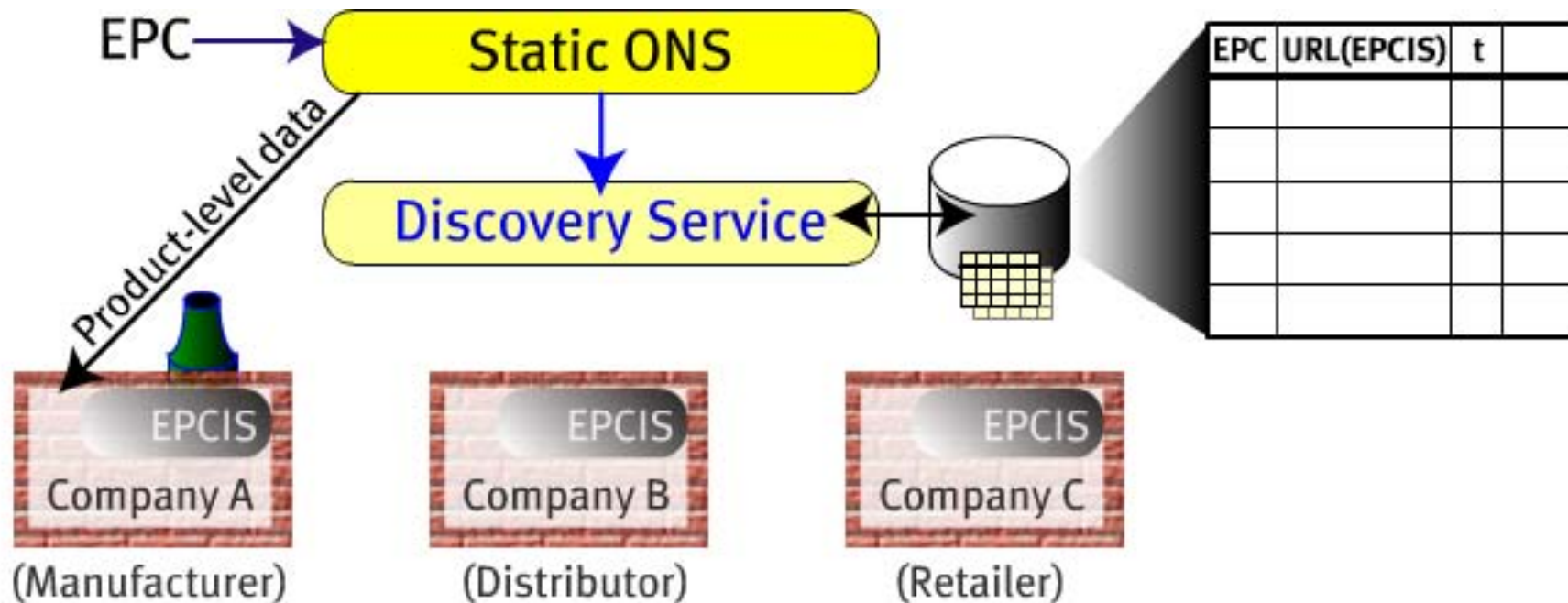
✓ Advantages of DNS	✗ Disadvantages of DNS
Robust, established technology	Updates to DNS are slow to propagate
Lightweight, efficient protocol	DNS does not normally require authentication or have access controls

ONS AND THE DISCOVERY SERVICE

- For real-time secure traceability, we need something beyond ONS v1.0
- EPCglobal and solution providers are considering “Discovery Services”.
- Discovery Services provide authorized authenticated clients with serial-level pointers to information services across the supply chain.
- The standard specification of Discovery Services is yet to be defined - but it would support real-time updates of its pointers.
- Discovery Services could also be used to support more pro-active product recalls and also be very useful in detecting diversion and counterfeit products with duplicate IDs.

DISCOVERY SERVICES

- Discovery Service registries can be updated by each custodian on handover, with serial-level EPC lookup



DISCOVERY SERVICE

We may want to update a Discovery Service about:

- change of custodian (arrival / departure)
- change of EPC to track
 - upon aggregation into a container
 - upon re-tagging / re-packaging
- the status of a particular EPC:
 - Recalled / Marked for recall
 - Dispensed
 - Returned



DISCOVERY SERVICES

- It's not yet clear who would operate Discovery Services:
 - Industry associations, e.g. HDMA
 - Government agencies, e.g. FDA
 - Manufacturers
 - Not-for-profit organizations, e.g. World Health Organization, EPCglobal
- Drop-box – Write access does not mean read access!
 - Authenticated supply chain parties might have an obligation to provide updates to a particular Discovery Service registry - without having the right to browse or search it.
- Secure access to Discovery Service is very important - need to use digital certificates to authenticate those who provide updates as well as those who query it.
- Discovery Services are not a replacement or alternative to e-pedigree. They are a useful tool for real-time traceability and forward tracking - but do not have a legal document status.



ROBUST ACCESS TO INFORMATION

WHEN IT IS NEEDED

- RFID tags can be damaged - so use a 2-D barcode as a machine-readable backup
- Send the list of objects' EPCs ahead of time via Advance Shipment Notices (ASNs) or Advance Pedigree Notices (APNs)
- ASNs/APNs allow the recipient to verify the EPC codes ahead of time - e.g. check that they are not duplicates, have not already been dispensed / expired / withdrawn
- ASNs/APNs allow the recipient to obtain the relevant information from networked databases of manufacturers and supply chain partners using ONS and Discovery Services to find the addresses - and EPCIS as a standardized query interface
- Pre-positioned data should be stored locally (cached) so that day-to-day operations can continue even if there is a temporary network outage.

E-PEDIGREES

- E-Pedigrees record every transaction / handover of each individual serialized item from the manufacturer to the point of dispensing - i.e. a secure chain of custody
- E-Pedigrees are a legal document - and each transaction needs to be digitally signed by the party involved in that transaction.
- Digital signatures consist of making a digest (summary) of the information in such a way that even a change of one letter completely alters the digest. The digest is then encrypted using the private key of the signer.
- Decrypting via the signer's public key can be used to verify that it could only have been that party which signed the particular transaction.
- Digital signatures are required at the individual level - not just the corporate level!
- E-Pedigrees could use an EPC as the mass-serialized ID code for traceability
- E-Pedigrees are signed, then forwarded to the next custodian on the supply chain.
- There is not yet a requirement to use Discovery Services, nor to record the address of information services in the pedigree document.

MASS-SERIALIZATION AND ANTI-COUNTERFEIT

- UHF Class 1 Generation 2 provides for a separate Tag ID written into read-only memory by the tag manufacturer.
- If the manufacturer records the corresponding Tag ID for each EPC record in their EPC Information Service, this can provide some hindrance to counterfeiters.
- However, a more robust anti-counterfeit strategy needs additional measures including:
 - Variable use of combinations of security markings (colour-shifting inks, holograms, etc.) - the particular combination for each EPC could be recorded in the Mfr's EPCIS and only readable to authorised parties
 - Verifying a secure chain of custody via the e-pedigree document
 - Use of real-time discovery services to detect duplicate EPCs appearing at unexpected locations in the supply chain
- The EPC Network is a technology infrastructure for managing information about mass-serialized items in a uniform way across the supply chain
 - this can assist in detecting and preventing anti-counterfeit but is only part of the total solution

CURRENT ACTIVITIES IN HEALTHCARE

- EPCglobal Healthcare and Life Sciences (HLS) Business Action Group:
- Mission:
 - Identify HLS industry end-user business requirements to the EPCglobal standards development process
 - Promote the adoption and implementation of the EPC and the elements of the EPCglobal Network for the HLS industry.
- Work Groups:
 - Strategic Planning (identify use cases, scenarios etc.)
 - Information
 - Policy
 - Research & Development
 - Technology
- http://www.epcglobalinc.org/action_groups/hls_bag.html

CURRENT ACTIVITIES IN HEALTHCARE

- Members of Auto-ID Labs have set up a Healthcare Research Initiative
- Mission:
 - To improve the safety, security and practice of healthcare through the application of advanced technologies like RFID
 - To help healthcare to provide the maximum benefits of technology
 - To help healthcare best practice to reach all corners of the globe
- Initial Research Activities:
 - Research issues are identified by Labs and Industrial Partners and undertaken within an evaluation environment
 - Stability of Pharmaceuticals in Radio-Frequency fields
(Not just heating effects - but detection of chemical / biological changes)
 - Serialization
 - Pedigree
- Contact Toni-Marie Pommet at MIT for participation
[tmpommet@mit.edu]

CURRENT ACTIVITIES IN HEALTHCARE

- Healthcare Research Initiative
- Further Research Activities:
 - Research issues are identified by Labs and Industrial Partners and undertaken within an evaluation environment
 - Hospital workflow analysis
 - Cost-effective RFID configuration
 - Return on investment (ROI)
 - Frequency
 - Safety
 - Performance / Technology
 - Integration with HIS / PACS / CPOE
 - Standards
 - Pilots
- For hospital related issues, please contact
[I. Mun, Ph.D](#)
[Director of Hospital Research](#)
ikm1@mit.edu

CURRENT ACTIVITIES IN HEALTHCARE

- Auto-ID Labs have set up an Anti-Counterfeit Special Interest Group
- Mission:
 - To develop practical concepts geared to combating counterfeiting, theft and illicit imports, using RFID technology.
- Research topics include:
 - Quantification of the impact of counterfeits on goodwill / brand name
 - Impact of a counterfeit solution on business processes
 - Low-cost tags with security features
 - Database access rights in a non-predetermined supply chain
 - Heuristics to transform the product history in a counterfeit test
 - Analyze attack scenarios of a track & trace infrastructure
- Contact Thorsten Staake at the Swiss Auto-ID Lab for participation
[thorsten.staake@unisg.ch]
- <http://www.autoidlabs.ch/sigac>

FURTHER INFORMATION



- www.epcglobalinc.org
- www.e-centre.org.uk



- www.autoidlabs.org