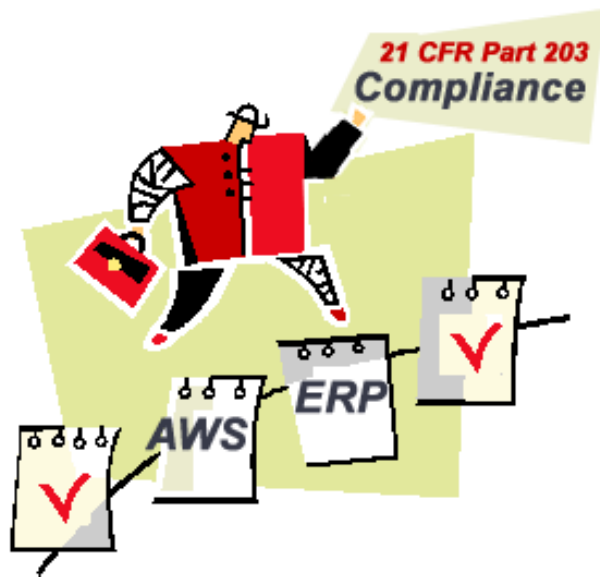


Pedigree Tracking

Automated Warehouse System/Enterprise Resource Planning software:
A **21CFR Part 203 Compliance** Stepping Stone



The FDA will no longer 'stay' the inevitable. Pharmaceutical companies will have to comply with 21 CFR Part 203 by the year 2011. An AWS, integrated with an ERP, gives pharmaceutical manufacturers the most complete manufacturing and tracing system necessary to uphold the integrity of their products as well as take the lead in establishing the requirements for the FDA pedigree tracking ruling that affects all parties in the pharmaceutical distribution chain.



Pedigree Tracking: AWS/ERP software considered an important stepping stone to 21 CFR Part 203 Compliance.

It's old, it's new, and it's the future. Pedigree tracking regulations were originally passed into law through the Prescription Drug Marketing Act of 1987 (PDMA). After two decades of postponing enforcement, the US Food and Drug Administration (FDA) has lifted its final stay. Pharmaceutical companies are expected to be in compliance with 21 CFR Part 203 by the year 2011.

The PDMA requires drug distributors to provide documentation of the chain of custody of drug products, hence the term "pedigree", throughout the distribution system. The act was devised to protect America's drug supply from the growing concern of counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs that threaten pharmaceutical consumers.

The FDA had believed that pharmaceutical companies would have the technology necessary to adhere to the regulations passed over 20 years ago. Deadline after new deadline, companies continued to fail to meet expectations. The FDA has determined that to continue postponing enforcement of this law only serves to promote confusion and opportunities for counterfeit practices.

The tracing of every entity that has handled a drug since leaving the manufacturing plant can be done on paper or electronically, and will include addresses and the lot number for the drug. The paper format of tracing, however, is subject to error and/or forgery and does not create the safeguard that the FDA intended. The FDA favors Radio Frequency Identification (RFID) for track-and-trace applications, but bar coding has been suitable for the pharmaceutical industry, and is much less expensive to implement.

In anticipation of future federal enforcement, all but 15 states have developed their own pedigree requirements. California takes the lead among those states as having the most stringent pedigree laws including a unit-of-use serialization requirement and electronic documentation tracking as far back as the manufacturer. Though all parts of the supply chain need to be in compliance, the California Board of Pharmacy focused primarily on the manufacturers in taking action necessary to serialize their products. This makes it possible for all the downstream partners like wholesalers and pharmacies to receive the pedigree and pass it on as the law requires. In addition, while manufacturers are not addressed under the PDMA, it's recognized that they have the highest degree of integrity to preserve in the product.

The board also raised several questions in support of including manufacturers in the pedigree requirements. For example, if one manufacturer acquires finished product from another, does that make the manufacturer a wholesaler? If product changes hands in the process of being repackaged, is the repackager now a distributor? At what point does a transfer of product from one hospital pharmacy to another become a wholesaling business? With so many "gray areas" in where responsibility for tracking lies, it makes sense to track a product beginning with the manufacturer.

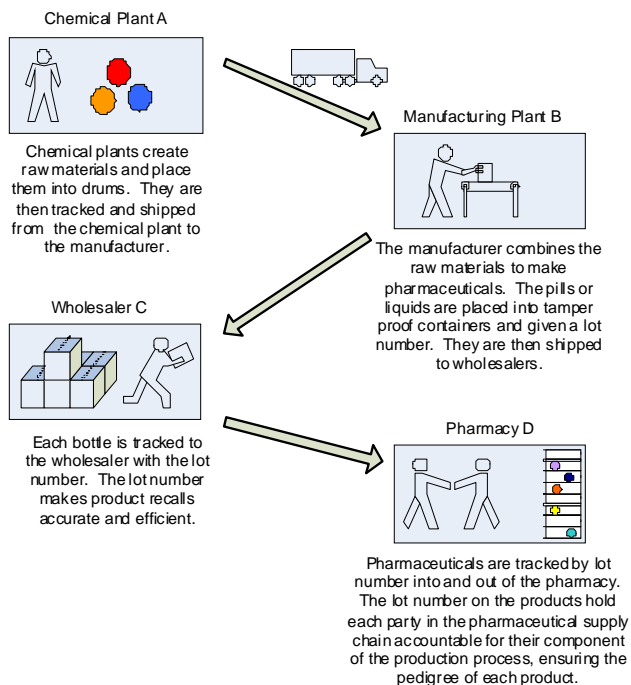
The FDA is working closely with the drug task force from the state of California to standardize its specific pedigree requirements so that all states will be able to follow the same protocols. In essence, by standardizing the regulations, it should mean that no business will be hampered by another business' discrepancies in compliance because of another state's requirements that are different. The pharmaceutical industry would certainly have a problem complying with multiple requirements.

The greatest challenge after standardization will be to bring all companies to full implementation of an RFID or bar coding system. The majority of pharmaceutical companies will not be ready for full compliance by the 2011 deadline. For this reason, the FDA expects to impose regulations in a phased-in manner in which it will prioritize pedigree rules. Those drugs that have the highest value in the US market based on high sales

volume or price, or the highest value for treating serious or life-threatening disease will be regulated first. Prior indicators, reasonable probability, and past violations of the law will follow in that order for FDA prioritization.

Understandably, with the repeated staying of the enforcement of regulations, companies have been hesitant to invest money into a system without knowing exactly what the rules are going to be and when they will be enforced. But barcode software systems are ready and available. For years now, software companies have been developing bar coding systems in anticipation of the FDA ruling that are simple, affordable, and pedigree tracking capable. The added bonus for many companies that have already been using an Automated Warehouse Solution (AWS) is that they won't have to implement anything new. An AWS system that integrates with an Enterprise Resource Planning (ERP) solution is even better – the bar codes follow the lot tracking that is documented on a product from cradle to grave.

Pharmaceutical Pedigree Tracking



There is also the option to use RFID. However, as stated earlier, they are much more expensive and not necessarily more accurate or compliant. Furthermore, pharmaceutical consultant Dr. Adam Fein questioned whether an RFID is actually capable of handling the large amounts of data necessary to provide drug traceability from manufacturer to consumer. It's also not something that typically works seamlessly with other software packages in the manufacturing component of the process. This creates an additional headache and paperwork process for the manufacturer that wants to link the lot numbers and serial numbers to the beginning of the distribution process.

An AWS, fully integrated with an ERP, is the “Cadillac” system for pedigree tracking. An AWS operating on a radio frequency backbone provides real-time inventory transactions. Labels are printed for all items so that inventory can be scanned with a hand-held scanning device. The labels include the item number, lot number, receipt date, and expiration date. Warehouse management is able to search and obtain critical information about any item. Inventory items can be issued, received, or transferred without manual entry. An AWS is also a tool for paperless physical inventory and cycle counts.

When an AWS functions synonymously with an ERP, sales orders can be selected without printing sales order pick tickets. Materials, labor, and finished good quantities can be posted to the batch ticket. On the purchasing side, a product can be received from a purchase order without paper. A real-time bar coding solution has the added bonus of increasing inventory accuracy with the tracking of all movement of inventory items. Also, dual entry is no longer necessary, thus reducing the number of potential manual errors.

It's apparent that the FDA will no longer “stay” the inevitable. Pharmaceutical companies will have to comply with 21 CFR Part 203 by the year 2011. With an easy-to-use, affordable, and available system such as an AWS, companies will no longer have a valid reason to appeal to the FDA for an extension of or exemption from the ruling. The process that makes the most sense is to begin the pedigree tracking at the point of manufacturing. An AWS, integrated with an ERP, gives pharmaceutical manufacturers the most complete manufacturing and tracing system necessary to uphold the integrity of their products as well as take the lead in establishing the requirements for the FDA pedigree tracking ruling that affects all parties in the pharmaceutical distribution chain.

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