

## Overview

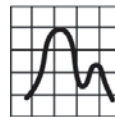
The *STATISTICA* Document Management System is a complete, highly scalable, database solution package for managing electronic documents.

The product enables you to quickly, efficiently, and securely manage documents of any type (e.g., find them, access them, search for content, review, organize, edit [with trail logging and versioning], approve, etc.).

It is specifically designed to ensure compliance with FDA 21 CFR Part 11 regulations, Sarbanes-Oxley legislation as well as ISO 9000, 9001, 14001 documentation requirements.

The key features include:

- \*Extremely transparent and easy to use
- \*Flexible, customizable (optionally Browser/Web-enabled) user interface
- \*Electronic Signatures
- \*Comprehensive Auditing Trails, Approvals
- \*Optimized Searches
- \*Document Comparison Tools
- \*Security
- \*Satisfy the FDA 21 CFR Part 11 Requirements
- \*Satisfy the Sarbanes-Oxley Legislation Requirements
- \*Satisfy ISO 9000 (9001, 14001) Documentation Requirements
- \*Unlimited scalability (from desktop or network Client-Server versions, to the ultimate size, Web-based worldwide systems)
- \*Open Architecture and Compatibility with Industry Standards



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## Compliance

FDA. The general requirements put forth in the Code of Federal Regulations (CFR) Title 21 Part 11 specify what a business needs to do in order to maintain electronic records acceptable for submission to the FDA (Food and Drug Administration).

Sarbanes-Oxley Legislation. The recent Sarbanes-Oxley legislation imposes new, extensive reporting and record keeping requirements on all publicly-traded companies and mandate that Executives of those companies take personal responsibility for the procedures of collecting data for the company's financial Reports and for the integrity of their contents. In order to comply with the requirements, companies need flexible software systems that facilitate record keeping and document management in a secure and efficient manner.

ISO. Guidelines for manufacturing in general (often collectively known as ISO 9000 standards) have been published by the International Organization for Standardization (e.g., see ISO 9001 4.5: Document and data control; also ISO 14001, Ch. 4.5.5.).

## Compatibility

Integrates with all *STATISTICA* products. *STATISTICA* Document Management System seamlessly integrates with all *STATISTICA* products, from desktop and network versions, to enterprise-wide installations such as *WebSTATISTICA*-based worldwide installations or *SEWSS* (for process analysis and quality control/improvement). You can easily access all its functionality from within your *STATISTICA* projects (e.g., all analysis projects, data mining, text mining, reporting, etc.) where directing your reports or data sets to the secure repository of the *STATISTICA* Document Management System is as easy as simply saving a file because your authentication can be based on your initial log-in into the system, so no entry of additional passwords is necessary. You can also build the functionality of the *STATISTICA* Document Management System into your shortcuts, automated *STATISTICA* applications, and other custom systems designed to simplify your work and enhance productivity.

Stand-alone, highly compatible application. It can also be used as a stand-alone system, or (thanks to its COM and SOAP-based architecture) called from other applications, integrated into existing systems, or expanded by adding custom functionality.

Compatibility with other standards. Please also inquire about the compatibility of *STATISTICA* Document Management System with the Open Document Management API (ODMA) standard, and the interfaces and support for the Web-based Distributed Authoring and Versioning (WebDAV) standard.

## Two versions

An Enterprise Version and an Entry Level version (designed for smaller groups of users) of *STATISTICA* Document Management System are available.

The Enterprise Version can be deployed in one of two ways depending on whether the user needs to build the respective functionality into an existing database system: Either (a) as a stand-alone complete application (optionally as part of *STATISTICA* Data Warehouse) driven by a high-performance general database engine (based on Microsoft SQL Server), or - (b) in case integration with an already existing database infrastructure or data warehouse is preferred by the customer - as a database schema (effectively a virtual database) compatible with most industry standard database management systems (such as Oracle, MS SQL Server, Sybase, Informix, or DB2), and easily deployed as part of your existing infrastructure. *STATISTICA* Document Management System will always seamlessly integrate into your existing database or data warehouse infrastructure and your security management system.

A smaller version *STATISTICA* Document Management System, Entry Level) recommended for smaller installations (usually with 5 to 10 simultaneous users, depending on the volume of their work), is also available. The Entry Level version does not include (or require) a high performance, scalable database engine, because it is based on a fixed database management component built into the product, and therefore, it is more cost effective when the volume of your work does not require installation of a large scale database system. It is still a fully functional, secure, and large capacity document management system, however. Also, it can be easily converted later - as your needs grow - into the fully scalable Enterprise Version (see above), preserving all its previous contents, indexes, users' access privileges, etc.

Overview and General Features:

How the *STATISTICA* Document Management System Works

To satisfy the diverse functionality and security requirements of various types of users, *STATISTICA* Document Management System implements a set of options to manage documents in a flexible and secure database.

*STATISTICA* Document Management System enables you to save documents (from within *STATISTICA*, *WebSTATISTICA*, or its stand alone console) to a secure repository database. Its self-explanatory user interface allows you to easily perform all document management operations (from any computer connected to the network or (optionally) via the Internet).

Most document types can be automatically maintained both in (a) the archival, review-only (non-editable) PDF format, featuring the appropriate electronic signatures, and also (b) in the respective editable ("source") format allowing the user with the appropriate access privileges to create new, modified versions. None of the edits or changes, however, will ever overwrite either the archival review-only, or the source files of the previous version - they will only add a new pair of files to the repository.

Strict security via electronic signatures (compliant with 21 CFR Part 11 and Sarbanes-Oxley Legislation requirements) is enforced, and different groups of users can be authorized to create, edit, or review documents in different parts of the archive.

Documents in the document archive cannot be deleted by end-users, other than using a designated process accessible only to the administrator with the top level access privileges. Every time a document is edited, a new version is created and logged with annotations (meta data) to identify the time and the author of the modifications, and other information (either optional or required by the local configuration).

Various options are available to control how far back in time a complete history of versions of documents is maintained (e.g., you may want to archive versions of documents that are older than 10 years); the program can also be configured so that no information (versions of documents) is ever discarded.

Documents (e.g., containing results from analyses) can be locked, to prohibit any further editing or creation of new versions.

Approval trail requirements can be established, so that documents must be reviewed, approved, and signed (via electronic signatures) by designated supervisors before they can be placed in designated parts of the repository.

A complete auditing trail of all document edits is automatically created, and can be printed or saved in electronic form, for submission to regulatory bodies or agencies.

Backup of the specific segments of the repository (e.g., all documents not older than 7 days) can be performed.

To satisfy formatting requirements for electronic submission of records, various options are available for generating reports in PDF and XPORT file formats (see FDA "Guidance for Industry: Providing Regulatory Submissions in Electronic Format - General Considerations")

Ensuring Security and Compliance

*STATISTICA* Document Management System is designed to deliver not only a flexible, high-performance system to manage your documents in a way that will increase your productivity by facilitating access to and management of crucial information, but also to ensure security and compliance with the requirements of regulatory agencies (e.g., FDA 21 CFR Part 11, Sarbanes-Oxley Legislation, and ISO 9000).

Security, Electronic Signatures

The *STATISTICA* Document Management System requires valid passwords to contain more than 6 letters, and not to be of a "common" type (e.g., "111111" is not allowed).

Passwords can be configured (by the administrator) to expire, so that users are forced to change passwords at regularly scheduled intervals.

The system applies automatic user-lockout and e-mail notification of the administrator(s) when a certain number of attempts is made to log into the system with the wrong password.

*STATISTICA* Document Management System offers groupware functionality, supports workgroups, and allows you to define users and groups of users with specific privileges, such as the permission to create documents, edit documents, review documents, approve documents, and so on.

Version Control and Audit Trails

In *STATISTICA* Document Management System "everything" is documented and traceable, which means for example, that documents are never deleted (unless the system is configured to retain only a fixed-length document history, e.g., only documents and version no older than 10 years old). When a document is edited, then a new version of that document is created, properly authenticated, and annotated with electronic signatures. Authorized and authenticated users may be required to explicitly "check out" the respective documents from the repository, and check new versions into the repository with notes and documentation regarding the nature and purpose of the edits.

On check in, the program can be configured to perform the configuration-specific verification and documentation maintenance operations. For example, it may require the users to complete a check-list or a custom form, stating the purpose of the edits or a brief summary of editing activities. The system is fully programmable during installation, so that custom reporting, annotation, signatures, or other requirements associated with the creation or editing of documents can be enforced.

Summary options are available to allow authorized users to review the complete audit trail for requested documents.

The "length" of the auditing trail (i.e., for how long back in time different versions of documents are stored) can be configured. If desired, the different versions of documents can persist indefinitely.

If a backup function is not automatically performed as part of the standard maintenance of an existing database installation or data warehouse (where *STATISTICA* Document Management System stores the repository of all documents and versions), the *STATISTICA* Document Management System can perform regular system backups.

Various options are available to perform simple or complex searches of the documents and different versions of documents managed by the *STATISTICA* Document Management System.

Recommended (and FDA Approved) Archival Document types

One of unique strengths of the *STATISTICA* Document Management System is its ability to store and exchange information in various file formats, including your proprietary formats, allowing it to share information internally in ways that are most convenient for your specific organization, as well externally with practically all industry standard applications or protocols for information exchange.

Most importantly, the program allows you to save results reports as PDF files, and data files or results tables in XPORT files. These formats are the preferred file formats, recommended in the FDA "Guidance for Industry: Providing Regulatory Submissions in Electronic Format - General Considerations."

Open Architecture System

Like the entire *STATISTICA* system, the *STATISTICA* Document Management System program is completely programmable, and all of its functionality is accessible to other applications; thus the system can be customized to accommodate highly domain-specific tasks, and can also be integrated seamlessly into existing systems for data and document management.

Please also inquire about the compatibility of *STATISTICA* Document Management System with the Open Document Management API (ODMA) standard, and the interfaces and support for the Web-based Distributed