

Infolinx and Pharmaceutical Records Management Solutions

In the highly regulated and competitive pharmaceutical industry, corporate records management programs have become indispensable to the continued well-being of the organization. Seeking compliance with requirements such as 21 CFR Part 11, the Health Insurance Portability and Accountability Act (HIPAA), and the Sarbanes-Oxley Act, pharmaceutical companies are actively seeking records management software and services to assist them in their efforts.

Under these requirements, pharmaceutical records, including product batch and history files, research notebooks, and intellectual property files must all now be governed by corporate policies implemented throughout their life cycle. Inherent in these policies is the mandatory ability to restrict, locate, track, and audit access to all such records. Increasingly, the pharmaceutical industry is turning to companies like Infolinx to ensure regulatory compliance and establish programs reflecting best records management practices.

Having provided records management consultation and software services for nearly twenty years, Infolinx has considerable experience helping pharmaceutical providers implement strategic and scalable records management solutions, meeting today's stringent requirements.



Infolinx records management solutions enable clients to:

- Comply with regulatory requirements such as 21 CFR Part 11, HIPAA, and Sarbanes-Oxley
- Demonstrate best records management practices to FDA auditors
- Provide records management software exempt from validation
- Implement a browser-based, true thin-client application
- Track records from point of creation through archiving and final disposition
- Implement an unlimited number of security groups restricting access to sensitive records and/or data
- Maintain complete audit histories for every record
- Minimize "lost" records with low-impact user compliancy and proven recovery strategies
- Integrate with existing software applications
- Seamlessly integrate barcoding, color-coded labels, and Radio-Frequency Identification (RFID)
- Encourage end-user "buy-in" with intuitive interface
- Collaboratively design and implement an unlimited number of retention schedules for the archiving or destruction of records
- Maintain record integrity via proven inventory practices
- Maximize end-user accuracy and efficiency through workflow improvements including automated data entry, records requesting, bulk updating, and merging of duplicate records
- Analyze process metrics identifying bottlenecks and potential workflow improvement areas

