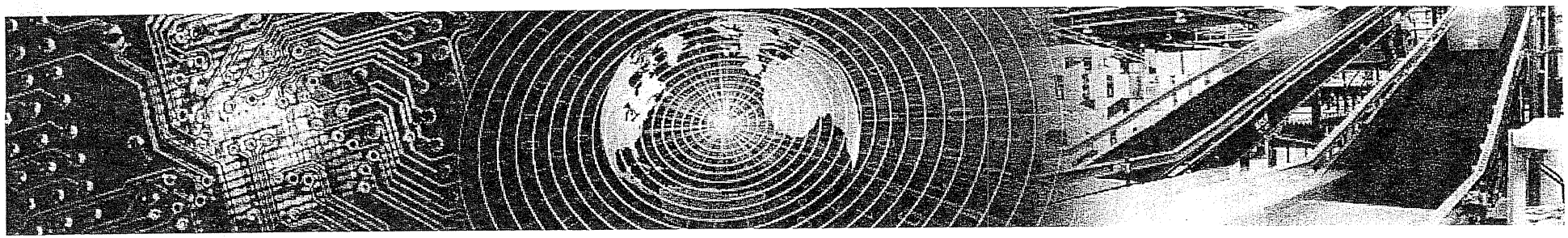

EPCglobal Update

State of Pedigree and EPC/RFID Standards

California Board of Pharmacy

April 18, 2007

Mike Rose, Tri-Chair, EPCglobal HLS IAG
Ron Bone, Tri-Chair, EPCglobal HLS IAG

Bob Celeste, EPCglobal North America

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Overview

- State of the Standards
- Brief Pedigree Overview
  - Structure
  - Business Scenarios
- Pedigree Review Follow-Up Items

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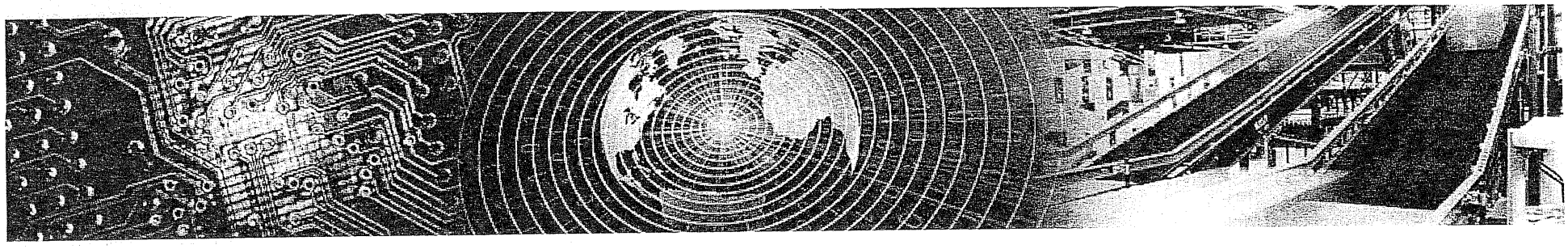

EPCglobal Healthcare Standards

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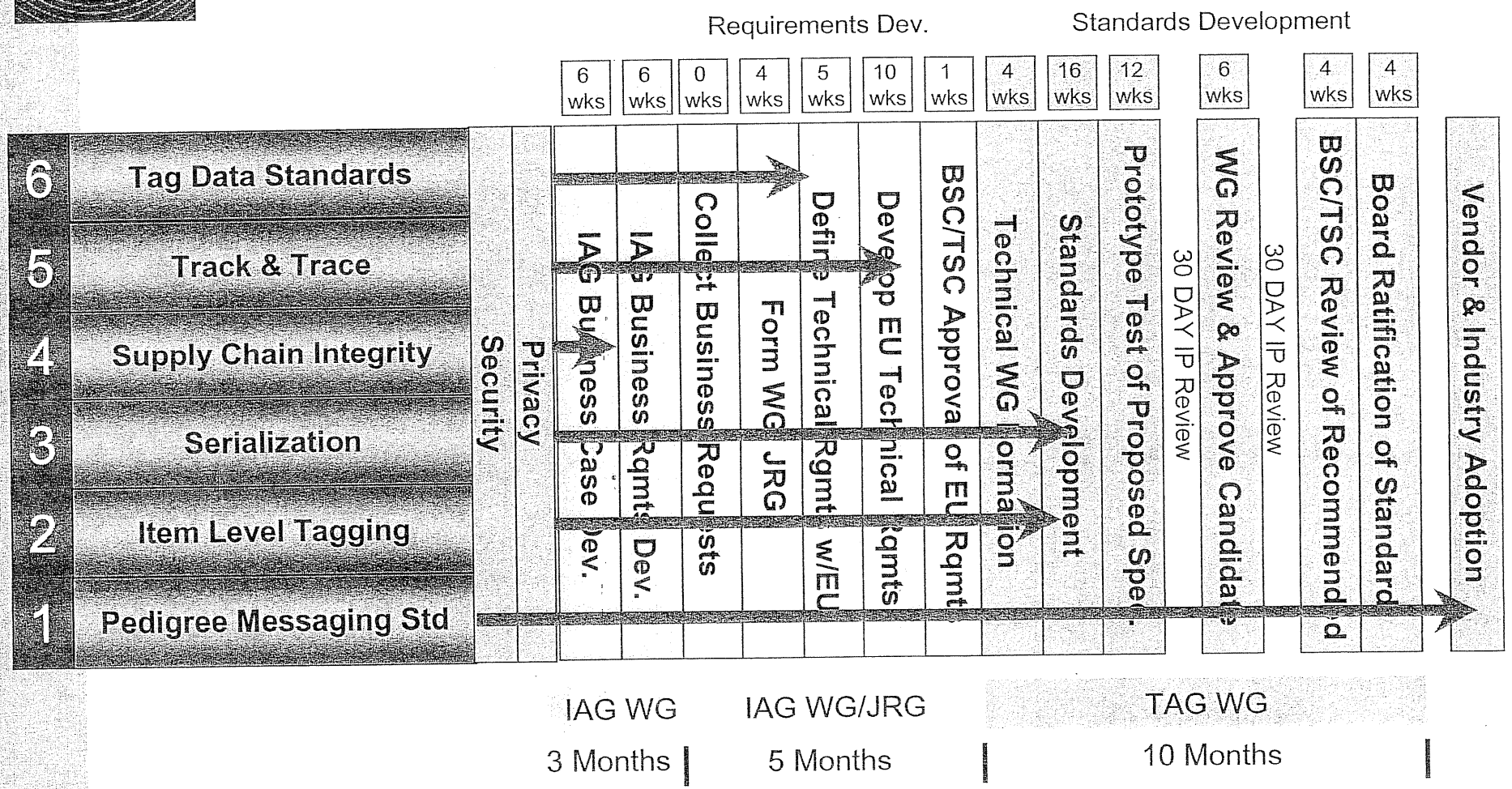
Standards Update



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Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define a standard format for a Pedigree Messaging standard that will meet all current Federal and State Pedigree requirements.

Status:

- All Standards work complete.
- **Ratified standard – 01/2007**
- Certification Program underway

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Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements for tagging pharmaceuticals at the item level. Include requirements for manufacturing lines, distribution environments, transportation and Retail environment.

Status:

- Requirements complete. Resulted in a High Frequency technical working group to define the standard.
- HF & UHF initiatives underway to provide uniform air interface protocol at item level.
- HF Standard expected '07.

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Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements for the EPC identifier to be encoded on an RFID tag.

Status:

- Requirements complete. Identified 2 GS1 identifiers [Global Trade Item Number (GTIN) and Serialized Shipping Container Number (SSCC)] to be used.
- Collaborating with GS1/HUG via the "Global Healthcare Initiative" -- starting with Serialization.
  - Joint HUG/HLS Work Team

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Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements and/or guidelines for authenticating and decommissioning tags consistent with optimizing tag utility and consumer/patient privacy.

Status:

- Work Group has been approved and will start in March 2007
- US Drug Enforcement Agency interest in this capability is extremely high
- Solutions expected to span a mix of hardware, software and process responses
- Potential for this work to expand cross-industry

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Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define supply chain use cases, processes and information needs for sharing EPC related data for forward and reverse logistics.

Status:

- Forward & Reverse Logistics (Returns) processes and data exchanges completed
- Common vocabularies and location identifiers drafted
- Additional use cases to be addressed:
  - 3rd Party Logistics Providers & Repackers
  - Product Recall
- Data Sharing Strategy & Guidelines are currently being addressed
- Pedigree-on-Demand concepts being Investigated
- Integrate with GS1 Traceability efforts
- **Integrate with Pedigree Model**

Standards Update

6	Tag Data Standards
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define additional user memory requirements for tags (ie. Lot Number, Expiration Date).

Status: Work underway. Defining common data structure that can be used by all industries.

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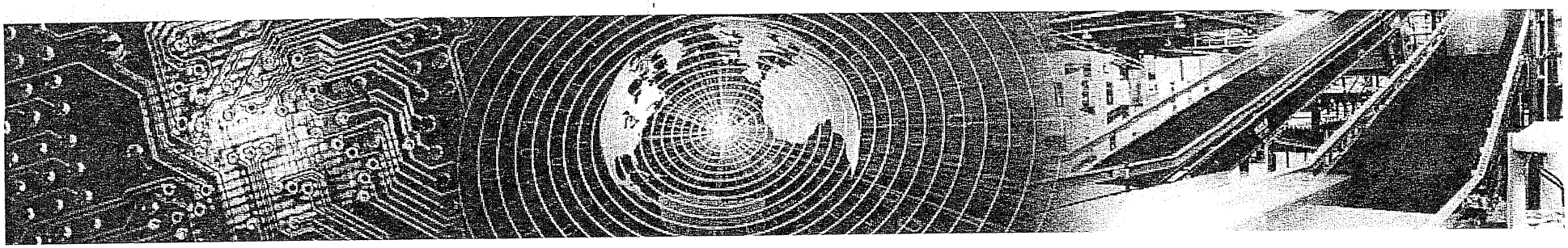

Pedigree Messaging Standard

Post-Ratification Activities

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Pedigree Messaging Standard

Post-Ratification Activities

Pedigree Standard
~~~~~
~~~~~

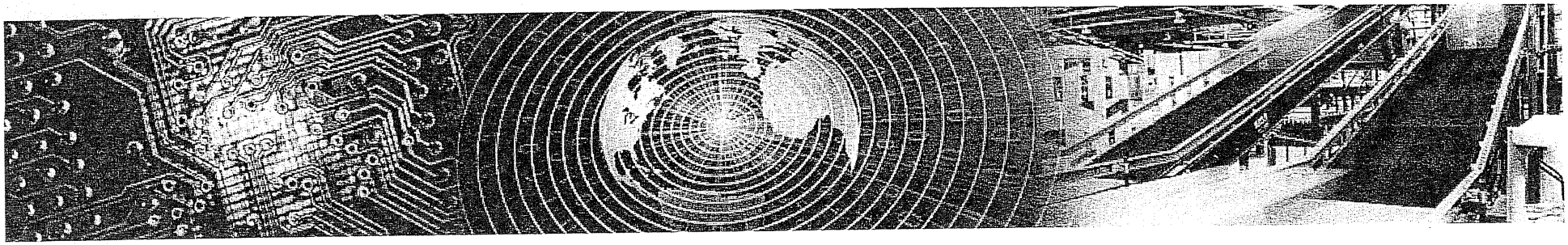
EPCglobal

Create Test Scripts → Create Test Platform → Create Test Guidelines → Test / Certify Pedigree Software → Pedigree Software ~~~~~ ~~~~~

Anticipated 6/15/2007

Industry

Capital Planning → Process Re-engineering → System Integration → Infrastructure Build-out → Scale up



Pedigree Overview

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Pedigree:
Participants

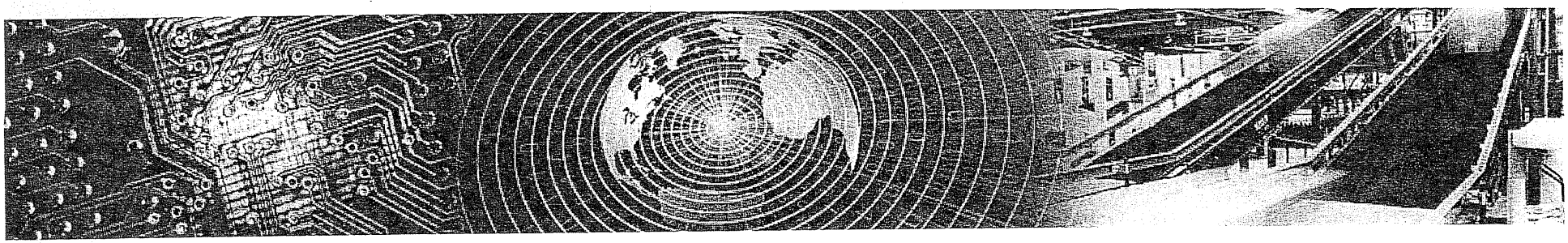
- Accenture
- Acsis
- Ahold USA
- Alcon Labs
- Amerisource Bergen Corp.
- Axway
- BEA Systems BMS
- Boeing
- Cardinal Health
- Cerfidia
- Cognizant Technology Solutions
- DHL, DHL Express
- Gedas Deutschland GmbH
- Glaxo Smith Kline
- GlobeRanger
- HDMA
- Hewlett Packard
- High Tech Aid
- ITRI
- Japan Telecom Co., Ltd.
- Johnson & Johnson,
- Mallinckrodt/Tyco Healthcare
- McKesson
- NCR
- NEC Corporation
- Novartis Pharmaceuticals Corp.
- P&G
- Philips Corporation
- Polaris Networks
- Raining Data Corporation
- rfXcel Corp.
- Savi Technology
- Stora Enso NBI
- SupplyScape
- ThingMagic Inc.
- TIBCO Software
- Track IT RFID Solutions
- Tyco Healthcare
- UPS SCS
- Unisys
- Verify Brand, Inc.
- VeriSign
- Walgreen Co
- Wipro

What is pedigree?

- A pedigree is a documented history of the chain of custody and/or the financial ownership of a prescription drug. Specific legislative requirements vary from state to state, but in general there are two types of information contained on the pedigree:
  - Static information about the drug - name, dosage strength, expiration date, lot #, etc.
  - The previous history of the drug - business name, date of transaction, receiving person, etc.

- Pedigree legislation implies that distributors and retailers will be required to maintain an association between the pedigree document and the physical product.

- **California Pedigree laws prohibits a DC or pharmacy from acquiring, selling, trading, or transferring a drug in that state without the accompanying pedigree. Failure to comply could result in administrative fines, revocation of license and/or criminal prosecution.**



Pedigree
Requirements & Data Structure

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Pedigree Format Requirements

- Support for one pedigree for each individual item
- Support for a collection of items sharing the same product information (same NDC, different Lots, same chain of custody) expressed on the same pedigree
- Pedigrees for both serialized and non-serialized items
- Representation of pedigrees in a portable format that can be transmitted electronically or via media
  - Exchange using existing business transfer mechanisms (e.g., EDI VAN, EDI INT AS2, FTP, SOAP, etc.)

Pedigree Creation Requirements

- **Pedigree initiated by manufacturer**
- **Pedigree initiated by wholesaler**
  - With transaction information for the first wholesale distribution
  - With authentication attachment to facilitate authentication by downstream trading partners (e.g., EDI ASN)
- **Pedigree initiated by repacker for a repackaged product**
- **Pedigree initiated by a subsequent trading partner**
  - From received pedigree for next sale, transfer, or return
  - From alternate representation of pedigree (e.g., scanned paper pedigree, PDF, X.12 documents, etc.)

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Pedigree Structure

- Pedigree format that contains the pedigree data elements
  - Product information, transaction information, recipient information, distributor information, and digital signatures
  - Item information to describe the specific non-serialized or serialized products in the transaction
- Pedigree envelope for sending collections of pedigrees to trading partners
  - Identifying information about the envelope (to, from, date, etc.)
  - Optional information about the relationship of pedigrees to items in cases to facilitate product-to-pedigree matching
  - Pedigrees for the products in the shipment

Core Pedigree Elements

Name	Description
DocumentInfo	Contains an identifier for the pedigree document.
ProductInfo	Detailed information about the product that is the subject of the pedigree, such as product name, strength, dosage form, etc.
ItemInfo	Identifies the physical item(s) associated with a pedigree by lot number, expiration date, quantity of units, and item serial numbers.
TransactionInfo	Information about a transaction in which ownership of the item passes from one supply chain partner to another, including information about the sender, recipient, business and alternate shipping addresses, transaction identifier and transaction date.
ReceivingInfo	Includes information about the receipt of items associated with a pedigree.
Signature	Expresses digital signature for shipping and receiving certifications. Includes information about the digital signature, algorithms used, properties of the certificate, properties of the certificate issuer, and the message digest.

Core Pedigree Elements

Name	Description
ShippedPedigree	Layer of a pedigree that represents an outbound pedigree transaction. This layer is signed before it is sent.
ReceivedPedigree	Layer of a pedigree that represents an inbound pedigree transaction.
InitialPedigree	Contains the initial pedigree product information. Can include transaction and attachment information if pedigree is initiated by wholesaler. This element is also used to represent the conversion of a pedigree in another form to this pedigree format, such as a scanned or alternate representation of a pedigree that represents the prior chain of custody for the product.
RepackagedPedigree	Contains the initial pedigree information for a repackaged product before the first outbound transaction. This includes the product information for the repackaged item and pedigree information about the source items used to create the repackaged items

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Review of Pedigree Standard
Features Supported

Feature	Required?	Support?
Item level serialization - Unique identification of each and every bottle of medication	No	Yes
Electronic Signatures - Ensures identity of Pedigree issuing company	Yes	Yes
RFID - Non Line of sight identification of Pallets, Cases or Items	No	Yes
Inference - Upon visual inspection, assuming content of containers (Pallets, Cases, Totes) based on Pedigree or Advanced Ship Notice (ASN)	No	Yes
Manufacturer initiated Pedigree - Manufacturer sends first pedigree to next participant in supply chain (as opposed to the first distributor)	No	Yes

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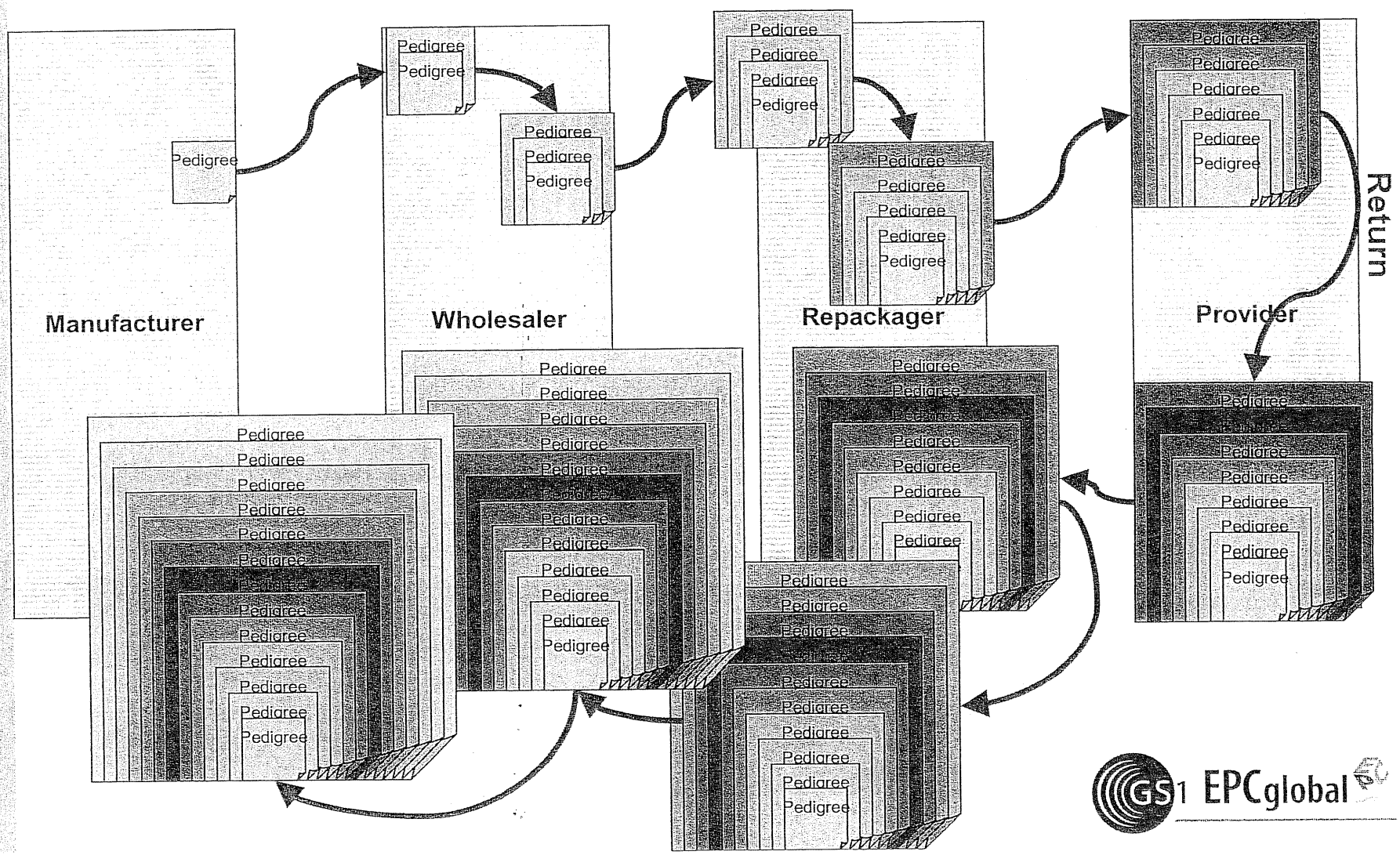
Document Based Pedigree

Passing the Pedigree through the supply chain



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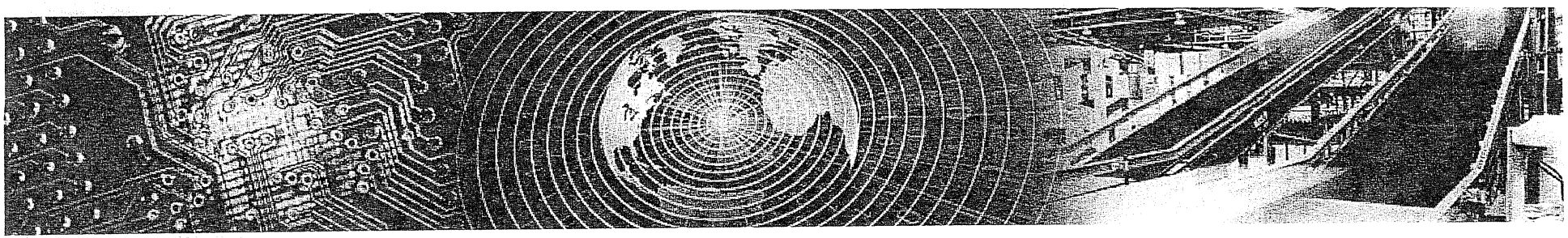

Electronic Pedigree Format

The basic components of a pedigree are shown in the following figure. The components in an actual pedigree depend on the specific business situation in which it is used (e.g., pedigree initiated by manufacturer, pedigree initiated by wholesaler, pedigree for repackaged item, etc.).

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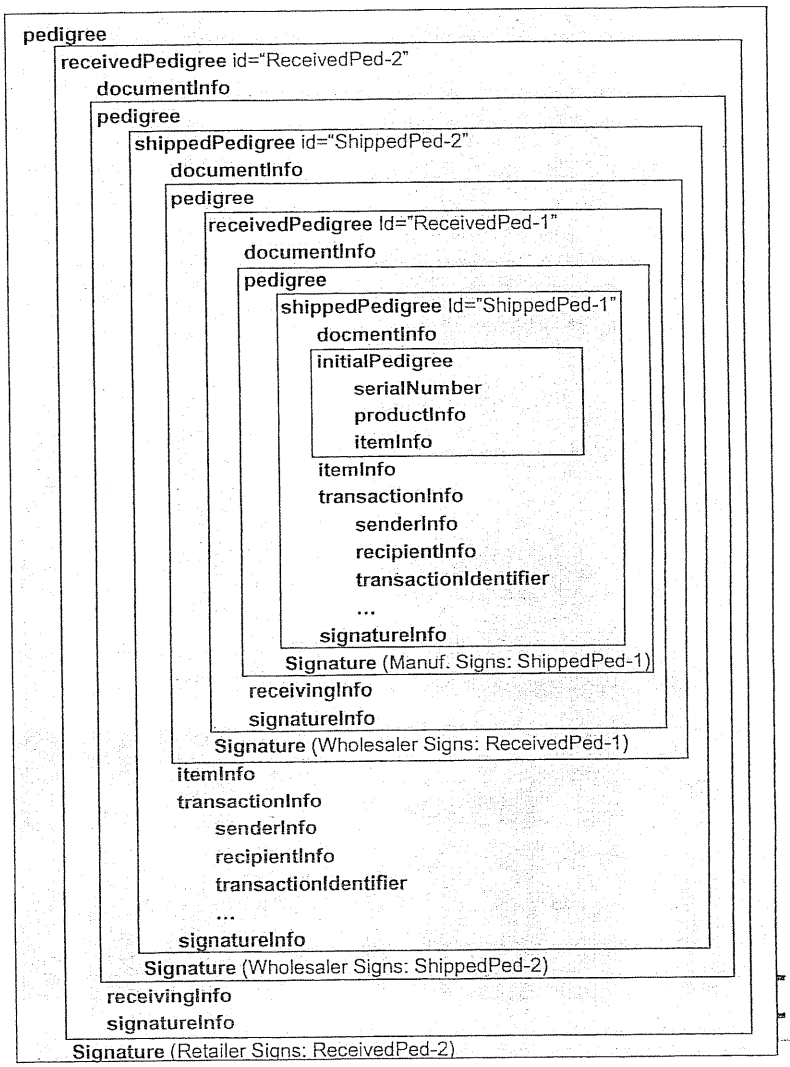
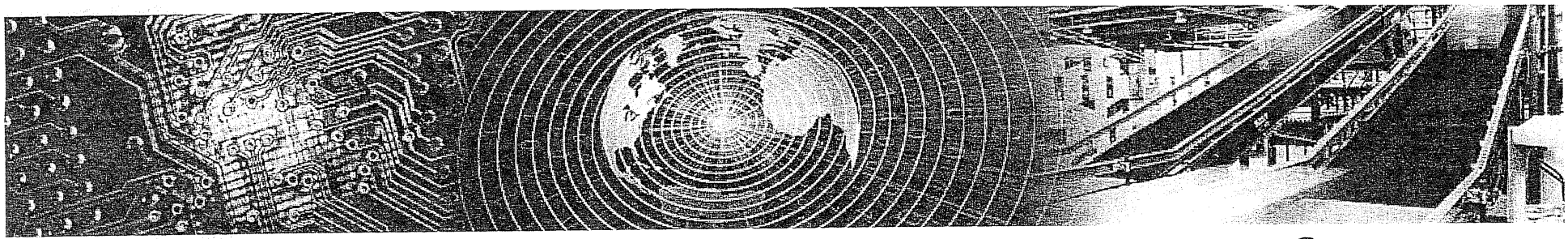
Electronic Pedigree Format





Forms for Pedigree Components for Specific Business Situations (non-normative)

A pedigree and data components within the pedigree may take one of several forms depending on the context of how the pedigree was created or received (e.g., manufacturer initiated pedigree, wholesaler initiated pedigree, pedigree for repackaged item, conversion of alternate pedigree, etc.). The table below provides a non exhaustive list of use cases and the corresponding form a pedigree component may take for each of these use cases.

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Sample Pedigree Forms

Signed manufacturer pedigree

(initiated by manufacturer, after the wholesale distribution, signed by both manufacturer and wholesaler)

pedigree
- **receivedPedigree** Id="ReceivedPed-1"
  - **documentInfo**
    - **serialNumber**
    - **version**
  - **pedigree**
    - **shippedPedigree** Id="ShippedPed-1"
      - **docmentInfo**
        - **serialNumber**
        - **version**
      - **initialPedigree**
        - **serialNumber**
        - **productInfo**
        - **itemInfo**
      - **itemInfo**
      - **transactionInfo**
        - **senderInfo**
        - **recipientInfo**
        - **transactionIdentifier**
        - ...
      - **signatureInfo**
    - **Signature** (Manuf. Signs: ShippedPed-1)
  - **receivingInfo**
  - **signatureInfo**
- **Signature** (Wholesaler Signs: ReceivedPed-1)

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Sample Pedigree F

Pedigree with return transaction

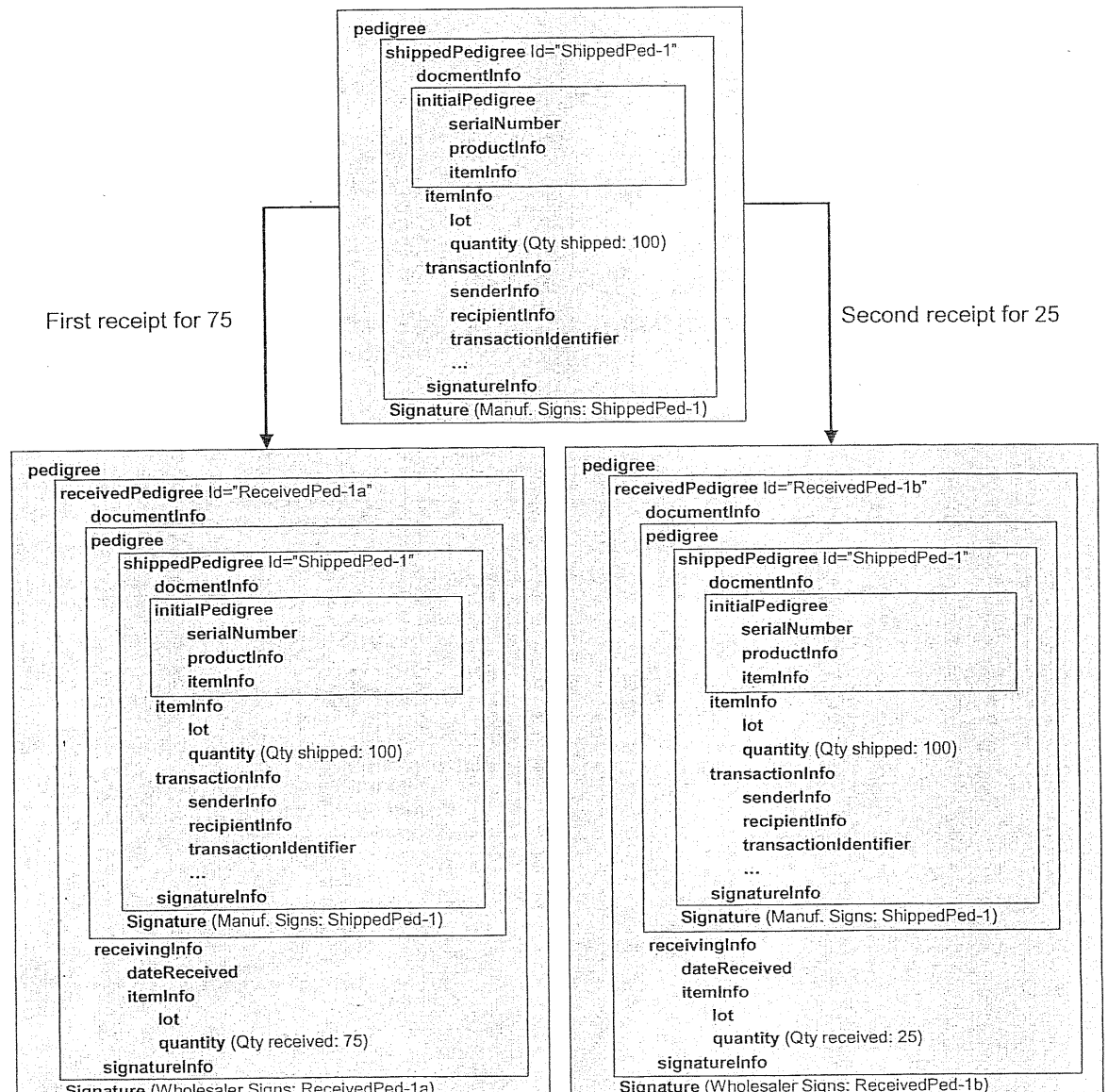
(initiated by manufacturer, received and signed inbound by wholesaler, return transaction applied by wholesaler for manufacturer return and signed outbound, received and signed inbound by manufacturer)

- **pedigree**
  - **receivedPedigree** id="ReceivedReturnPed-2"
    - **documentInfo**
    - **pedigree**
      - **shippedPedigree** id="ShippedReturnPed-2"
        - **documentInfo**
        - **pedigree**
          - **receivedPedigree** Id="ReceivedPed-1"
            - **documentInfo**
            - **pedigree**
              - **shippedPedigree** Id="ShippedPed-1"
                - **docmentInfo**
                - **initialPedigree**
                - **serialNumber**
                - **productInfo**
                - **itemInfo**
                - **itemInfo**
                - **transactionInfo**
                - **senderInfo**
                - **recipientInfo**
                - **transactionIdentifier**
                - ...
                - **signatureInfo**
              - **Signature** (Manuf. Signs: ShippedPed-1)
            - **receivingInfo**
            - **signatureInfo**
          - **Signature** (Wholesaler Signs: ReceivedPed-1)
        - **itemInfo**
        - **transactionInfo**
        - **senderInfo**
        - **recipientInfo**
        - **transactionIdentifier**
        - ...
        - **signatureInfo**
      - **Signature** (Wholesaler Signs: ShippedReturnPed-2)
    - **receivingInfo**
    - **signatureInfo**
  - **Signature** (Manuf. Signs: ReceivedReturnPed-2)

Sample Pedigree Forms

Partial Receipt of Products against Pedigree

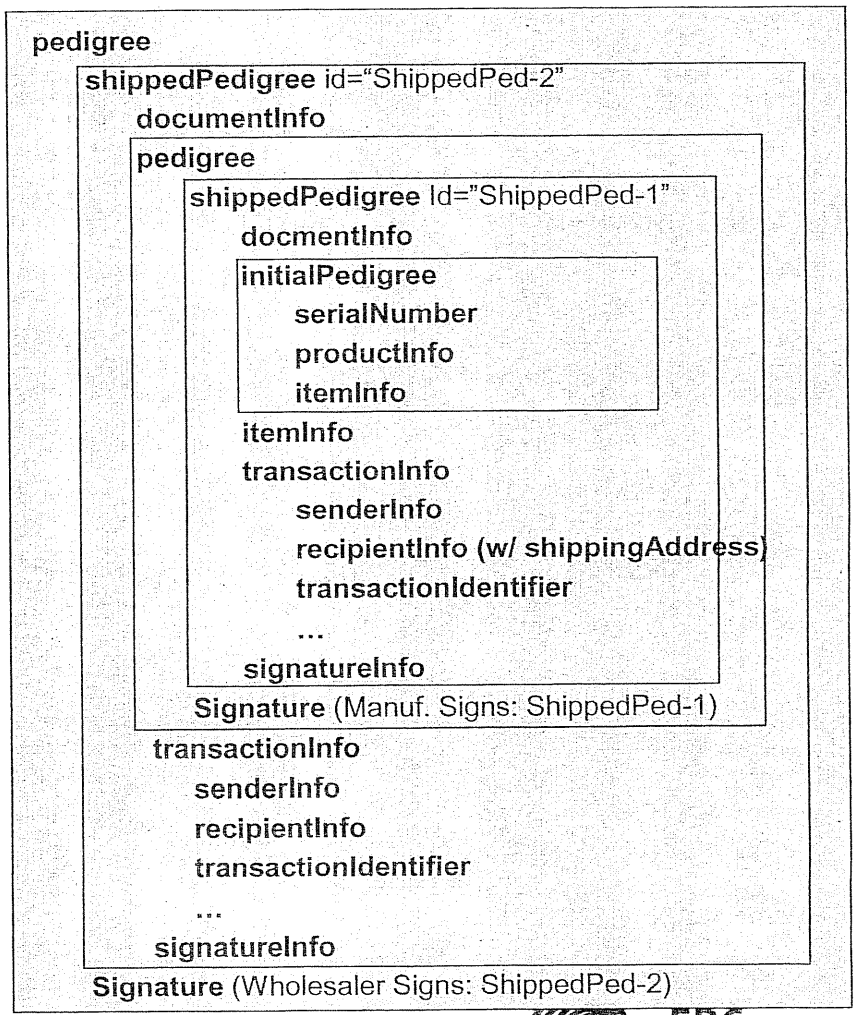
The partial receipt of product against pedigree is described for a sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. The wholesaler receives the products in two partial shipments and updates each partial receipt against the original pedigree, resulting in a new received pedigree for each partial receipt.



Sample Pedigree Forms

Pedigree Flow for a Manufacturer-initiated Drop Ship

The pedigree flow is described for a drop ship transaction brokered by wholesaler, where pharmacy purchases the product from the wholesaler, but the manufacturer ships the product directly to the pharmacy. In this scenario, the manufacturer initiates the start of the drop ship pedigree documenting the sales transaction from the manufacturer to the wholesaler with the shipping information indicating the direct shipment to the pharmacy. The wholesaler adds only the second part of the drop ship transaction to the pedigree documenting the sales transaction from the wholesaler to the pharmacy.



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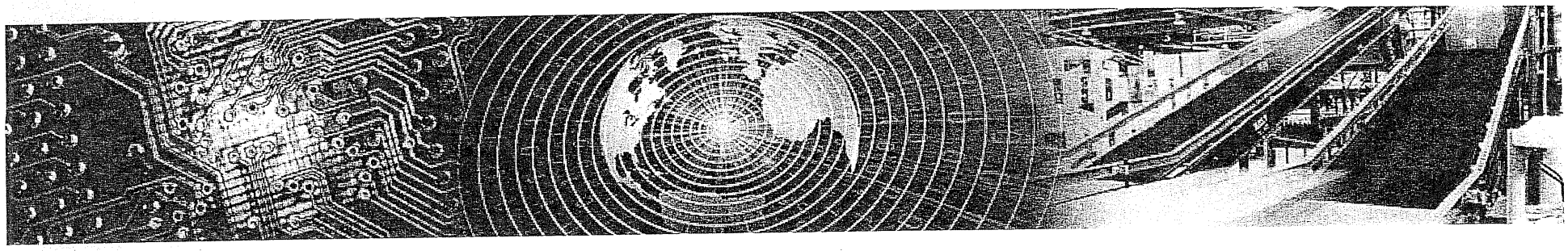

Pedigree Scenario Walk Through

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Pedigree Trace Scenarios

- **Scenario 1:** This scenario depicts the pedigree flow for the sale of a serialized product from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. The wholesaler then sells and ships one of the product items to a pharmacy DC.

Not Applicable in California

Scenario 2: This scenario depicts the sale of a non-serialized product from a wholesaler to a retail pharmacy DC, when no pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.

Not Applicable in California

Scenario 3: This scenario depicts the sale from a wholesaler to a retail pharmacy DC, when a paper pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.

- **Scenario 4:** The pedigree flow is described for a sale from a repacker to a wholesaler, where the repacker initiates the pedigree for a repackaged item. The repack pedigree contains the pedigree for the source product used to create the repack products

- **Scenario 5**: This scenario depicts the kitting of several products and the subsequent sale from a kit manufacturer to a wholesaler.

- **Scenario 6**: This scenario depicts the partial receipt of product for sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. It then includes another transaction from one wholesaler to another, which depicts the receipt of a pedigree without signing the pedigree on inbound receipt. The pedigree is subsequently signed on the next outbound transaction to the retail pharmacy.

Not Applicable in California

Scenario 7: This scenario depicts the pedigree flow for the sale of a non-serialized product from a manufacturer to a wholesaler, when the wholesaler initiates the pedigree. The wholesaler then sells and ships the product to a pharmacy DC, then the pharmacy DC returns the product to the wholesaler. Then the wholesaler sells and ships the product to another pharmacy DC. This pharmacy DC also returns the product to the wholesaler.

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Pedigree Track Scenarios

The following are "Track" Scenarios and are <u>not supported</u> by the current Pedigree standard.

Not Supported by Current Standard

- **Scenario 8:** This scenario depicts the ability for a company to identify the location of all the units of a particular NDC/lot or a particular EPC at downstream trading partners that they have sold product to in order to support faster recalls.

Not Supported by Current Standard

- **Scenario 9:** This scenario depicts the ability for a company to see the aggregate inventory levels and product movement of all of a particular NDC/lot at downstream trading partners that they have sold product to in order to support more effective forecasting & replenishment.

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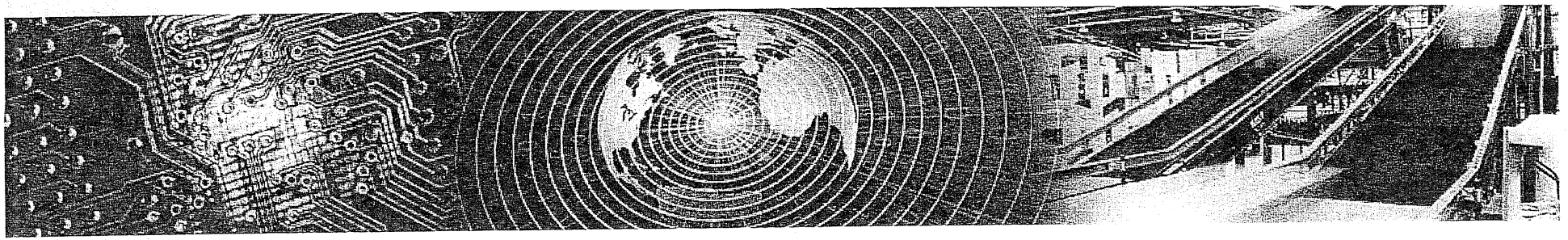

Follow-up Items

from California Board of Pharmacy
Pedigree review meeting

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Pedigree Review Follow-up

1. Unit Dose Serialization
2. Partial Shipments
3. Drop Shipments
4. Signature and Certification of in-bound shipments
5. Return of saleable product to Mfgr by Whlsr and later resold by Mfg.
6. Pedigree status for intra-company transfers into CA.
7. Voided Pedigrees
8. Inference

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For more information on the Pedigree Messaging Standard

- Planned Web Seminars:
  - April 16 at 9:00 am Eastern
  - April 24 at 11:00 am Eastern
  - May 9 at 2:00 pm Eastern
  - May 15 at 2:00 pm Eastern

To register for a Web Seminar, please contact Bob Celeste at:

rceleste@epcglobalna.org

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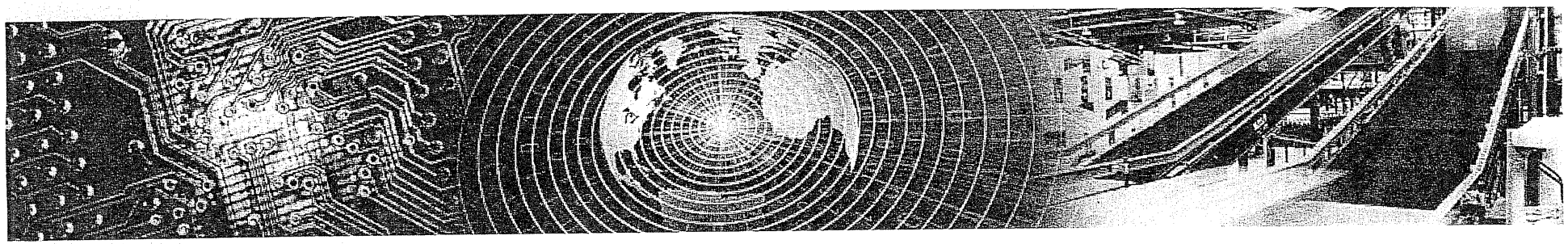

Questions

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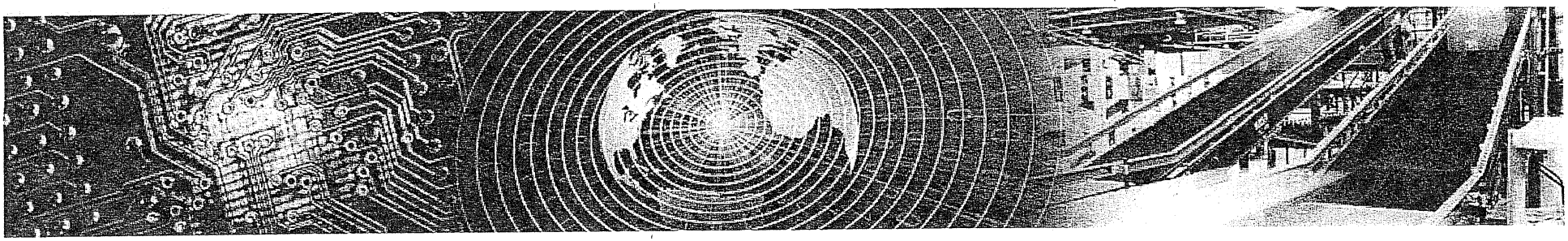

Additional Slides

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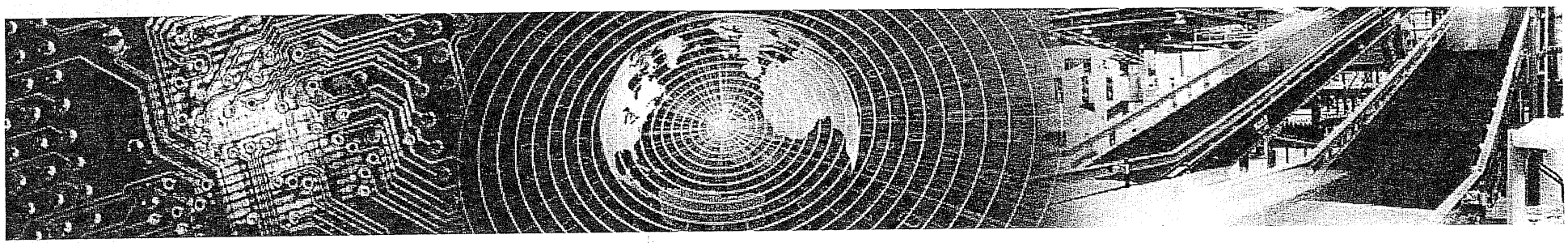

Pedigree Related Terms

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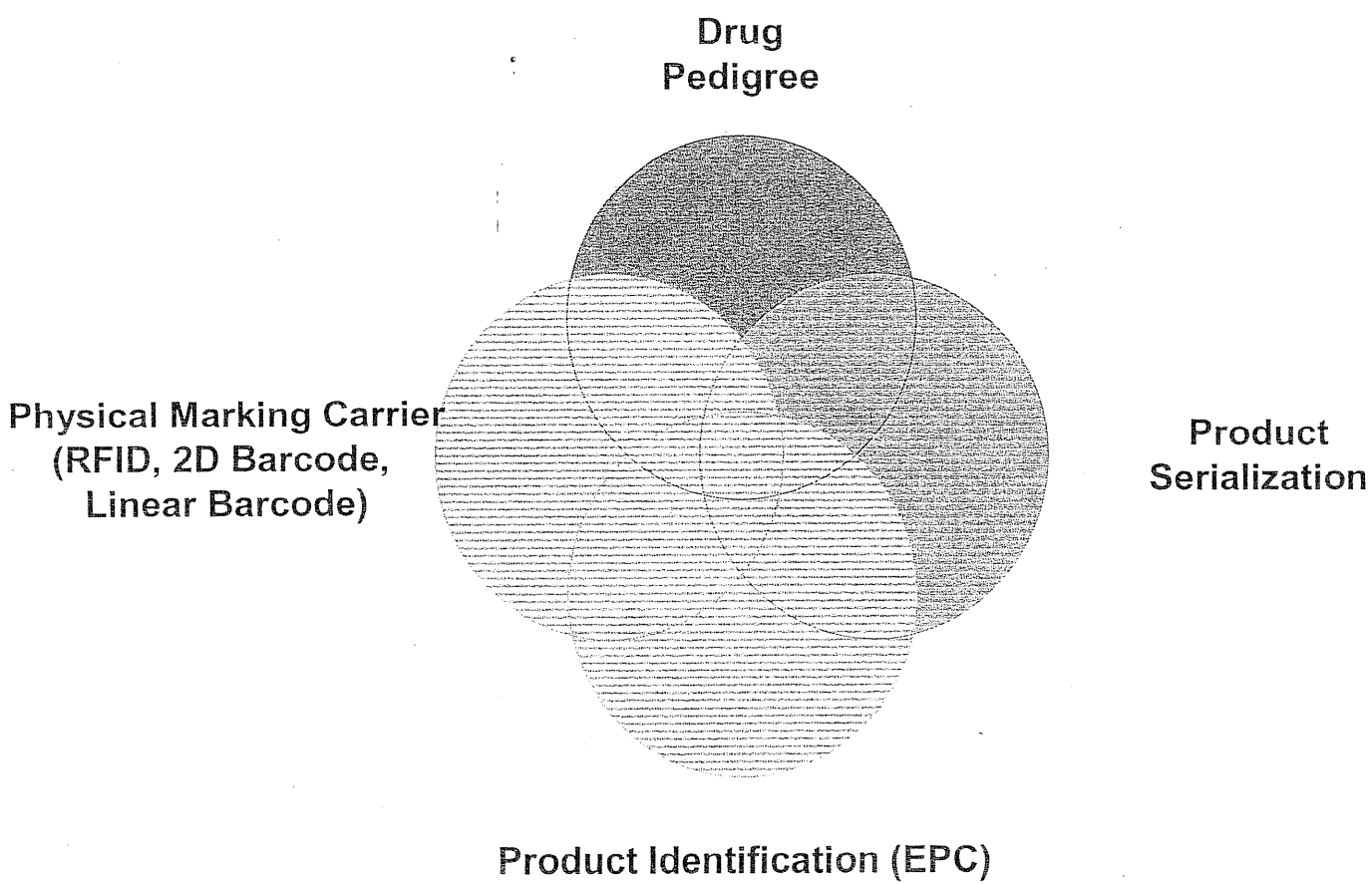
Definitions

Confusion over related topics



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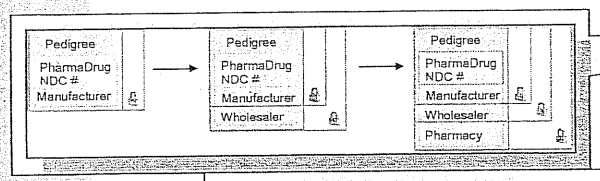
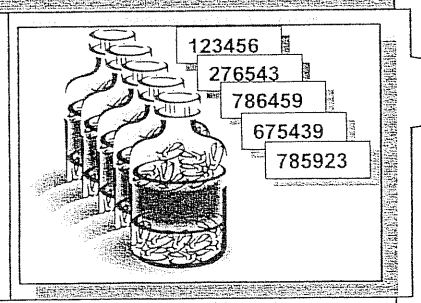
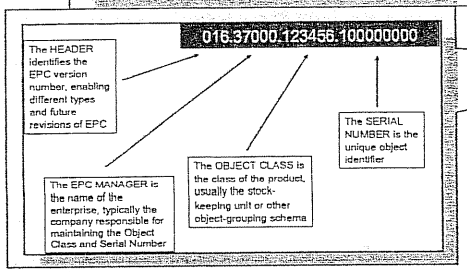
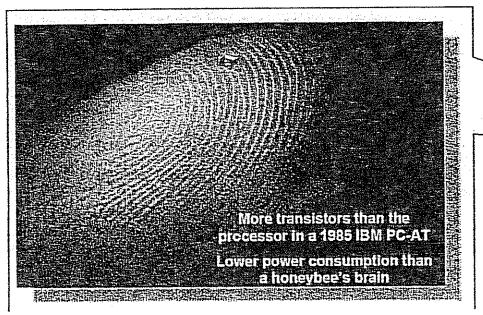
Definitions

Pedigree, Serialization, EPC, RFID









- **Pedigree:** The document, electronic or paper, which communicates the custody history for a particular medication.
- **Serialization:** A unique number assigned and affixed to a particular unit of item. Used to identify the particular bottle.
- **EPC:** Electronic Product Code – A globally and multi-industry acceptable identifier standardized by EPCglobal used to serialize items in many supply chains around the world.
- **RFID:** The technology that can carry an EPC. Made up of a tag (computer chip), antennae and substrate.

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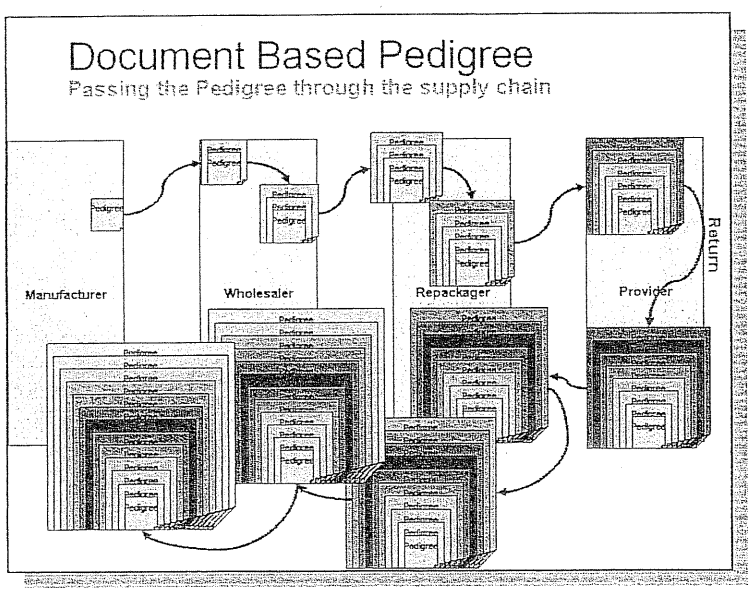
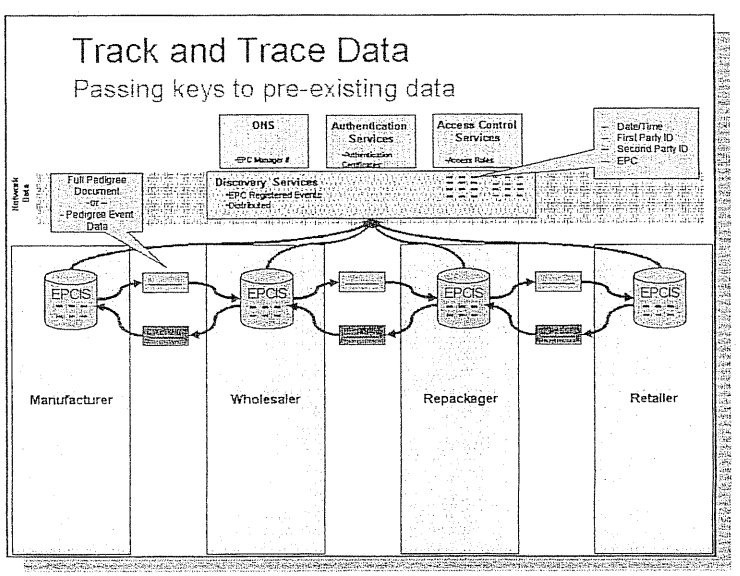
The Future of Pedigree

- Continued use of the Pedigree Messaging Standard
- Investigating the use of the EPCglobal Network architecture to provide "Pedigree on Demand"





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