Managing the Document Lifecycle from Creation to eSubmission and Beyond

White Paper

Complete Document Lifecycle Management

In order for businesses to stay on top in an Internet-paced environment, they must work smarter and more efficiently. The inability to effectively manage complex documentation to meet regulatory compliance and new product approval - with increasing regulatory demands - are major factors in slowing the time it takes to bring a product to market. These delays cost companies hundreds of thousands of dollars in potential lost revenue.

The 1997 release of the final ruling of 21 CFR Part 11 outlines FDA guidelines for accepting electronic documentation and electronic signatures. This ruling opened the door for the life sciences industry to bring products to market faster by allowing electronic submissions for New Drug Applications (NDAs) and Biologics License Applications (BLAs).

In an effort to support life sciences organizations' efforts to benefit from the esubmissions process, MasterControl Inc. has teamed with industry-leading submission software vendors to provide a complete solution that addresses the entire FDA process from creation to esubmission. The result of this partnership is a software system that helps companies easily manage, assemble and publish documentation for fast, reliable and completely compliant submissions.

Managing the document lifecycle from creation to submission

There are two main areas that need to be addressed when companies tackle the time consuming and resource-intensive task of developing and bringing a drug or biologic to market.

The following includes a detailed description of how the integration of MasterControl offers life sciences companies a complete electronic change management and publishing system.

MASTERCONTROL DOCUMENTS:

Regulatory Compliant Document Control & Collaboration

When regulated products are being developed, the entire process – from research and development to clinical trials – must be documented in detail. With the MasterControl Documents, documentation can be managed and maintained entirely in electronic fashion from the time a document is created and approved until it is published. MasterControl Documents The capability to distribute controlled documentation on a secure network database or website rather than on 50 sets of 3-ring binders distributed company-wide. Although this represents a significant saving of paper, that is only a small benefit compared to how the system expedites document approvals, eliminates man hours wasted updating binders and provides instant document distribution. Following is a detailed description of how MasterControl Documents effectively and efficiently facilitates the documentation process:

- ***Electronic Signature Flexibility on Network or Internet***
  MasterControl Documents implements electronic signatures with separate password and approval IDs to ensure security and integrity of controlled documents. Signature manifestations are built into the software including first name, last name, date, time and signature intent.

- ***Audit Trail and Reporting Functionality***
  All of the FDA reporting, auditing and electronic signature elements for 21 CFR Part 11 compliance are met within MasterControl Documents. An audit trail of every action, for the life of the document is available to satisfy internal and external monitoring and regulation needs.

- ***Speed Up All Document-Related Processes***
  Time is money. In a regulated environment, the process of document approval, notification, and distribution has added weeks, if not months, to implementing change within a company. MasterControl Documents can dramatically cut the time it takes to get documents changed, approved and distributed while maintaining compliance with GxP requirements. Reaction time to problems can cut waste and improve output. A reduction in document approval can dramatically reduce the time it takes to bring a product to market.

- ***Computer Systems Validation Plan and Implementation***
  MasterControl has developed a comprehensive validation test plan to perform necessary validation steps within your facility (IQ/OQ/PQ). Often, consultants must be hired to write, test, and validate a company's software implementation. This can be very expensive. Validation plans for MasterControl and its family of software applications can be acquired for a fraction of the cost typically spent on validation. The professional services staff at MasterControl can also assist with onsite validation.

- ***Submission - Organization***
  After complete document control is achieved in a 21 CFR Part 11 compliant manner, documents must be organized or assembled in the acceptable format mandated by each FDA agency MasterControl Documents supports the templates that conform to each agency format and help streamline the dossier creation process. Formats include:

  - New Drug Applications (NDA)
  - Biologic Licensing Applications (BLA)
  - Common Technical Document (CTD)
  - Investigational New Drug (IND)

  MasterControl Documents allows users simple drag and drop capabilities of approved documents required to be inserted into the proper folder.

- ***Submission - Assembly, Delivery and Publishing***
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  This is when the integration of MasterControl with industry esubmission software comes together.

Esubmissions, document assembly, delivery & publishing

Leading esubmission vendors provide document assembly, delivery and publishing solutions for the process of publishing complex regulatory documents and submissions for the life sciences industries. These solutions provide advanced publishing and secure delivery required to meet business critical deadlines and guidelines for reports and submissions.

- ***Maintaining Document Integrity***
  When putting together a report or submission, time and accuracy are of the utmost importance. Time should be spent on what is most important – quality of content. Esubmission software ensures the quality and integrity of the source documents so that they are never altered. The publishing attributes and enhancements are created as overlays to existing documents allowing preservation of original content for later use or reference. By preserving document integrity, quality control and quality assurance is made easier before submission time.

- ***Accommodate Late Changes***
  Late changes to documents are guaranteed to happen. When publishing manually, late changes can be daunting under the pressure of a deadline. Esubmission software allows for these changes and accommodates resolution of hyperlinked cross-references, page numbering and other publishing attributes quickly and efficiently - ensuring accuracy under time constraints.

- ***XML Publishing***
  Getting data created in multiple formats standardized across borders - whether electronic borders or global borders – is the key to efficiency. XML format provides a gateway for this standardization. Esubmission software has the ability to publish your XML content in various formats, including PDF – the file format requested by the FDA.

- ***Template Capabilities***
  Regulatory agencies frequently revise guidelines for reports and submissions in order to make the assembly and review process easier, while still maintaining the strict standards for the approval. Keeping up with these changes is a challenge. Esubmissions software allows for the use of templates approved by CDER or the creation of company-specific document templates. Changes to templates are an easy adjustment made by the administrator, so a report or submission will never be left on hold waiting for an entire software upgrade due to guideline changes.

- ***Cross-Referencing***
  Cross-referencing is one of the fundamental tasks of preparing a submission. Often, it is a moving target as different submission sections are drafted in parallel. When part of a particular document for submission is not written, it is complicated to make a reference to that document. Esubmission referencing software creates hyperlinked cross-references between documents and volumes that span the entire submission. Resolution can be implemented at any time throughout the document creation process. This means references to an uncreated document can be updated with the click of a mouse once all parts of the submission are complete.

- ***Document Output***
  With FDA's acceptance of electronic submissions esubmission software can enable electronic output of hyperlinked PDF file sets, consistent with FDA guidelines for distribution on CD-ROM or the Web. This allows a smooth transition from paper to electronic to meet FDA requirements.

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