



Document Management (*Base System*)

The Document Management base portion of TMSWeb is designed to solve costly problems surrounding compliance to quality standards and regulations with regards to managing documents. Below is a list of popular features.

MAJOR FEATURES	SUMMARY OF FUNCTIONALITY
Federal Regulations 21 CFR Part 11, ISO and other Quality Standards	Documents are tracked and stored within the TMSWeb database for access control and optional document approval. This feature meets 21 CFR Part 11 (electronic signature and record) requirements.
Document Security	Documents reside on a protected web server and TMSWeb provides extensive control over accessing documents via locations and user permission groups. Access to prior (archived) versions is available with appropriate rights.
Extensive Document Search Functions	Each user is able to setup a favorite search, use a drill down search or an extensive filter search function. Automatic fill-in while typing for major fields.
Automatic Conversion to PDF	Optional conversion to PDF when publishing documents is available on a per document basis. System will control both the native format and the PDF format for viewing. If using PDF conversion, optional watermark, revision stamping and other PDF controls can be added.
Individual Activity/Task Lists	Via the "My Activities" page, individual users receive activities for different functions surrounding documents such as: reviewing, signing, training and other activities types.
Integration to E-Mail	This feature provides automatic e-mail notification for all activities with optional elevation to department managers and/or supervisors. Automatic e-mail reminders can be scheduled for the following: documents requiring review and approval; training activities; overdue activities with optional elevation to managers. E-mail provides a link to add the activity to your outlook calendar.
Revision Control	Controls and simplifies the entire revision process when making changes to documents. Initial Reviewer, Standard Reviewers and Final Reviewer can be defined for extended routing functions with a checkin/out feature. Standard Approvers and a Final Approver can be defined. Redlining versions are available during the entire process.
Related Documents - Hyper-linking	Ability to assign related or referenced documents which provides easy hyper-linking between documents.
Historical Information	TMSWeb automatically archives prior revisions along with the individuals who approved and reviewed the revision. Access to archived documents is controlled via permissions.
Unlimited Free Use Field Definition	Ability to assign user-definable fields to documents. All free use fields are automatically searchable.
Proactive Review Process	TMSWeb can automatically notify owners when documents require reviewing. Proactive review provides the ability to record the review of a document without changing the revision number.
Multiple Relationships	Relationships to distributions, jobs, employee training, approval signatures, notes, activities, and workflow are easily accessible.
Adding Quizzes	When issuing self-study training on documents, you are able to attach quizzes which require individuals to pass before training records are updated.
Overdue notifications	Activities/tasks are issued either automatically or by administrators. Individuals are sent a reminder if activities are not completed by assigned due dates.
Signature Page	When using PDF conversion, optional signature page displays a visual representation of the electronic approval signatures.
Validation	Validation package (including scripts and execution) is available with IQ, OQ & PQ for meeting FDA requirements.