



MDS Drug Pedigree System

MDS Drug Pedigree - an integrated hybrid system to get you compliant quickly and painlessly



MDS Pedigree lets you easily comply with PDMA legislation for chain of custody for prescription drugs.

MDS Drug Pedigree System from TSH allows manufacturers and distributors to meet the regulatory requirements for prescription drug pedigree, to track the chain of custody throughout the supply chain and provide authenticated proof upon delivery.

Why are Pedigrees required?

In an effort to make our nation's drug supply safer, recent legislation requires members of the supply chain to produce drug pedigree information to prove the authenticity of prescription drugs.

Counterfeit drugs are becoming a serious issue for distributors. Industry estimates indicate that nearly 10% of pharmaceutical drugs are counterfeit. With the intricate structure of supply chains and loose borders allowing the entry of counterfeit drugs into the U.S. drug supply, it is often difficult to trace the authenticity of a particular drug. Recent regulations are aimed at solving this issue. Several states have adopted new regulations that require trading partners to provide an "authenticated pedigree of all prescription drugs that pass through their custody". Florida's pedigree law was the first, other states are following.

Section 503(e)(1)(A) of the (PDMA) Act establishes the pedigree requirement for prescription drugs. A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them. Under the pedigree requirement, each party

engaged in the wholesale distribution of a prescription drug in interstate commerce, and who is not the manufacturer or an authorized distributor of record for that drug, must provide to the person who receives the drug a pedigree for that drug.

What is a Pedigree?

At its most basic level, a drug pedigree is an authenticated, signed document that tracks a product as it moves through the supply chain. Pedigrees can be paper or electronic, but they must include: the proprietary and established name of the drug, dosage, container size and number of containers, lot or control number, the business name and address of all parties to each prior transaction involving the drug starting with the manufacturer, and the date of each transaction*.

Typically, Manufacturers create the pedigree, and distributors must add to it. Every time the drug changes hands, information is added regarding the transaction, and the pedigree is digitally or manually 'signed'. When the drug reaches its final destination, the pedigree must be authenticated. Currently, the FDA does not have specific requirements for authentication verification.

Pedigrees serve a dual purpose. First, they provide a verifiable means for each company in the supply chain to verify a drug's chain of custody. This gives all involved a secure knowledge that the drug was always handled properly by legitimate companies. Second,

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Features:

- **Fully integrated to MDS** - eases data entry, tracking and data integration as well as training
- **Reduces startup time** - Virtually eliminates startup lag time and the costly pitfalls of installing a separate pedigree system
- **Supports latest regulations** - TSH will keep system current and make sure it supports latest State and Federal regulations
- **Extends MDS business monitoring capabilities** - System will alert managers to potential pedigree issues so they can be addressed early

Key Benefits:

- FDA compliance with the PDMA (Prescription Drug Marketing Act)
- Easy way to manage pedigree documents
- Better Inventory Management (expiry-date management based on the environment's effects on the active ingredients)
- Prove drug is genuine and stop counterfeits from entering the U.S. market
- Easier notification and action regarding drug recalls
- Improved drug tracking throughout the supply chain



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drug pedigrees help inspectors identify problems such as tainted or counterfeit drugs and facilitate the recall process.

Paper or Electronic?

Currently, companies can comply with legislation via paper or electronic pedigrees. A paper pedigree securely retains the paper trail containing all authentication information for a particular item. An electronic pedigree is a tamper proof record documenting every stage a drug passes through from manufacturer to its final dispensary point.

Which to choose? - With MDS, you don't have to! MDS does both - you choose the appropriate pedigree for each product - paper or electronic.

The MDS system is a unique hybrid that will allow adoption of Electronic Pedigrees as the Industry creates a standard, and facilitate regulatory compliance for those companies that fall under current legislation. MDS allows both scanning and manual input of pedigree and authentication information. From the point of receipt of the product into the warehouse to the point of shipment, each item is tracked and is associated with an internal pedigree code. This code is unique to a product at single or multiple levels of packaging. It is stored along with related data in the MDS database and is made available for pedigree authentication.

This code allows MDS to identify each lot and item and attach the appropriate pedigree information. The pedigree is then included with each shipment. Alternately, the Pedigree can be made available to appropriate parties via a distributor's website.

If manufacturers provide a pedigree, MDS accepts it and adds to the pedigree where appropriate. If not, MDS creates one.

A paper, or physical, pedigree involves tracking or scanning the documents received and adding or creating new documents while the drug is in your custody. MDS facilitates this process by capturing necessary data to build the pedigree.

Typically, a worker at each stop would scan the product, confirm receipt, and create a digital record of this transaction. Through this process, a complete record of a drug's distribution has been created so that when the drug is delivered, all appropriate documents are attached to the shipment.

Most of the data that companies add to a pedigree comes from their existing Information systems (WMS or ERP). Other systems use interfaces to ERP systems to compile and store data. With MDS, the pedigree system is fully integrated and will automatically provide appropriate available information such as lot numbers and expiration dates as well as PO receipt, release and shipping details. (MDS also uniquely provides for additional required information, such as tablet quantities, to be manually entered if it cannot be scanned in.) This data is then available throughout the MDS system to facilitate drug recalls and to perform product searches on pedigree information.

With MDS, manufacturers, distributors and pharmacies do not have to agree on a single electronic pedigree format. Open-standards recommendations are being considered to streamline the creation and exchange of electronic pedigrees among trading partners. When available, MDS will integrate this technology.

In addition, MDS utilizes Pedigree data for other objectives, such as proper inventory management (to avoid out of stocks), tracking drug shelf life, and assisting product recalls. A supplementary benefit of the Pedigree system is that it allows distributors to collect additional information on an individual product level. This gives distributors more detailed product information than in the past.

The MDS Pedigree solution takes advantage of your existing ERP system architecture to enable the real-time monitoring of all business events to extend to pedigree issues. MDS monitors pedigree compliance and alerts managers to potential concerns before they become problems. In addition, the integrated workflow assures pedigree compliance within a familiar structure, virtually eliminating the costly pitfalls of installing a separate pedigree system.

The Systems House, Inc. (TSHINC), established in 1979, is widely recognized as one of the premiere suppliers of software and computer solutions for the healthcare supply chain. Our corporate philosophy: "Our word is our bond" has led to our longstanding reputation for outstanding customer service with our many clients throughout the United States and Canada. Our commitment "to understand the complex needs of our customers and create value-added solutions that enhance the competitiveness, profitability, and customer satisfaction of our clients" ensures that TSH stays ahead of industry trends and standards.

For more information on Pedigree and Master Distribution System from The Systems House, Inc., contact TSH at 1-800-MDS-5556, or email sales@tshinc.com

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