



# **RFID implementation in the pharmaceutical supply chain**

Peter Schmallegger

NXP Semiconductors / BLID – MST RFID

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## From China to Panama, a Trail of Poisoned Medicine

By [WALT BOGDANICH](#) and [JAKE HOOKER](#)

[Panama](#) is the most recent victim. Last year, government officials there unwittingly mixed diethylene glycol into 260,000 bottles of cold medicine — with devastating results. Families have reported 365 deaths from the poison, 100 of which have been confirmed so far. With

Panama's death toll leads directly to Chinese companies that made and exported the poison as 99.5 percent pure glycerin.

Barcelona, Spain, and Beijing, to its beginning near the Yangtze Delta in a place local people call “chemical country.”



# The Counterfeit Problem

- ▶ WHO estimates put counterfeits at more than **10% of the global medicines market**, [1].
- ▶ The CMPI (Centre for Medicines in the Public Interest) in the U.S., predicts that **counterfeit drug sales** will reach **USD 75 billion** globally in **2010**, an **increase of more than 90%** from 2005, [1].
- ▶ An estimated **25% of the medicines** consumed in **developing countries** are believed to be counterfeit. In **some countries**, the figure is thought to be as high as **50%**, [1].

Source: [1] WHO; Counterfeit medicines; February 2006



# The Counterfeit Problem

- ▶ A study conducted in WHO's South-East Asia Region revealed that **38% of 104 anti-malarial drugs on sale in pharmacies in 2001 did not contain any active ingredients**, [1].
- ▶ The Dutch Healthcare Inspectorate warned consumers in early 2006 not to buy Tamiflu through the Internet, after counterfeit capsules were found in the NL containing no active substance. In UK counterfeit Tamiflu, worth £500 000 was found, [1].
- ▶ During a meningitis epidemic in Niger in 1995, more than 50 000 people inoculated with fake vaccines. **The error resulted in 2500 deaths**, [1].
- ▶ In China a counterfeit drug smuggling ring was recently broken up that involved almost a half-million fake pills including LIPITOR and all free major erectile dysfunction drugs ( CIALIS, LEVITRA, and VIAGRA), [2].

Source: [1] WHO; Counterfeit medicines; February 2006

[2] Global identification; May 2006



# Counterfeit Example LIPITOR, SEROSTIN



- ▶ The counterfeit Lipitor tablets on the left are nearly identical from the authentic tablets on the right. Only distinguishable to the consumer by their bitter taste, the counterfeit tablets were among more than 18 million counterfeit Lipitor tablets removed from the U.S. supply chain in 2003, [4].



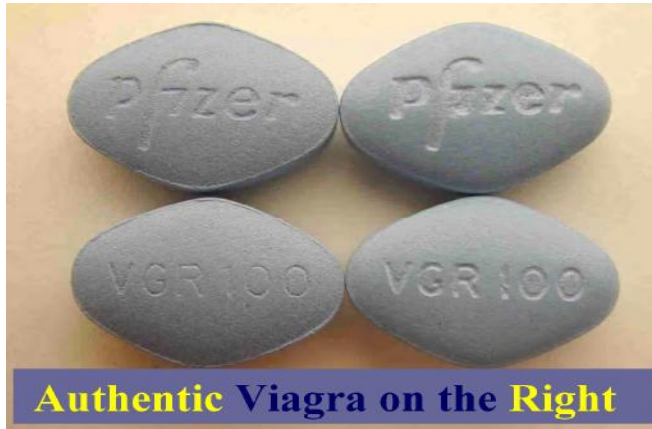
- ▶ Comparison of an authentic Serostin and a counterfeited one, [5].

Source:

[4] US Congress Rogers

[5] FDA: Counterfeit Drug Photographs

# Counterfeit Example VIAGRA



- ▶ Comparison of an authentic Viagra (on the right) and a counterfeited Viagra.



- ▶ This is a Viagra counterfeiting site in Egypt. Counterfeit tablets were being given their blue coloring using an old cement mixer. Clearly, the manufacturing conditions were far from sterile, [5].

Source: [5] FDA: Counterfeit Drug Photographs

# US FDA Task Force

## ▶ Multi-Layer Approach

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

## ▶ Measures

- Widespread use of electronic track and trace technology would help secure the integrity of the drug supply chain by providing an accurate drug “pedigree,” which is a record of the chain of custody of the product as it moves through the supply chain from manufacturer to pharmacy;
- RFID is a promising technology as a means to achieve electronic pedigree (e-pedigree);
- Widespread adoption and use of electronic track and trace technology would be feasible by 2007; and
- The effective date of certain regulations related to the implementation of the PDMA should be delayed until December 1, 2006 in order to give stakeholders in the drug supply chain time to focus on implementing widespread use of e-pedigree.

Source: US FDA Memorandum, June 8<sup>th</sup> 2006



# Value Proposition of RFID in Pharma

## ▶ Patient Safety

- Counterfeit protection
- Efficient technology for pedigree and regulative compliance
- Brand reputation and protection from law suites

## ▶ Supply Chain Efficiency

- Reduced inventory cost and out-of-stock revenue loss
- Improved replenishment cycle and reverse logistics
- Enhanced clinical trials and compliance monitoring

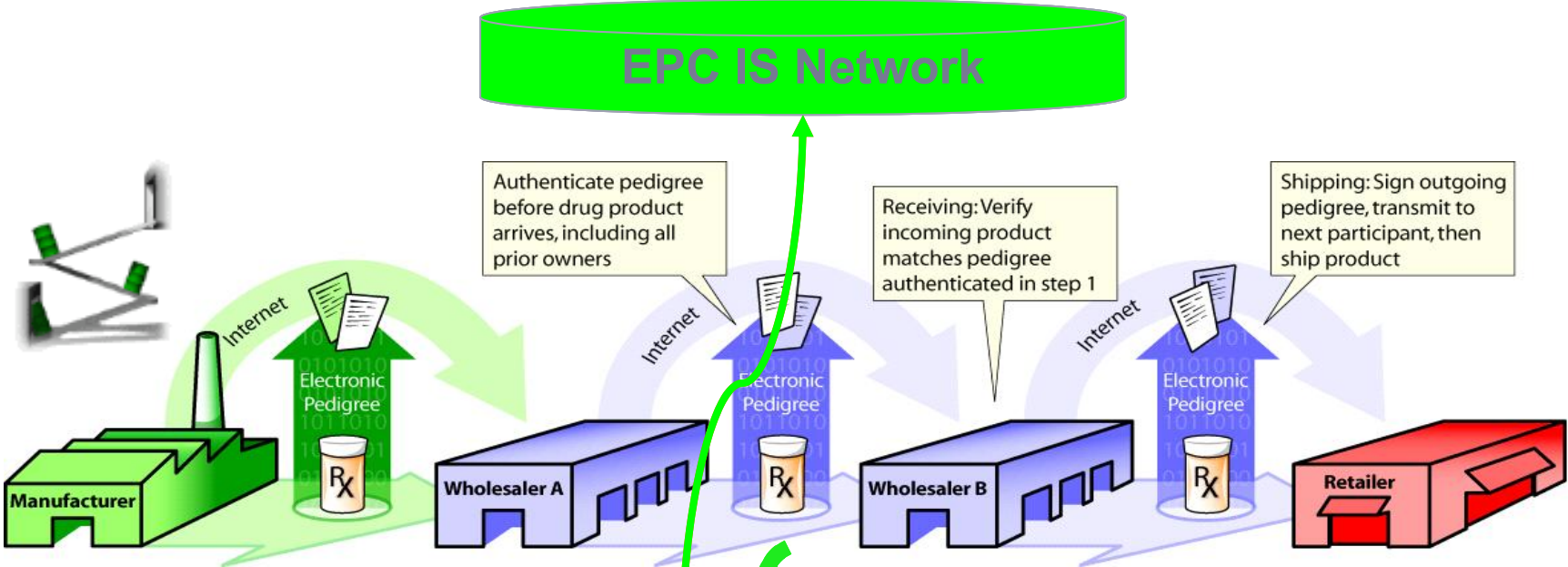
## ▶ New Business Opportunities

- Service to authenticate drugs
- Accessibility and delivery of information on pharmaceutical products
- Support of medication convenience and compliance

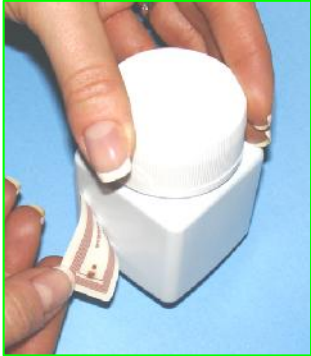




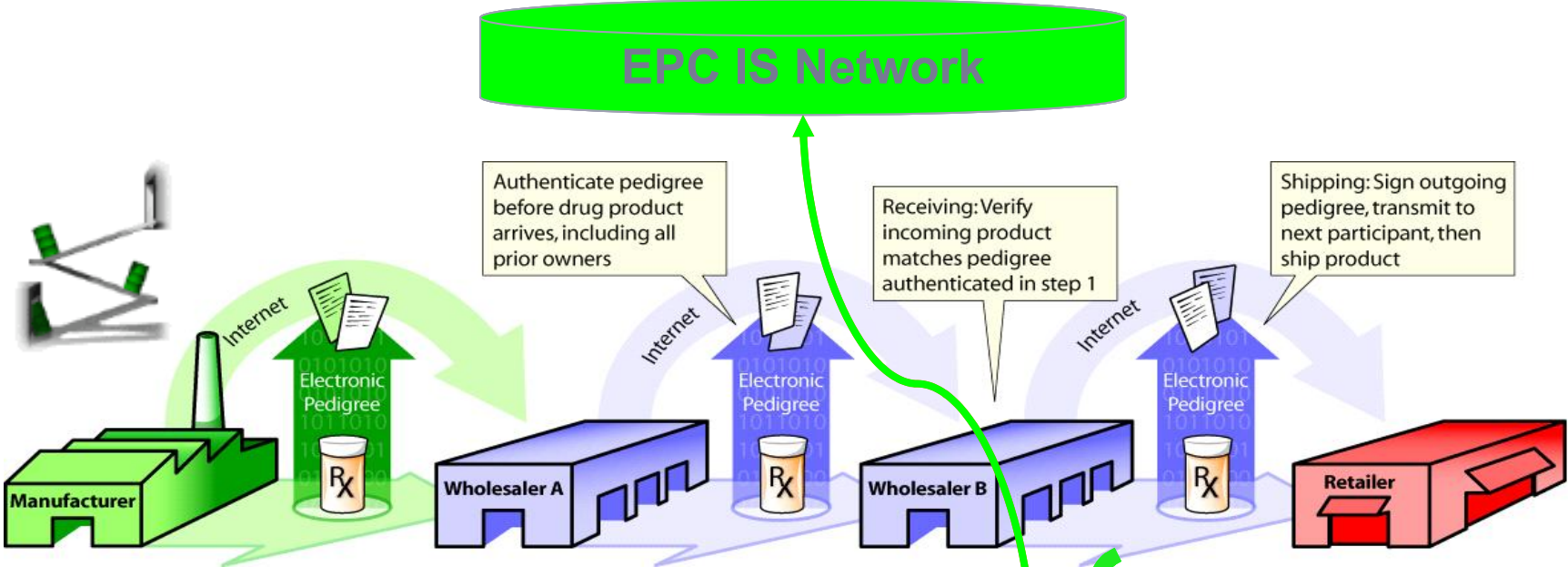
# e-Pedigree - Securing the Pharmaceutical Supply Chain



e-Pedigree  
PharmaDrug  
EPC serial #  
Manufacturer



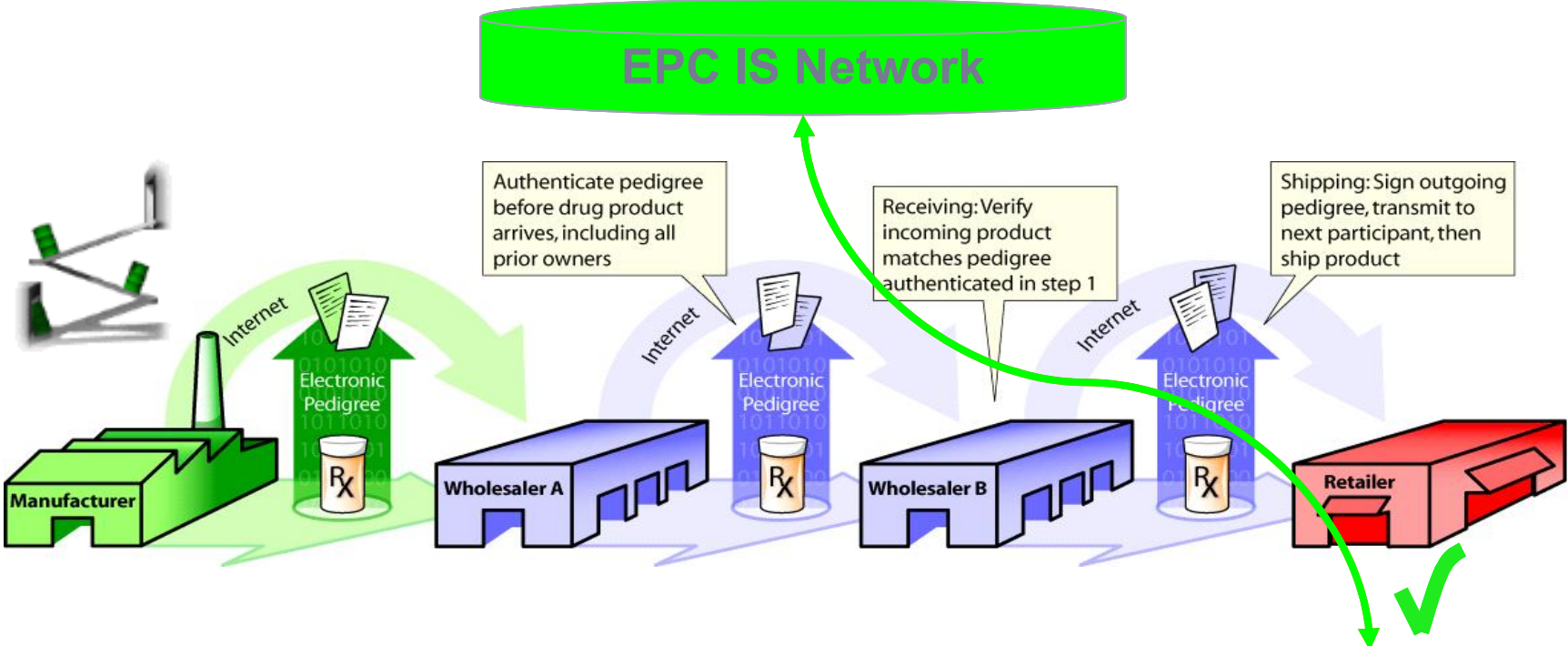
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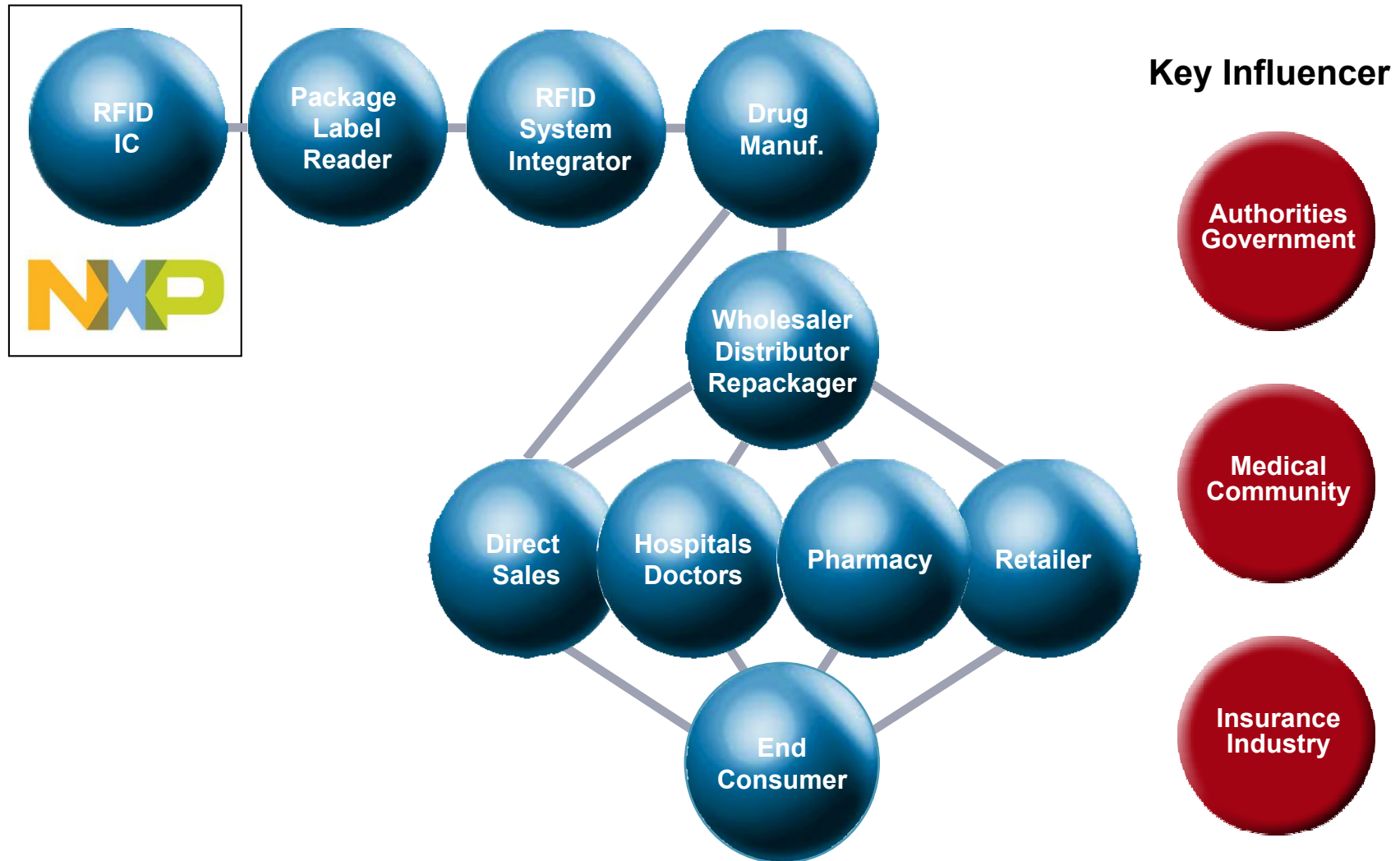
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# The RFID Pharmaceutical Eco-System

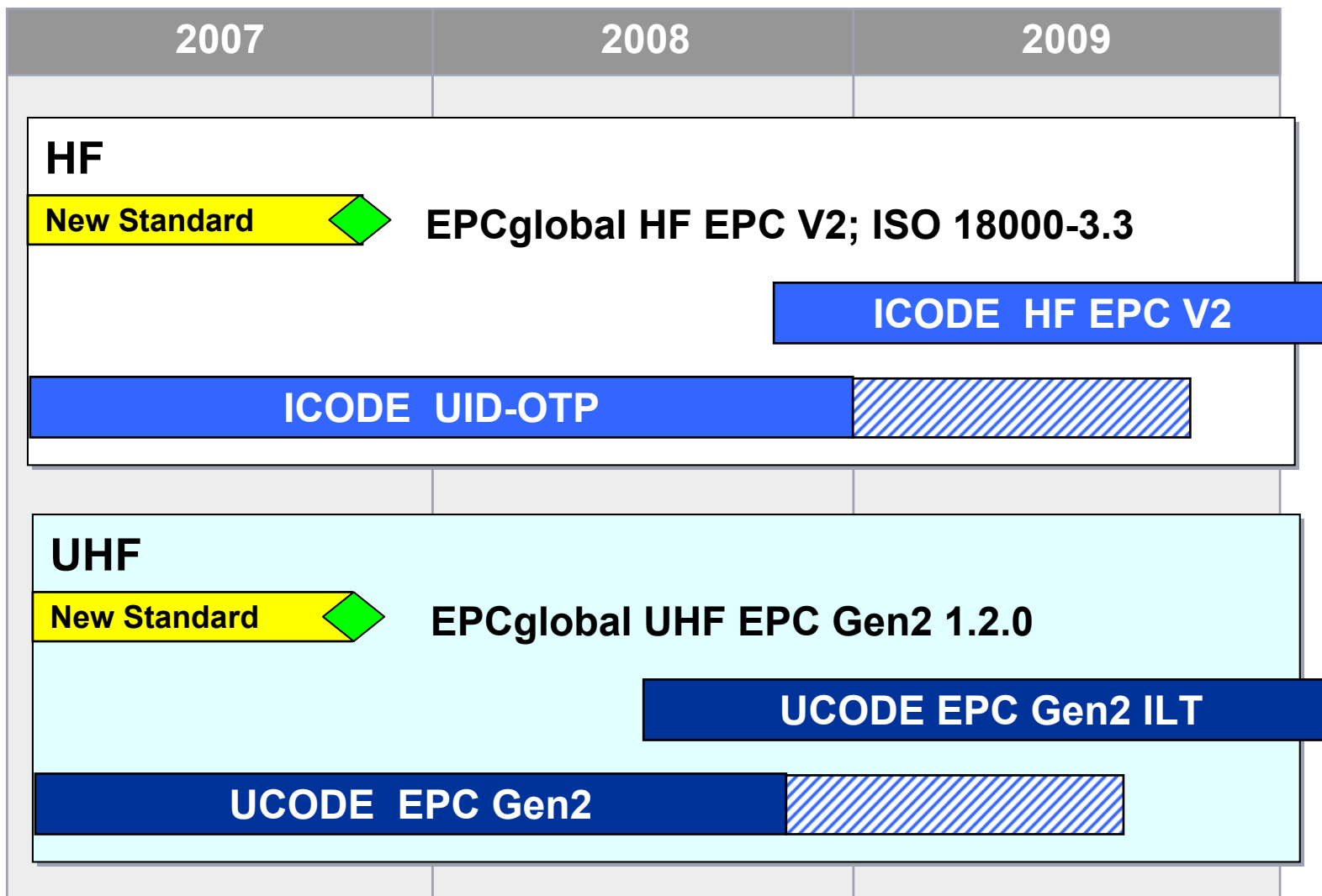


# RFID Technology

- ▶ HF is the technology of choice of leading pharmaceutical manufacturer and most widely used in pilots and roll-outs today
  - *experience in combination with liquid drugs*
  - *global harmonized regulations and standards*
  - *proven and reliable technology*
  - *total solutions available*
- ▶ UHF is also used by pharmaceutical manufacturer



# Technology Roadmap



# Conclusions

- ▶ Drug counterfeiting is a **serious and global problem**, that requires a joint effort of involved stakeholders; industry and authorities. It poses a threat to the **integrity of our health care system**.
- ▶ RFID is considered as **the most promising technology** for pharmaceutical counterfeit protection and e-pedigree.
- ▶ Leading drug manufacturer **started with the implementation and roll-out** of RFID for counterfeit protection and supply chain efficiency
- ▶ The introduction of RFID requires **technology implementation and organizational development** - processes and workflows.
- ▶ **RFID total solutions for pharma are proven and available** - and technological advancement and cost reduction will further continue.
- ▶ For pharmaceutical manufacturer and the distribution industry **the path to leading edge starts today.**



