

FDA Compliant Standard Operation Procedures

- Change Control Management Software
- Electronic Signatures (21 CFR Part 11)
- Corporate Repository for OSHA-required MSDS's (Material Safety Data Sheets)

Optical Image Technology, Inc. (OIT) provides an electronic system used for the circulation, review, approval, and distribution of FDA-regulated documentation required by the Current Good Manufacturing Practices and Quality System regulations (21 CFR Parts 211 and 820).

This documentation includes:

- Standard Operating Procedures
- Finished product specifications
- Packaging and raw material specifications
- All other records associated with the manufacture, testing and distribution of drug products

This system has been successfully installed and implemented throughout a multi-divisional, multi-location company involved in the manufacture of pharmaceuticals, diagnostics, pet products, medical devices and consumer products.

A paper-intensive system including microfilm and filing was replaced with a system using OIT's DocFinity® Imaging, DocFinity COLD-ERM, DocFinity WorkFlow, DocFinity IntraVIEWER® (Browser Access), and DocFinity Electronic Signature Server modules.

The system, with over 350 users, has resulted in the following benefits:

- A one-third workforce reduction in the documentation area
- A 95% decrease in the amount of paperwork circulation and distribution
- A reduction in the time to circulate and approve documents in the change control system
- The auditing of all activities in the system, enabling users and administrators to determine what is going on at all times during the review, circulation, and approval process.
- A decrease from days to minutes to process information requests from the Credit department.

As required by regulation, the company notified the FDA regarding the use of this system. Prior to the notification, an independent computer validation company was brought in to perform a critical evaluation of all aspects of the system for compliance with 21 CFR Part 11. This review included design, implementation and validation. It was the opinion of the consultant that the system was in substantial compliance with the regulations. Additionally, the system was examined as part of a comprehensive FDA inspection and no FD 483 comments were made.

The OIT system implemented at this company won the prestigious Process Innovation Award from Kinetic Information, which honors superior applications for their business effectiveness. The winning deployment includes a pioneering content and process management system that utilizes e-Signature and electronic workflow technology in its Internal Procedures Division.

Since 1986, all of OIT's products have been developed in-house for complete, seamless integration and are designed with an open architecture and nonproprietary SQL database compatibility. API's and front-end source code allow a high degree of customization. In addition, OIT's extensive table-based security options protect a company's valuable information.





Whether you are a large corporation looking for a multi-department document management system, or a small firm wanting to eliminate a few filing cabinets, the DocFinity Solution is your solution. Product scalability and total integration gives customers the flexibility to add on, expand and grow in the future without difficulty. OIT's non-proprietary software runs on a wide variety of platforms using industry standard hardware, making it very affordable and easy to implement. Multiple servers are supported.

Since OIT's DocFinity Suite of Document Management software maintains its own database tables, indexes, etc., the user can simply add the OIT software to a current SQL engine on the network. For example, if a client has a Microsoft SQL server in existence, OIT's software can add its index tables to that server. This reduces the cost, backup, maintenance, etc., associated with having yet another SQL server on the network.

database engines

Core components of OIT's DocFinity Solution use Native Mode and ODBC interfaces, which provide a common, vendor-independent method of accessing data from a variety of databases, including Sybase, Microsoft SQL Server, Oracle, Ingres II, and SQL Anywhere. The database connection can be made remotely, on a local server, or both.

workstation requirements

OIT recommends a Pentium with 32 MB RAM running Windows 98 or 64 MB RAM running Windows 2000 or Windows NT with a database connection.

storage devices

OIT software supports all known devices that workstation's can access including WORM, Re-Write, CD-ROM, Virtual Drives, DVD, Jukeboxes, Rapid Changers, RAID, Tape, etc. Drives can be local, departmental, or Enterprise-Wide servers.

network protocols

NetBui, IPX/SPX, Net BIOS, TCP/IP protocols are supported.

server platforms

UNIX, Novell, Windows NT, OS/2 Lan Manager, Microsoft Lan Server, Banyan Vines, Lantastic, Windows for Workgroups, and other servers that provide a shareable resource drive letter are supported.

system scalability

OIT is the single source for ALL document/content management software needs. The DocFinity Product Suite is available in five series: Global Enterprise and Unlimited User Corporate Enterprise, Enterprise, Workgroup and Workgroup "Lite".

OIT's award-winning DocFinity Suite of Document Management Products includes: DocFinity COLD-ERM, DocFinity Imaging, DocFinity Workflow, DocFinity IntraVIEWER (Browser Access), DocFinity Hierarchical Storage Manager (HSM), DocFinity Print/Fax Server. OIT has gained prominent industry recognition by organizations such as AIIM, Doculabs and Kinetic Information. OIT's DocFinity Suite of Document Management Solutions enables people to be more productive and makes information more manageable.

Optical Image Technology, Inc.

www.docfinity.com