



MasterControl Submissions Ready™

MasterControl Submissions Ready™ allows organizations to accelerate the preparation and organization of submissions documents utilizing FDA- and ICH-compliant submissions templates in combination with MasterControl's unrivaled document management solution. MasterControl's integrated solution ensures that authors are using the most up-to-date version of a template and that submission documents are securely stored and organized in a logical file structure.

Who Can Benefit from MasterControl Submissions Ready?

- **Manufacturing/Operations:** Rather than wasting time rewriting internal reports for submissions, manufacturing and operations personnel can use MasterControl to reuse documents and author documentation on compliant templates at the correct level of granularity.
- **Medical Writers:** By providing compliant templates and a correct format up front, MasterControl eliminates the need to rewrite reports and other documents for submissions purposes. MasterControl also minimizes revisions by ensuring that each document has a consistent voice.
- **Regulatory:** MasterControl simplifies the search for and inventory of submissions documents. The system automates the routing of documents for approval and provides an easy-to-follow trail of document approvers.
- **Clinical:** With MasterControl, clinical personnel don't have to worry about tearing apart study reports to rewrite them with correct templates. In addition, MasterControl's centralized electronic document repository eliminates the need to search paper archives for trial documentation.
- **Management:** MasterControl can provide a comprehensive solution for any organization regardless of existing in-house capabilities. Whether the organization simply needs training on the system's functionality or requires assistance configuring the system to specific needs, Submissions Ready can be packaged with any level of service and support the organization requires. An organization lacking knowledge of particular requirements that must be addressed can have MasterControl's expert advisory team analyze the circumstances and develop and clearly map out those requirements.

Features and Benefits of MasterControl Submissions Ready:

Accelerated Creation of Submissions-ready Documents: MasterControl decreases the time required to prepare submissions-ready documents by:

- Allowing authors to create new documents using CTD-compliant templates.
- Automatically creating PDFs with bookmarks.
- Enabling cross-functional teams to collaborate on critical documents and accelerate the document author/review cycle.
- Automating the creation of submission folder structures for organizing submissions documents.
- Providing out-of-the-box best practices configuration for clinical trial and submissions documentation.
- Organizing and "pre-publishing" submissions dossiers with no effort.
- Eliminating labor intensive manual processes such as PDF publishing, bookmarking, and table of contents creation.

Unparalleled Services: MasterControl's experts can get the Submissions Ready solution up and running quickly in order to maximize time and resource savings. MasterControl services professionals provide much more than just installation support; MasterControl experts can help build processes, structure file systems, design forms, configure reports, validate, or provide any other support services necessary to reach customer objectives.

Additional Services beyond the Submissions Ready Solution: MasterControl experts can do anything a client needs to reach required objectives. MasterControl can even serve as an organization's training department—whether it is individual training for new employees or educating an entire department on new processes that have been implemented, MasterControl has a solution. Trainees can learn via recordings or in a classroom environment with a live instructor.

MasterControl is renowned for having industry experts readily available for clients. Preparing for an audit? Struggling with validation? Pitching a big client? Looking for better vendors? Whatever it is, MasterControl's experts have seen it before. Whether it's a long-term consulting relationship or a short-term project that requires management, MasterControl can help.

Connected System: MasterControl ensures that all authors, medical writers, and publishers stay connected. Features of the system include:

- Groups can collaborate on documents and easily view author and time-stamped redlines.
- Outside reviewers can be given access to documents using external links.
- Auto-load network folders make it easy to maintain and monitor the collection of documents from clinical trials. Users can simply drop trial documents into the system and they will be automatically routed for approval.
- The MasterControl Submissions Gateway™ allows for a simple export of organized submissions documents to a publishing solution or consultant.
- MasterControl's Submissions Locker provides a secure repository for the final submission after publishing is complete.

Inclusive Process: MasterControl's secure system allows all participants in submissions processes to work with their preferred applications. The Submissions Ready solution is easy to validate, easy to configure, and easy to expand. Other benefits of the system include:

- Document authors have an approved set of submission documents templates to use for the creation of new documents, even from within Microsoft Office Word.
- Submission managers are provided a folder view that matches the submission project via the MasterControl Organizer.
- Document inventories can be created effortlessly in the Organizer and users can quickly view which documents are approved and which are in draft.
- Clinical staff can easily find all documents associated with a specific study or site using the dictionary-driven metadata and virtual folders.
- Submission managers can automatically export submissions documents to a file share to get the documents to contract submissions publishers.
- Submissions lifecycles can be efficiently managed using MasterControl's Submissions Locker. The Submissions Locker ensures that submissions documents are controlled before and after publication without preventing them from being available for necessary review.
- Scanning and publishing integrations are available.

Components of MasterControl Submissions Ready:

Challenges

Inefficient Data Collection and Tracking: Under a manual process, auditors use paper forms and spreadsheets to collect and track data. They enter the data into an electronic system, a cumbersome task prone to errors.

MasterControl Solution

Efficient Data Collection and Tracking: MasterControl provides an integrated platform for automating, streamlining, and managing the audit process, from preparation and scheduling through execution, collection of observations, verification, and completion.

About MasterControl

MasterControl Inc. creates software solutions that enable life science and other regulated companies to deliver life-improving products to more people sooner. MasterControl's integrated solutions accelerate ROI and increase efficiencies by automating and securely managing critical business processes throughout the entire product lifecycle. More than 1,000 companies worldwide, ranging in size from five employees to tens of thousands, rely on MasterControl cloud solutions to automate processes for new product development, clinical, regulatory, quality management, supplier management, manufacturing and postmarket surveillance. MasterControl solutions are well-known for being scalable, easy to implement, easy to validate and easy to use. For more information, visit www.mastercontrol.com.

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