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ePedigree Introduction

An ePedigree is an electronic pedigree or electronic record of the lineage of a prescription drug. This entails tracking the packaged product through its manufacturing process, through warehousing and distribution, all the way through the supply chain to the final point of sale (pharmacy) or distribution (samples).

Ultimately, the ePedigree regulations are intended to protect the consumer from two primary issues surrounding prescription drugs:

- counterfeit drugs or
- legitimate drugs that have been found to be defective through a faulty manufacturing process, tainted ingredients, or mis-handled during distribution.

The various state and federal regulations are very specific about what information must be present in the ePedigree record for each individual product and at what levels, so this information will not be reiterated. What is important to note, however, is the mandate for interoperability based on a global Electronic Product Code standard. *This is important to note because it determines the success or failure of various ePedigree solutions available to the Life Sciences industry.* Initial design, structuring, and mapping of manufacturing and distribution data is **critical** to implementation of a successful ePedigree solution.

The collection of this data happens at many stages during a product's life cycle and must be passed from point to point without any loss or duplication of information; each product batch must remain unique and fully traceable. An individual product (smallest dispensable container) must be tracked and traced from each raw and packaging materials that went into its production through any bulk cartons, cases, totes, pallets, or shipping containers utilized for its transport. Additionally, location information must be encoded each time the product changes locations. This enables a true "Track and Trace" system whereby any given product batch can be traced to its current location, example:

Floconaze Lot 64R006N Trace

- Piper Pharmaceuticals Distribution Center, Metuchen, NJ
 - o 1,000 SKUs Shelf B
- Best Transport, Jersey City, NJ
 - o 1,000 SKUs Shipping Container xt7704
- Stop&Save Pharmacy, Bridgewater, NJ
 - o 20 SKUs
- Etc.

Conversely, an individual product container (professional sample or consumer saleable) can have its ePedigree verified back to the point of manufacture and every change of hands in the distribution process.

Again, the criticality here is the collection and secure management of data. There are three key areas of understanding that are essential to a successful implementation of an ePedigree system:

The Manufacturing Process (SOPs, equipment, materials, instrumentation, process controls, and data collection)

Enterprise Systems (ERP/MRP/MES, logistics, distribution, warehousing, various supply chain components)

Database Design & Management – This is listed as its own entity, because without a strong and clear focus on upfront data design and mapping, the implementation will result in vast amounts of disparate and incompatible data.

ePedigree Solutions

There are three basic categories of solutions available to the industry that address the current ePedigree state and federal mandates:

Complete Turnkey Solutions – all instrumentation, serialization, data collection, data management & tracking is provided by one vendor. The vendor will provide all of the following required for implementation:

- barcode and RFID labeling units
- barcode readers, linescan cameras, RFID readers
- data collection software
- SQL, ORACLE (or other) database information center
- Registry management for tracing and sharing pedigree data between manufacturers, distributors, and consumers

Hybrid Solution A – utilizes various off-the-shelf components and services to assemble an ePedigree system:

- Industry standard Intermec, Motorola, Symbol Technologies, Zebra label printers & readers
- Numerous Third Party software for data collection and management (usually includes SQL/ORACLE DB)
- Contracted Third Party Registry Management
- Integrators for manufacturing devices and database applications

Hybrid Solution B – utilizes a combination of off-the-shelf and custom components and services to assemble an ePedigree system:

- Industry standard Intermec, Motorola, Symbol Technologies, Zebra label printers & readers
- Customized software solution for data collection and management including SQL/ORACLE DB
- Contracted Third Party Registry Management
- Integrators for manufacturing devices and database applications

Vantage Consulting Industry e-Pedigree Experience

Vantage Consulting is actively engaged in exploring all of the above options for several large Pharmaceutical clients, as well as solutions providers.

In case number one, we are looking at a pilot line implementation for a large Pharmaceutical Co-packer of a turnkey system from IBM. We are involved at the manufacturing level, to verify the types of devices and data to be collected, the manner and location for it to be stored, as well as insuring that it will be presented to the Websphere servers in the right format.

In case number two, we are in discussions with a major Pharmaceutical manufacturer about the deployment of two pilot systems; one being a hybridized system utilizing all-off-the shelf components that need to be integrated by us and the second being a hybridized system that would be a highly customized software and database solution.

In case number three, we are involved with two companies that provide solutions at different spectrums of an ePedigree implementation. One is an industry leader in providing packaging line inspection, verification, and data collection. The other is an industry leader in providing Enterprise solutions.

Vantage Consulting Life Science General Experience

Vantage Consulting Group has been providing technical services and solutions to the Life Sciences industry for over fifteen years. Our knowledge and experience ranges from plant floor instrumentation and vision systems to database design and management.. We have been involved in all aspect of a Project Life Cycle from Design through implementation and Validation. Our Engineers have an average of 15+ years of specific industry experience. Following is a brief outline of our services and capabilities:

Our Capabilities

Design

- Functional Requirements, Specifications, and Drawings
- Cost and Resource Projection & Analysis
- Process & Packaging Engineering Design

Validation

- Validation Master Plans, IQ, OQ, PQ, & CSV
- OEM, Vendor/Supplier, & Contract Manufacturing Audits

Process/Packaging Automation

- Line Integration & Control

- Servo Motion Control & Robotics
- PLCs, Operator Interface & SCADA Systems

Process Optimization

- OEE Monitoring, Analysis, and Improvement
- PAT Initiative Implementation
- ePedigree Initiative Implementation

Information Management

- System Architecture Design & Implementation
- MES, MRP, ERP Development and Support
- Manufacturing Data Modeling & Integration

Project Management

- Subcontract Coordination & Factory Acceptance Testing
- Installation/Startup & Post Project Support

Quality Systems

- Analytical Test Method, SOP, & Protocol Development

Training & Documentation

Our Experience

Process

- Wet/Dry Raw Material Handling
- Batch & Continuous Mixing (S88 standards)
- Batch Reactor Processes
- Minor/Micro Ingredient Handling & Dosing
- Various Bake/Dry/Cool & Autoclave Processes

Packaging

- Various Tube/Bottle/Container filling operations
- Form/Fill/Seal for Medical Devices
- Blister-pack lines for OTC & Pharma
- Various Cartoning/Wrapping/Casing Operations
- Vision Systems, Metal Detection, Checkweighers & assorted Printers

Facility Utilities

- RO, RODI, WFI, & Clean Water applications
- HVAC, Chillers, Cooling Towers, Compressors
- Waste Water Treatment
- Class 10 & up Clean Rooms

Building Automation/Management Systems

- Honeywell BAS/BMS systems
- Honeywell EBI systems
- Seimens (TI) BAS
- Seimens (Landis & Staefel) BMS