

# Features

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## General aspects

SOP-Speed is a program suite for the planning, creation, maintenance, reliable management and archiving of QM documentation in **QM systems of any sort**. The software offers extensive safety solutions, for both paper-based and purely electronic document distribution.

The system offers genuine multitenancy (with any number of clients) and the scale of the program can be adjusted to different numbers of employees, different company sizes and to one or several separate company sites.

SOP-Speed works as a client-service system, with central data archiving (file server) and the possibility of exporting pdfs. There is an **extensive set of validation routines**, including CRC32 checksum testing, and this provides the greatest documentation traceability with a minimum of maintenance effort – even for external agencies. Browser-based solutions are also available for pure document distribution.

The main area of use is QM documentation in technical, medical sciences or pharmaceutical areas (certification, accreditation, orientation towards GLP and FDA instructions), with an intermediate or high number of documents and with high demands on the safety and traceability of the documentation.

To ensure the **greatest possible documentation safety**, the program is self-sufficient. **No other applications, database solutions or additional packets are needed** in principle for QM documentation! For this reason, there is no need to revalidate QM documentation, e.g. after MS Office up-date cycles!

***The main activities of QM documentation are subsumed in the following function modules:***

## PRESENTER-Module

Module for the electronic provision on QM documents, including supplemental documents. With functions to confirm acknowledgement (with electronic signature) and for the employee suggestions system or for continuous improvement.

Any number of workplace- or user-specific sections of the documentation can be displayed as so-called „collections“. In addition, structured document groups can be provided by export in the HTML or PDF formats.

## VIEWER-Module

Module for rapidly viewing individual documents.

*For a wider set of functions für document distribution see also the PRESENTER-Module*

## CREATOR-Module

In the strictest configuration, SOP-Speed even works on the draft phase of documents, with an internal editor in the program, for documents, forms and electronic journals. The program has its own documentation format, which is protected against manipulation. All QM-relevant information and meta-information is stored in this.

*External documents such as .doc-, .xls- or .pdf-files can be incorporated (mantled).*

## INSPECTOR-Module

Module for the traceable checking and approval of documents with electronic signature (safety standard in accordance with customer's instructions).

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## ARCHIVE-Module

This module includes the software's database, with extensive sorting, listing and search functions (editable SQL queries). It provides the necessary document and user information for the other function modules, archives and administers the documents and offers additional maintenance functions to the system administrators.

## CONFIGURATOR-Module

Module at the highest password level to define the structural QM instructions, document types and general program functions.

## MANAGER-Module

Module for the QM Manager. For example, user assignments (such as initiating document revision or checking documents) can be controlled and monitored here, user rights assigned and acknowledgement and resubmission lists can be kept.

In addition, the module offers numerous validation routines for overall QM documentation.

## Safety-Aspects

The program offers numerous functions to support the **continuous improvement process (CIP)**, for example, the accompanying letter for suggested revisions. The steps in the program follow the **PDCA scheme** (Plan-Do-Check-Act). **Interactive checklists** monitor even the draft phase of documents. Electronic document distribution offers the **automatic display of additional information** („New version in preparation“, „Documents which came into force within the last 30 days“ etc.). If individual documents are released as pdfs, they are automatically labelled (e.g. uncontrolled copy“). The display module Viewer is installed separately (e.g. for customers, monitors etc.) and provides the possibility of **specifically providing documents and metadata, without transmitting the content of the database!** Numerous preselected filters (according to status, key components etc.) facilitate **rapid document access**.

Integrated user administration with password hierarchy and timer (compulsory renewed log-in) regulates all authorisation (e.g. process, check, release) in the document flow within a matrix. The access is automatically recorded, giving the user, date, time and type of change (**document record/audit trail/log file**).

The program has a special file format, to guarantee **self-sufficient, long-term archivable QM documents, protected from unauthorised access**. It avoids „undocumented“ process steps in documentation, as may occur if MS-Office elements are involved. All content elements can also be exported in text format (MS-Word etc.) or as pdfs. Printing functions can be specifically blocked for each document type and **uncontrolled print-outs can be automatically labelled**.

**Document/file integrity is verified with CRC32 checksum testing.** This also considers integrated electronic attachments and added documents of external origin. The program automatically stores safety copies of all documents. Critical text operations (permissible typefaces, type sizes) can be set centrally.

**Numerous validation routines** are available, including testing for inconsistent document status after manual changes (Version 4 effective, but Version 3 in draft), for the completeness of supplemental documents and for database integrity. The report function „System status“ is an important validation document.

(Changes are possible as a result of technological progress).