



Synchrony™ ePedigree

Synchrony™ ePedigree delivers unmatched reliability and market-tested performance to tackle the growing problem of counterfeit drugs. Throughout the drug supply chain manufacturers, wholesalers, and retailers benefit from ePedigree's powerful validation and tracking features. ePedigree helps the pharmaceutical industry meet evolving regulatory requirements, increase supply chain safety, protect brand revenue, and minimize operational impact.



a>proven <way to ensure regulatory compliance

- Be in compliance with evolving laws, regulations, and standards
- Leverage your existing investments in IT
- Connect to all your supply chain partners
- Utilize real-time visibility and alerting
- Gain control of system access and archives

Axway is the leading global provider of collaborative business solutions.

Defying boundaries, Axway accelerates and optimizes cross-business processes within and among enterprises. We establish the connections that make companies easier to do business with — improving value-chain efficiency, regulatory compliance, and quality of service.

That's business in motion. That's Axway.

Challenges

Combating counterfeit drugs is a focus of many government regulators and the pharmaceutical supply chain because of the obvious risks to patient safety. Manufacturers of high cost, high value pharmaceuticals are also concerned about the impact of counterfeit drugs incidents to their brand and revenue.

However, despite regulatory and product security efforts across the supply chain, the problem of counterfeit drugs continues to grow. Drug industry analysts estimate that nearly 10 percent of drugs worldwide are counterfeit. Also, the World Health Organization estimates that US \$32 billion in legitimate corporate sales are lost each year due to the sale of counterfeit drugs. This number is expected to grow to US \$75 billion by 2010.

To help combat the growing problem of counterfeit drugs, state and federal regulators in the United States require pharmaceutical supply chain constituents to provide drug pedigrees, or custodial histories. These pedigrees trace each drug's chain of ownership from the pharmacy back to the manufacturer. While some states allow this to be a manual paper-based process, it requires significant effort from the various supply chain participants to maintain complete records, and has questionable success. Most regulators are looking for a tighter, more secure process than manual tracking.

In California, new legislation requires electronic pedigrees to be exchanged and includes an ability to uniquely identify individual products or serializations. This makes the tracking and retrieval of Pedigree easier for all members of the supply chain, and for regulators.

Solutions

Synchrony ePedigree automates the creation, transmission, tracking, and retrieval of electronic pedigrees to help prevent counterfeiting and safeguard the drug supply. It ensures compliance to regulatory mandates by various states and supports the recommendations by the U.S. federal government.



Built on the reliable, market-tested platforms used by many manufacturers, wholesalers, and retailers, Synchrony ePedigree documents the chain of custody and/or changes in financial ownership of a pharmaceutical drug as it moves through the supply chain. It validates authenticity, digitally signs for unalterable security, and stores forms for easy retrieval at each step of the process.

Synchrony ePedigree also delivers:

- Comprehensive archiving, reporting, and alerting for regulatory compliance and exception management
- Support for serialization at the item, case, and/or pallet level
- User friendly interface for complete visibility into the custodial history of a drug or drug lot
- Easy integration into customer service web portals to enable self-service pedigree retrieval
- Web forms to enable technically challenged supply chain partners to exchange electronic pedigrees
- 21 CFR Part 11 compliance for electronic records and digital signatures

Benefits

In addition to complying with regulations, Synchrony ePedigree enables companies to minimize the impact to operations through configurable business rules. How compliance is achieved should be decided by the business, not by the pedigree software. Synchrony ePedigree gives you the flexibility to make decisions about when pedigree data is collected and when the pedigree is created. This flexibility significantly reduces the total cost of ownership for deploying and maintaining a pedigree solution.

Most importantly, you can leverage your existing investments in supply chain automation and enterprise systems to improve the speed and quality of shipping and receiving, expedite returns processing, and improve recall precision.

Safer Drug Supply

Synchrony ePedigree delivers value at each step in the drug supply chain:

Manufacturers

- Create and send electronic pedigrees
- Store and access electronic pedigrees
- Validate electronic pedigrees for returns processing

Wholesalers

- Validate electronic pedigrees
- Correlate electronic pedigrees to physical inventory
- Create and send electronic pedigrees as inventory is split
- Store and access electronic pedigrees

Retailers

- Validate electronic pedigrees prior to dispensing drugs
- Correlate electronic pedigrees to physical inventory
- Create and send electronic pedigrees for returns processing
- Store and access electronic pedigrees

Synchrony ePedigree provides a proven solution to create, transmit, and track electronic pedigrees. It enables pharmaceutical manufacturers, wholesalers, and retailers to:

- Comply with evolving state and federal pedigree laws
- Increase patient safety
- Protect brand revenue
- Leverage existing IT solutions
- Minimize operational impact

Find out how ePedigree can impact your business, and help you ensure regulatory compliance. Call your Axway sales representative today. Visit www.axway.com.

business. in motion.



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About Axway

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Axway is a leading global provider of collaborative business solutions. Axway establishes the dynamic connections—within and among enterprises—that make companies easier to do business with. Spanning all industries, over 8,400 organizations in more than 100 countries depend on Axway to manage and control their business-critical information in motion—improving value chain efficiency, regulatory compliance, and quality of service. Built on a service-oriented architecture (SOA), Axway's Synchrony™ solutions feature a highly flexible integration and B2B framework, business and technical analytics, and professional services. Axway also offers customized solutions for the financial services, life sciences, and automotive industries. Many of Axway's solutions are available in a software-as-a-service (SaaS) model. A subsidiary of Sopra Group, SA, Axway is headquartered in Scottsdale, Arizona.

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