



Pedigree Update: RFID and Diversion

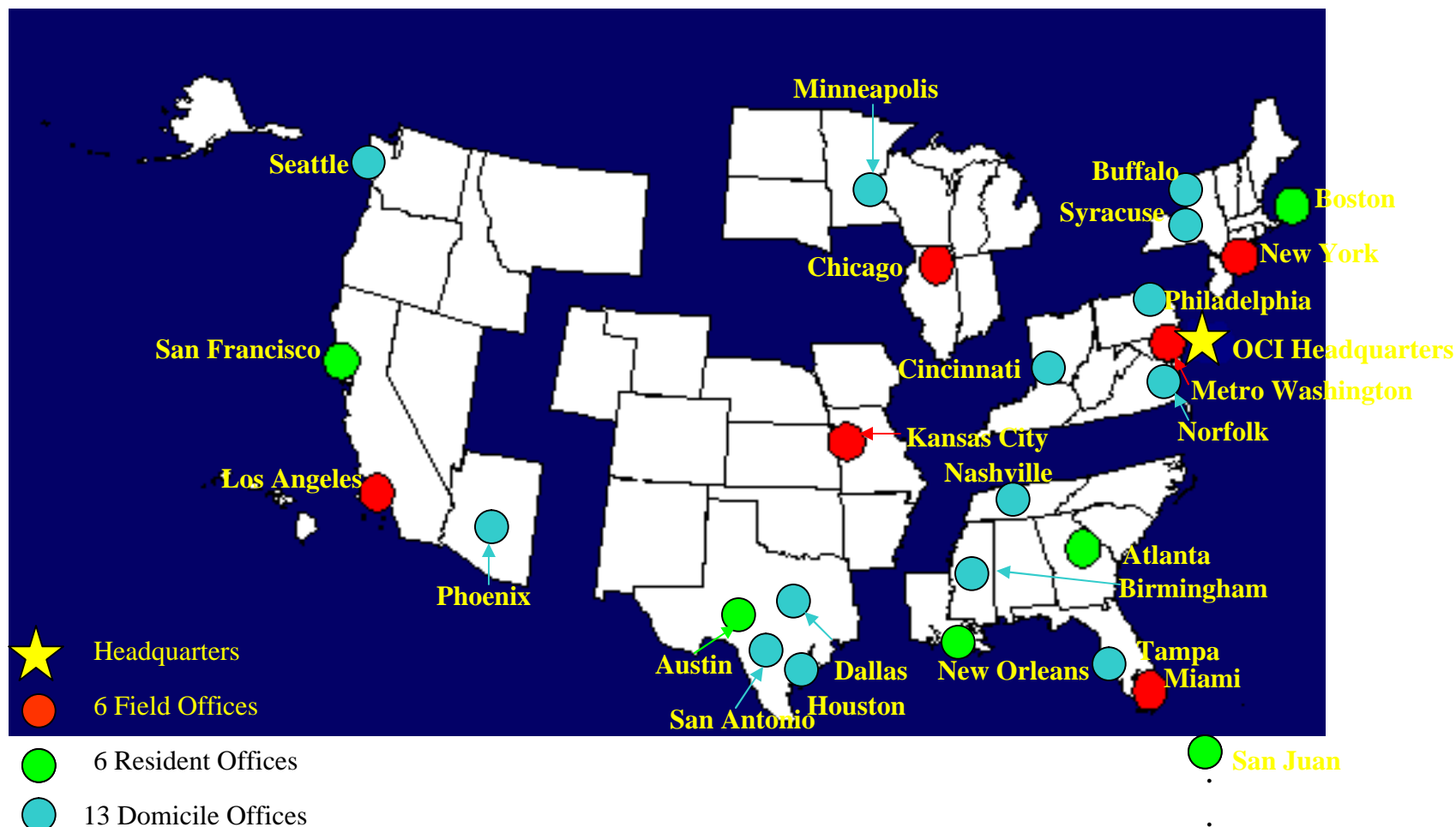
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Overview

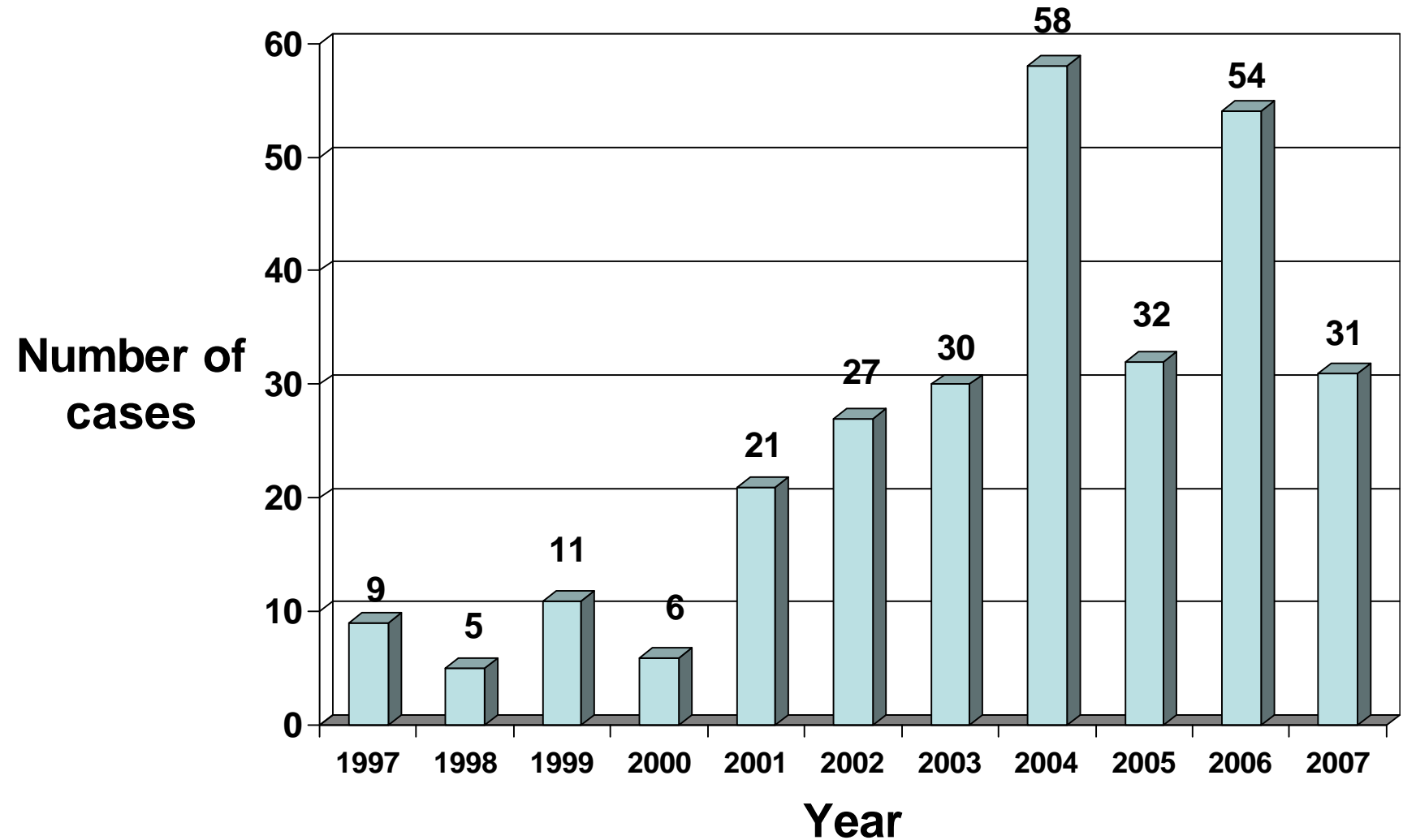
- **Background**
 - Counterfeiting/Diversion
- **Technology approaches for secure supply chain**
 - RFID
 - Others
- **Status: Track&Trace and E-pedigree**
 - Standards Development
 - GS1/EPCglobal
 - FDA

FDA/Office of Criminal Investigation Field and Resident Offices





Counterfeit drug cases opened by FDA's Office of Criminal Investigations per fiscal year





Counterfeit Stats – FY2007

- **OCI opened 39 investigations re: counterfeit FDA regulated products (31 for drug products)**
- **71 arrests**
- **50 convictions**
- **>\$ 26,500,000 in fines and restitution for counterfeit drug investigations**

Framework– U.S. Action Plan

“Anti-counterfeiting strategy must be a multi-layered approach”

- **Secure:**
 - *product and packaging*
 - *movement of drugs* through the supply chain
 - *business transactions*
- **Ensure appropriate regulatory oversight and enforcement**
- **Increase penalties**
- **Heighten vigilance and awareness**
- **International collaboration**

Legal Framework

- **Federal**

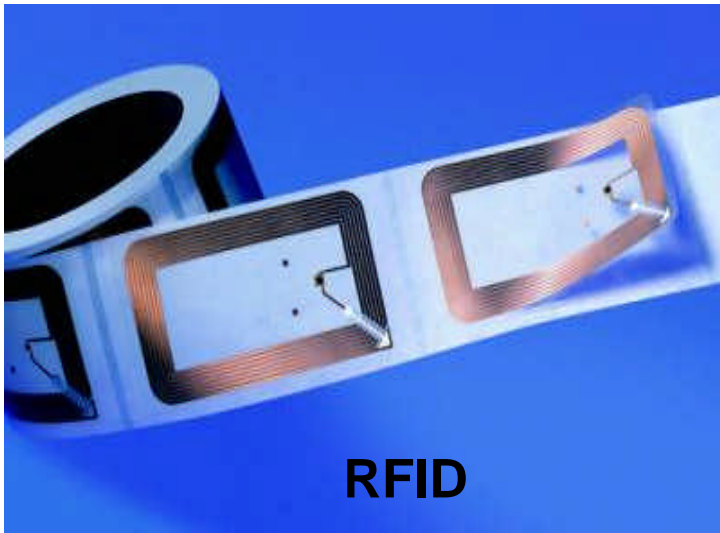
- Prescription Drug Marketing Act
 - Pedigree requirements in effect
 - Limited by preliminary injunction – appeal pending
 - Common carriers
 - 21 CFR 201.3 (h) **Distribute means** to sell, offer to sell, deliver, or offer to deliver a drug to a recipient, except that the term "distribute" **does not** include:
 - » (1) Delivering or offering to deliver a drug by a **common carrier** in the usual course of business as a common carrier
 - 21 CFR 201.30 Sample distribution by mail or common carrier
- Food and Drug Administration Amendments Act of 2007 (FDAAA)
 - Section 913 – Supply Chain Security

- **States**

Technology Based Approach

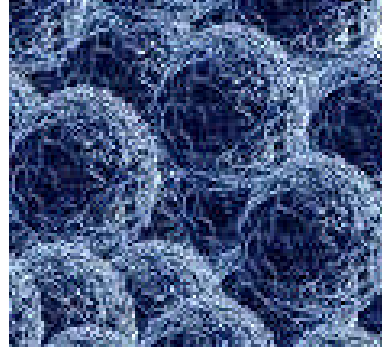
Secure product, packaging, and movement

- **FDA goal: electronic pedigree**
 - Universal: From manufacturer to the pharmacy
 - Uniform: Same pedigree across US
- **Track and trace**
 - Develop and implement infrastructure to enable e-pedigree
 - Mass serialization – for every product....essential
 - Data carrier: eg, RFID, 2D barcode
- **Authentication**



RFID

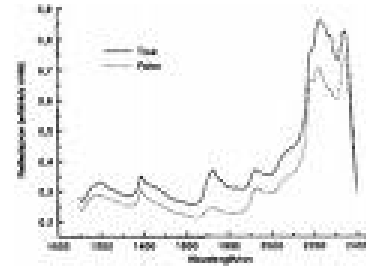
Nanotechnology



Encryption



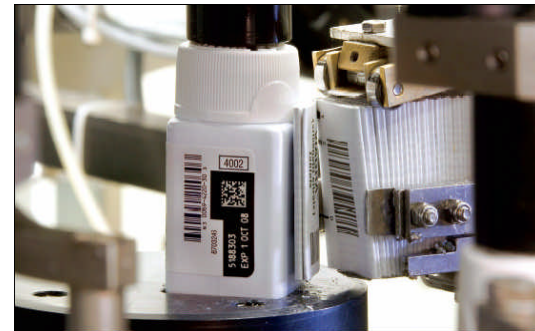
Holograms



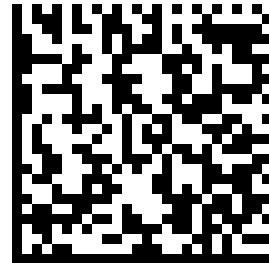
Taggant



Color-shifting ink



Bar codes



What is RFID?

- **Radio-frequency identification**
- **“Tag” composed of**
 - Silicon microchip
 - Antenna
- **Each tag contains a unique serial number**
- **As the tag is “read” by wireless technology, information about the product, its location, and the serialized number is transmitted to a database**



RFID implementation efforts: *Status Snapshot*

- **Progress toward implementation**
 - Few products on the market with tags
 - Pilot programs
 - cross-supply chain
 - individual companies
- **FDA compliance policy guide- 400.210**
 - Drug products (not biologics)
 - Enforcement discretion
 - Call for data on impact of RF on drug product
- **Standards under development –**
 - GS1/EPCglobal
 - FDA
 - Others
- **Product quality testing**
 - Little data submitted



FDA RFID Compliance Policy Guide 400.210

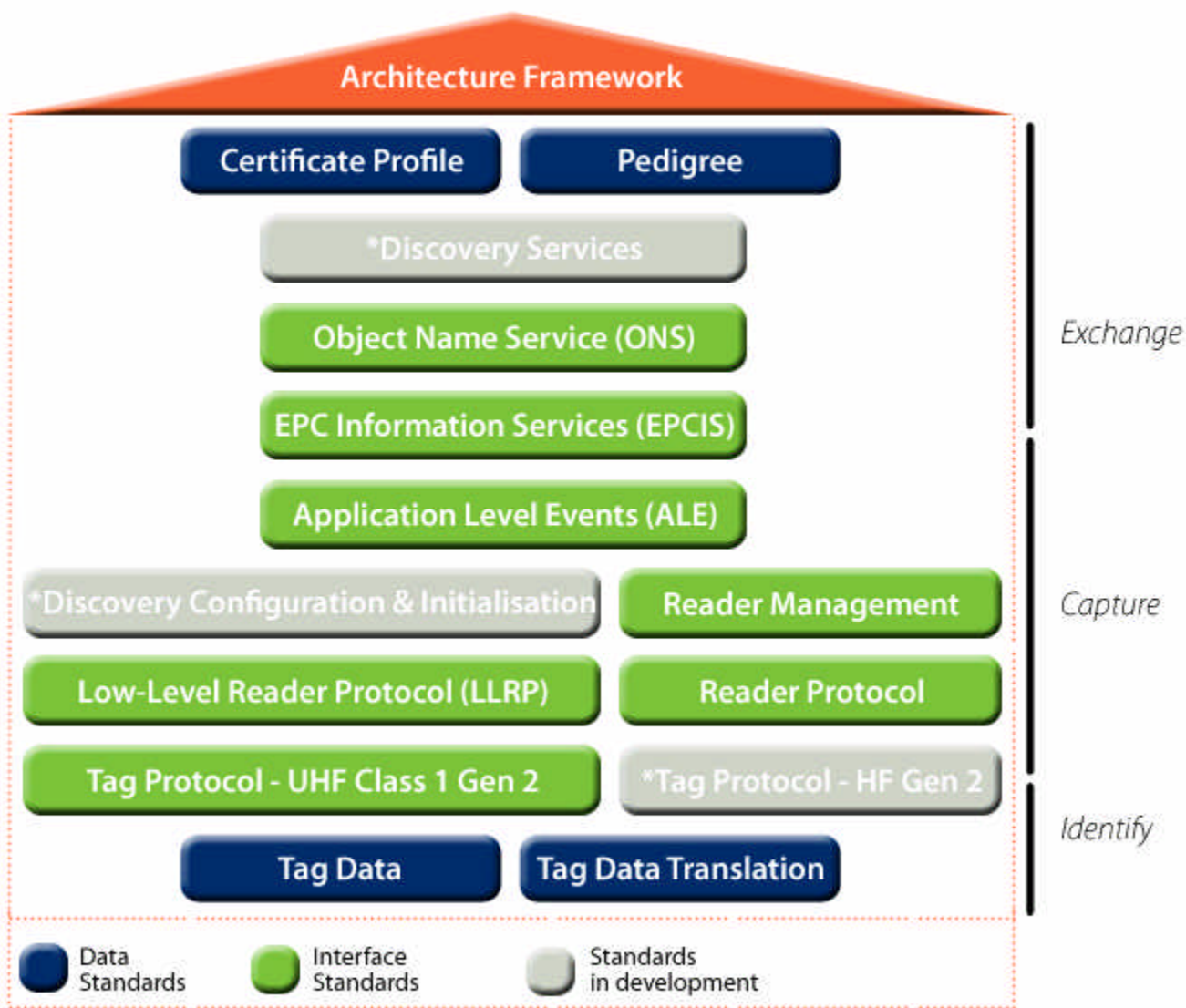
- **RFID tags for drugs (excludes biologics)**
- **Enforcement Discretion:**
 - Any RFID-triggered requirements of 21 C.F.R. & 314.70 and section 506A of the Act. (reporting)
 - Any RFID-triggered submission requirements under 21 C.F.R. part 314 and section 505 of the Act, except for field alert report requirements.
 - Any RFID-triggered requirements of 21 C.F.R. part 11 (electronic records)
 - Any RFID-triggered requirements of 21 C.F.R. parts 210 and 211 and section 501(a)(2)(B) of the Act (current Good Manufacturing Practices). (CGMP)
 - Any RFID-triggered requirements of 21 C.F.R. part 207 and section 510 of the Act (registration and listing).
- **Expires 12/31/08**

Standards

- ↳ Standards Development Process
- ↳ Standards
- ↳ Specifications

EPCglobal Standards Overview

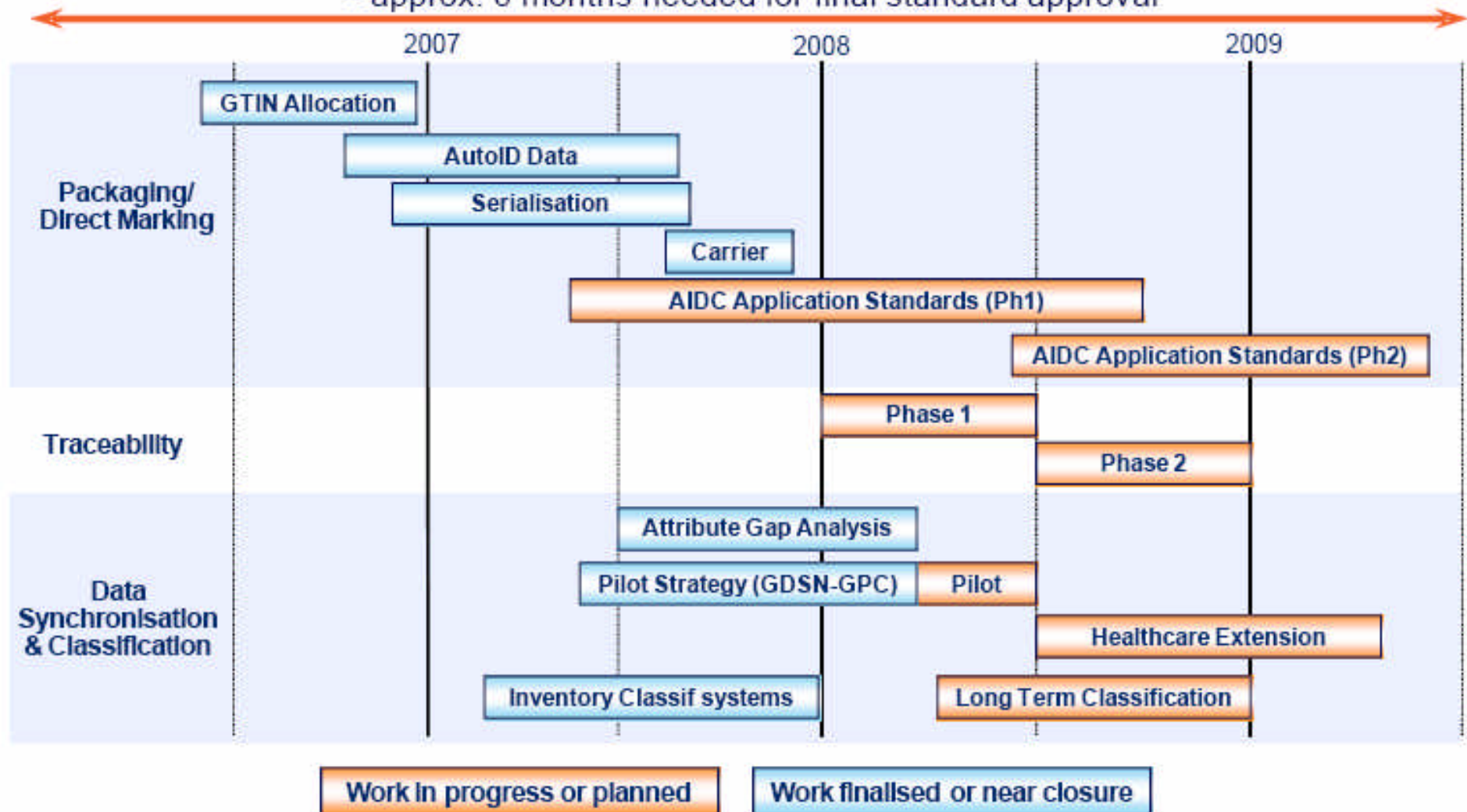
Click the graphic buttons below to access the standard & supporting documents



[Tag Classification Definitions](#)

GS1 Healthcare Roadmap towards Global Standards

Schedule for deliverables to the GS1 Global Standards Management Process
 – approx. 6 months needed for final standard approval




FDA Standards- Supply Chain Security

505D(a) – In general

- **The Secretary shall develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, and expired drugs.**

FDA Standards Development – Supply Chain Security 505D(b)(1) - General

- **Secretary shall prioritize and develop standards for**
 - Identification
 - Validation
 - Authentication
 - Tracking and Tracing
- 

Rx drugs
- **In consultation with**
 - Manufacturers, distributors, pharmacies, and other supply chain stakeholders. The consultation must include DOJ, DHS, Commerce, and other appropriate Federal and State agencies under 505(b)(4).



FDA Standards Development- Supply Chain Security

505D(b)(2) – Standard numerical identifier

- **The Secretary shall develop a *standardized numerical identifier***
- **Harmonize with international consensus standards, to the extent practical**
- **To be applied to Rx drug at point of manufacturing and repackaging**
- **Pallet or package level**
- **No later than 30 months after enactment (March 2010)**



FDA Standards Development- Supply Chain Security

505D(b)(3) – Promising Technologies

- **Standards shall address promising technologies, which may include**
 - RFID
 - Nanotechnology
 - Encryption technologies
 - Other track and trace and authentication technologies

FDA Standards Development

COMMENTS DUE TODAY!!!

- **Standards Development Federal Register Notice**

<http://www.fda.gov/OHRMS/DOCKETS/98fr/E8-5597.pdf>

- What standards are currently adopted/established/need to be developed
- What standards are currently under development
- What standards are planned for the future
- What specific issues need to be resolved, by FDA or others, in order to further the standard development
- Other issues
- Projected timelines for standards development

- **Technology Federal Register Notice:**

<http://www.fda.gov/OHRMS/DOCKETS/98fr/E8-5599.pdf>

- Available technologies
- Emerging technologies
- Cost of using specific technologies
- Standards necessary for use of specific technologies

FDA Standards – Supply Chain Security Inspection and Enforcement

505D(c)

- **Secretary shall expand and enhance resources and facilities of FDA that are involved in regulatory and criminal enforcement of the FDCA to secure the drug supply chain**
- **Undertake enhanced and joint enforcement activities with other Federal and State agencies and establish “regional capacities” for validation of Rx drugs and inspection of Rx drug supply chain**

RFID/Pedigree

- **Common carrier issues:**
 - RFID
 - Read distance
 - Serialized number – disclose contents?
 - Pedigree
 - Included?
 - Capacity?
- **Timing for standards/implementation**
 - ??????



SUMMARY

Comments or Questions??

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