



## Drug Pedigree Guidelines and How Software Can Help

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### Introduction

Counterfeit and adulterated drugs are an increasing problem, particularly in the United States. Not only do these activities strip profits from legitimate drug manufacturers, but they can also pose a health risk to the consumer. As a result, the US *Food and Drug Administration* (FDA) has issued guidelines covering "cradle-to-grave" tracking requirements that pharmaceutical companies must comply with for the drugs they produce. We'll look at a brief description of the pedigree guidelines, compliance options, and outstanding issues.

### What Are Pedigree Guidelines?

Simply stated, the FDA's pedigree guidelines require data to be captured at each stage of the production and distribution process, until the drugs reach the customer or end user. The players principally affected by the guidelines are pharmaceutical manufacturers, drug distribution companies, drug wholesalers, and drug retailers.

From the manufacturer's perspective, the guidelines essentially require pharmaceutical companies to maintain data on each case of drugs leaving the shipping dock. This data starts with the drug manufacturer and includes, but is not limited to, such information clusters as the brand name and *product identification* (ID); manufacturing, shipping, and expiration dates; corporate and manufacturing addresses; quantity, weight, and lot number of the case; and the item description. The data collection gets considerably more complex if parts of the manufacturing process are contracted to third parties. Data must then be transmitted from the subcontractors, and consolidated into the primary manufacturer's pedigree database. As we will see later, there can be a heavy reliance on data residing in the existing *enterprise resource planning* (ERP) solution.

Once cases arrive at a distributor's warehouse, the pedigree is updated by adding warehousing data such as the address of the distribution center, the date of receipt, the warehouse location, and any additional product and lot information added to the case. Once cases leave the distribution center, the destination address is captured. The process can be continued up to the point where the consumers purchase drugs from their local pharmacy.

It would be wrong to think that there is a standard format by which the data is captured and transmitted to a drug manufacturer's customer. If it didn't work for *electronic data interchange* (EDI), why would it work for drug pedigrees? Major drug retailers can typically dictate the format and content of the pedigree data, so long as they comply with the local state's requirements.

The key to the pedigree data is twofold: (1) the eighteen-digit pedigree ID, and (2) knowing what you are receiving before you receive it. The first five digits designate the manufacturer, and are assigned by **EPCGlobal**, an industry-entrusted organization created to establish the global standard for real-time, automatic identification. The next twelve digits make up a sequential number, and the eighteenth digit is typically a check digit. In situations where both parties are using EDI, the ID can be included with the *advance ship notice* (ASN). Otherwise, an external file containing the same ID must be used to transmit the information. As the cases are received by the distributor, the label is scanned, and the unique pedigree ID is compared with the ID contained in the ASN. Mismatches may signify a counterfeit situation, or possible alteration. Included in the ASN or external file is the pedigree data collected to the point of receipt by the distribution center.

While some might like to include *radio frequency identification* (RFID) under the pedigree guideline umbrella, this would overcomplicate the process. Whether barcode labels or RFID tickets are used is a function of the technology and equipment used by the manufacturer (or required by the customer). From a software perspective, writing labels or tickets requires the same level of effort. In any case, few pharmaceutical companies have RFID technology fully deployed in their warehouses. Other manufacturers only have one or two customers demanding RFID compliance. Accordingly, manufacturers are using a “slap’n’ship” technique to implement RFID whereby RFID tickets are generated based on the ship-to customer, and at the end of the process. Hence the term “slap’n’ship,” where the ticket is printed and slapped on the case just before being placed on the truck, is most appropriate.

## Compliance Options

Before considering options for complying with the pedigree guidelines, the functional challenges must be understood. First, the guidelines require a significant increase in the amount of data shared between trading partners. This data may have to be harvested from existing applications, or it may represent a new request for information. Second, each player in the supply chain must maintain complete, accurate, and secure records for drug pedigree, typically encompassing multiple years. Third, the information must be reliable and available. Pedigree information must be captured before the product can be shipped. If not, one of the key aspects of the guidelines—namely, knowing what you are receiving before you receive it, cannot be satisfied. Finally, each player must authenticate the custody of data back to the manufacturer, and certify that shipments have complete and accurate pedigrees.

There are three alternatives for complying with the pedigree guidelines. The first alternative is to modify existing systems. The advantage of this alternative is that no re-training of the user community is required, and no new software needs to be purchased. However, you may have to modify legacy systems to take advantage of new technology like RFID and mobile printers. Depending on the age of the applications, all this may be easier said than done. While you may not have to buy software (and assuming that the company does not have in-house programming resources), the consulting costs can be prohibitive, requiring a fair amount of customization. Even if in-house resources are available, planned revenue-generating projects may have to be delayed.

The second alternative is to build a new, stand-alone interface. Other than data extraction, the obvious advantage of this alternative is that existing systems do not have to be modified. However, you should be concerned as to the size of the interface project and its inherent risks. The project team will require diverse skills, which are typically difficult to find in one organization, possibly requiring third party contractors to backfill missing expertise.

The third alternative is to buy an off-the-shelf pedigree interface. An external, bolt-on pedigree solution is preferred, since there is then no need to modify existing applications or manufacturing processes. However, finding a vendor with pharmaceutical experience, coupled with a pedigree guideline track record, may be difficult inasmuch as few vendors have risen to the challenge.

Assuming that you identify a vendor with these pedigree qualities, maximum use can be made of the software vendor’s familiarity with both the industry and the pedigree process. This knowledge and experience can be used to quickly flatten the learning curve. What can make this alternative particularly attractive is the vendor’s inclusion of integration tools with the price of the pedigree solution. These tools can greatly facilitate and simplify the process of extracting existing ERP data, even with little or no technical ability. Some minor customization may be required to the format and sequence of data, varying from one customer to another. Accordingly, the flexibility of the reporting module provided by the vendor should be considered.

## Outstanding Issues

The pedigree law is scheduled to start in Florida (US) in July 2006, closely followed by Indiana (US). For California (US), the law is on schedule to take effect on January 1, 2007. Another fifteen US states have similar legislation in the pipeline. But already issues are arising on how the programs are to be implemented.

The first issue is to what level of detail the drug pedigree is to be taken. A *chief executive officer* (CEO) of a major drug retailer has already come out against taking the pedigree down to the store level, citing the fact that the cost would run in excess of \$100 million (US). This objection is causing Florida to rethink its program, and the state may go with a partial rollout. For a full-service pharmaceutical company—namely one that encompasses manufacturing, distribution, and retailing, the programming implications could be significant both in terms of time of implementation and cost. You should look to the software vendor to help work through the requirements on a state-by-state basis and develop a reasonable implementation approach. However, expect to hang on for what will surely be a bumpy ride.

In another successful lobbying effort by pharmaceutical companies, all stakeholders in the pharmaceutical supply chain have the option of providing paper or electronic versions of the pedigree data. Suffice it to say that this is only a temporary reprieve for the drug companies, because surely electronic submissions will be the only form of approved communications. Obviously, RFID-compliant pedigree programs will become the standard. The concern, however, is that

some US states, like Indiana, are considering even more burdensome pedigree requirements. The pedigree requirements and processes to support them are presently fluid, to say the least. Whatever pedigree solution you choose to implement, it must be flexible, adaptable, and capable of turning on a dime.

Since communications between trading partners is essential, interoperability and data interchange among pedigree solutions are critical. However, since today there are very few software vendors offering an implemented pedigree solution, some vendors are taking a "build as you go" strategy. As a result, pharmaceutical companies looking to purchase an off-the-shelf solution should investigate the means and methods for transferring pedigree data from one trading partner to another.

### **Recommendations**

A time when all states will require some form of pedigree guidelines is inevitable. If you are a drug manufacturer, it is appropriate and prudent to work with your major customers and distributors to formulate a realistic plan of attack while you still have the luxury of time. As we have seen with the rollout of RFID and demands from large enterprises, we can expect the larger drug retailers to follow suit by placing deadlines on its suppliers when compliance with pedigree guidelines is required.

Of the compliance options discussed, the stand-alone bolt-on pedigree solution appears to be the optimal approach, with the following two caveats. First of all, the software vendor must have pharmaceutical industry experience and "done it before" pedigree credibility. Second, superior integration and reporting tools must accompany the pedigree solution, in order to avoid labor-intensive technical programming and report generation.