



Alinion Sentinel

Document Lifecycle Management

Anytime Anywhere Access to Documents —

No matter if you are in the lab, factory floor, at home or on the road, your documents are available to you 24 hours a day, seven days a week.

Take Control of Documents —

Completely schedule, manage and monitor the development and revisions of documents. Collaborate with consultants, partners and suppliers, giving them strictly controlled access to specific documents.

Revision and Change Log Management —

Track changes to documents and revisions. Maintain a complete history of document usage and version.

Directly Link Documents to the Policies and Procedures Running Your Business —

Convert shelf-ware and binders into active documents that directly link to the processes they are intended to manage and monitor.

Take Control of Your Document Management Program

For many organizations, document management is an expensive and time-consuming challenge. Legacy document management systems are very expensive to acquire, costly and time-consuming to implement and require significant internal resources to maintain and manage. Nevertheless, the life science industry requires all companies — regardless of size or complexity — to effectively and efficiently store and manage the hundreds of corporate policies, legal documents, operating procedures and collaborative documents that drive the day-to-day business operations.

With **Alinion Sentinel™**, your company can easily meet the challenges and requirements of document management *and* improve the way your business is run. Alinion Sentinel is a cost-effective and easy-to-use solution to create, revise, manage and store all of the documents supporting your business operations. With our software-as-a-service web-based solution, you can quickly implement a true-enterprise document management solution at a fraction of the cost of a legacy alternative.

And, because of Alinion Sentinel's innovative technology, your organization can not only manage documents in a powerful and robust repository, they can integrate the requirements outlined in those documents directly to those procedures, projects and policies they are designed to govern.



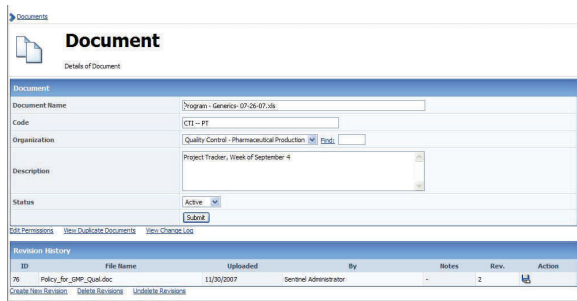
Managing the Life Science Document Lifecycle

Alinion Sentinel offers a powerful central repository system for document control of all operations across your life science business, from GxP monitoring to QA to training or validation. Alinion Sentinel is a comprehensive solution for managing the entire Life Sciences Document Lifecycle. It controls and manages, secures and protects and organizes and stores all documents developed, revised and published. In addition, Alinion Sentinel stores and manages any document type, including drawings, graphics, narratives and pictures.

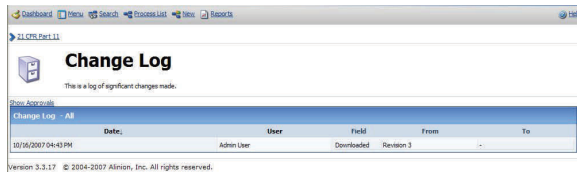
Alinion Sentinel provides full document management functionality. It limits access to authorized users and organizations; assigns, monitors and schedules work relating to document development and updating; controls revisions; provides change logs for status and approval; allows filtering and query for visibility; supports collaboration; and provides an organization and structure for document management not found in other solutions.



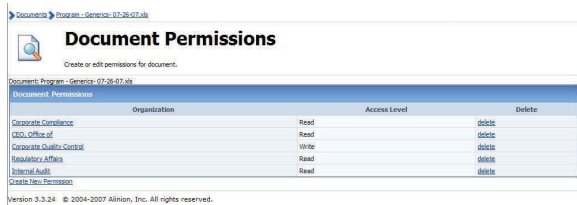
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Alinion's document management capability provides comprehensive control and management throughout the lifecycle of development, revision, training or governance process. This includes searching documents by title, description or organization.



Sentinel keeps a complete change log record of initiation, revision and approval.



Views and access can be restricted by process, organization or role. Sentinel features a powerful permissions manager that grants rights to read or write.

Secure and Protect

Document Access — Sentinel manages access to documents and folders through its powerful roles and permission function as well as by process and organizational permissions. This ensures that only those authorized can see documents in the system. In addition, access is further limited by read-only and write permissions.

Signature and Approval — Sentinel provides a password driven electronic signature and approval of document status, that includes a client configurable reason for signature. Signatures are date and time-stamped and can be given to a specific document assignment, document folder or a task

A Comprehensive Document Management Solution

Control and Manage

Revision Management — Sentinel provides automatic document revision control to ensure that only the current version of a document is available. Each time a new revision is created in the document library, the processes containing the document are updated so only the current version is available to the user. The document history shows the current version as well as preceding versions.

Audit Trails — Comprehensive audit trails are created each time a document is loaded and revised. Sentinel identifies the user uploading the document, as well as date and time. It also notates that changes have been made.

Easy to Search — Sentinel's powerful query and filtering functionality is leveraged in the document management. Users can quickly search for documents using code, title, keywords, organization and process. Process lists can be organized to view documents attached.

Assignment Management — Document development and revision is managed by Sentinel's powerful scheduling and assignment management functionality. Specific owners can be assigned to develop and review and tasks can be sequenced according to defined document practice. Status of document development and revision process is tracked on the dashboard and with Sentinel's reporting functionality. Overdue notices to process chain of command are automated.

Collaboration — Using roles and permissions, documents can be shared throughout the lifecycle process with authorized users from both within and outside of the organization. Sentinel's anytime, anywhere web-based access promotes collaboration with outside consultants, outsourcers and advisors.

Status and Tracking — Sentinel provides visibility into the status of document development and revision processes. Notifications are automatically sent when status conditions change.

Organize and Store

Manage Different Document Types — Sentinel manages document types at multiple levels throughout the solution. Users can create and attach non-library documents to any process component, providing quick reference to procedures, policies and programs. In addition, Sentinel accepts the management, routing and storage of any type of document that can be created on a PC.

Gating and Relationships — Sentinel's innovative process management technology allows users to create relationships and dependencies between documents and processes. For example, an SOP document may require new training. Sentinels process relationship will inform users when dependencies are not being met.

Document Folders — Users can organize documents into group folders, providing the ability to move or copy as well as uniquely organize documents. This is especially beneficial when developing or revising within the document lifecycle process. Documents can be reviewed and approved and even moved among folders, processes and libraries.



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Document ID	Description	Organization	Uploaded	Notes
Document 58 - CCA - 01 - 21 CFR Part 11	Final Rules, CFR Part 11	Regulatory Affairs	10/16/2007	Amended with new FDA rules
Document 46 - CTI - APQC - Approval for Personnel for Operational Qualifications.pdf	Approved September 1, 2007	CTI Client Services	09/07/2007	
Document 47 - CTI - CSV - Control System Verification.pdf	Approved September 1, 2007	CTI Client Services	09/07/2007	
Document 49 - CTI - EL - ESD Control Plan.pdf	Approved September 1, 2007	CTI Client Services	09/07/2007	

Sentinel's powerful reporting engine allows authorized users to quickly create dynamic real-time reports on the status of documents stored in the repository. The reporting engine creates reports with just a few clicks of the mouse on every type of data and activity in the system.

ID	Code	Process Code / Document Name	Size	Rev.	Uploaded	Show
24	GENEX03	2305.402.2 - QC - Review Existing SOP	1,494,298	1	07/20/2007	🔗
45	GENEX04	1985.005.4 - QA - Audit QC Procedures - 0702	1,157	1	08/08/2007	🔗
23	GENEX05	2305.402.2 - QC - Review Existing SOP	11,380	1	07/20/2007	🔗
57	GENEX PROCESS UPDATE 9-07-07	CTI - Genex CRM SDC Writing	24,064	1	09/07/2007	🔗
14	SPIL03	SPR-01-003 - RI - Medical Incident Process - Lafayette 2007-06-23	32,256	1	07/12/2007	🔗
9	SOP 1.2.456	2305.402.3 - RI - Develop new SOP - Plasma Refrigeration & Storage	24,064	1	07/10/2007	🔗
10	SOP 1.1.234.2007	2305.402.4 - RI - Review Existing SOP - Plasma Collection Procedures	24,064	1	07/10/2007	🔗
17	GENEX09	002 - 1 - Check & Test New Employee	48,608	1	06/12/2007	🔗

Sentinel links documents to the processes they directly control and govern. Users see only the most current revision of a document, meaning they are always working from a correct version. In addition, documents can be attached to processes, controls, events, tasks and tests, providing easy-to-access reference to work being done.

Transform Your Business Maturity Model

A key benefit of Alinion Sentinel is that you directly link the documents managed in your repository with the processes they are intended to manage. Documents don't just reside in a repository; they become an active and dynamic operational tool for the policies and procedures they regulate. For small and middle-sized organizations, Alinion Sentinel provides the necessary discipline for integrating documents into process, thereby setting up your organization to meet the stringent engineering and operating requirements of a heavily regulated industry.

Easy-to-Use and Low Cost

Alinion Sentinel is designed for all users in your organization. Our scheduling and task management make it easy to quickly respond to document management requests — from creation to edit to approval to implementation. And because Sentinel is an on-demand and hosted service, there is no impact on your IT department. We manage all the maintenance and servers, so there is no need to have assign your IT staff to support new applications and hardware. Sentinel is served from a SAS 70, Type II data center that meets the highest standards for security and access protection to your data.

Sentinel is subscription priced. Your service costs are based on a low-cost monthly platform fee plus the number of actual users participating in your document and process management initiatives.

Unlike most legacy document management systems, Sentinel is easy to use and not costly to implement. Our innovative process management methodology means you can begin using the document repository and start managing processes within a matter of days.

About Alinion™

Alinion empowers you to dramatically improve and simplify how you manage and monitor the documents and processes controlling your regulated business. Our innovative Alinion Sentinel software-as-a-service helps you quickly **take control now** by improving efficiency, reducing operating costs, enhancing visibility and consolidating information. It is easy to use and cost-effective to run. Sentinel integrates powerful document control with process management, providing you with a closed-loop system for continuously improving how you run your business.

For more information, contact us at

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