Freedom to Write: New Tools for Streamlining Document Development From Start to Finish

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Medical writing is a dynamic and evolving field, and writers need to keep up with changing regulatory submission guidelines, style/formatting conventions, and pharmaceutical company mergers and acquisitions. These ongoing shifts impact document content, structure, and style. Now, more than ever, streamlining document development is critical for success. Fortunately, today, medical writers have an expanding array of tools to help address these challenges through the use of artificial intelligence (AI) and automation, integrated Microsoft (MS) Word toolbars, cloud-based options, and more. This article presents new tools and programs that are emerging as solutions for boosting accuracy and efficiency during document development.

Automating aspects of document creation and quality control (QC) review can save time and allow medical writers to focus on the science and how the data are described and interpreted. These tools can automate a wide range of tasks, including

- creating standard text and tables,
- running QC on abbreviation lists and hyperlinks,
- managing references,
- enhancing document collaboration, and
- anonymizing sensitive information.

A summary of the resources reviewed in this article may be found in the Table on page 88.

Document Editing

Document editing can present a major time sink for medical writers and involves repetitive, error-prone tasks. Software solutions are emerging that dramatically cut down time spent on these tasks.

Med-Brighter, *Pearce Clinical*, https://pearceclinical.com/
This product is a brand-new MS Word add-in for regulatory medical writers that automates many of the most tedious and time-consuming aspects of creating documents.[1]

- Med-Brighter applies QC algorithms to catch and correct common mistakes made with abbreviations; hyperlinks; bookmarks; tables, figures, and listings (TFL); and more.
- It creates and maintains lists of abbreviations, hyperlinks, section references and headings, and bookmarks, as well as cross references and table captions.
- It automatically generates correctly formatted end-of-text and in-text tables directly from TFL files.
- Pearce Clinical claims the software can reduce the time medical writers spend working on abbreviations by up to 70%.
- Although the current Med-Brighter toolbar is customized for regulatory medical writers, in the future, Pearce Clinical plans to apply similar algorithms to help other medical writers automate work on a wider range of technical documents.

PerfectIt, *Intelligent Editing*, https://intelligentediting.com/
This software is another MS Word add-in program for all medical writers that boosts accuracy and efficiency before, during, and after document creation.[2]

- PerfectIt operates on the basis of consistency checks, allowing the user to enforce style rules, locate undefined abbreviations, customize in-house styles, and more.
- It uses the Word sidebar in tandem with the document as an interface to accept or reject suggested changes, which provides context so the user can quickly decide whether the change needs to be made.

DocQC, *GenInvo*, https://www.geninvo.com/
This program offers a suite of authoring tools for regulatory medical writers, including DocQC, which automates QC checks and document/data anonymization, respectively.[3]

Table. Selected Automation Tools for Medical Writers

Category	Tool	Fee	Company	Capabilities
Document Editing	Med-Brighter	Yes	Pearce Clinical	• QC: abbreviations, hyperlinks, bookmarks, and TFL • Creates and maintains tables and captions, LoA, hyperlinks, section references, headings and bookmarks, and cross references
	PerfectIt	Yes	Intelligent Editing	• Customizes and enforces style rules, locates undefined abbreviations • Uses MS Word sidebar as an interface to accept or reject suggested changes
	DocQC	Yes	GenInvo	• Real-time or batched checks within document and from source documents • Includes data sets, TFL, patient safety narratives, CSRs, risk-management plans, and publications
Authoring	DocXtools	Yes	Litera Microsystems	• Ensures style and formatting compliance • Inspects for PDF generation • Organizes/modifies all abbreviations • Fixes deviations from best practices • Automated ToC, appendix, cross-reference, figure, and table generation
	Sage Submissions	Yes	Sage Submissions	• MS Word–based templates • Enforces the global eCTD submission standard and supports FDA CDRH and GHTF STED presubmissions and submissions
	StartingPoint	Yes	Accenture	• "Author" MS Word–integrated toolbar automates compliance with ICH and regional structure and formatting requirements • >450 eCTD and >100 medical-device templates
	Regulatory Document Templates	No	TransCelerate BioPharma	• Suite of authoring templates: CPT, CSR, and CSAP • Streamlines the clinical development process across stakeholder groups
	NLG Tools	Yes	Yseop	• NLG solutions • For CSR, PSN, and PV
Document Collaboration	SmartDocs	Yes	36Software	• Cloud-based, integrates with MS Word and SharePoint • Share content across documents and authors, create and centralize documents from existing content, and centralize documents • Content maps, customizable document wizards, smart searching across documents and users, usage tracking, bulk publishing, etc
	Cloud Collaboration	No fee up to 10 GB storage	Box	• Cloud-based • Safely share content within and outside of the organization and across any device • Comment and assign tasks directly within files • Seamless, automated workflows • Integrates with >1,400 apps
	Vault-RIM RIM Suite	Yes	Veeva	• Cloud-based • Workflow includes submission-document management, product-registration management, health-authority correspondence and commitments, and submission archiving
	PleaseReview	Yes	Ideagen	• Cloud-based, secure for internal and external collaboration • Coauthoring and redaction capabilities, life-cycle document reviews, comments, changes, and discussions for all stages of the document
Data Anonymization	Shadow	Yes	GenInvo	• Automates data and document anonymization • Risk-analysis tools, assessment of data utility after de-ID, generates redaction proposals and anonymization plans and reports • Stores and applies de-ID strategies in metadata repository at multiple workflow levels, generates performance metrics, etc
	ClinGenuity Redaction Management Service	Yes	Synchrogenix	• AI-enabled NLP solution for automatically identifying and redacting sensitive information • Access to expert consulting on regulatory policy and guidance
Reference Management	EndNote	Yes	Clarivate Analytics	• Integrates with MS Word • Customizable formatting, reference organization/storage, and search tools
	Mendeley Cite	Yes	Elsevier	

AI, artificial intelligence; CDRH, Center for Devices and Radiological Health; CPT, Common Protocol Template; CSAP, Common Statistical Analysis Plan; CSR, clinical study report; eCTD, electronic Common Technical Document; FDA, US Food and Drug Administration; GHTF, Global Harmonization Task Force; ICH, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; ID, identification; LoA, list of abbreviations; MS, Microsoft; NLG, natural language generation; NLP, natural language processing; PDF, portable document format; PSN, patient safety narrative; PV, pharmacovigilance; QC, quality control; RIM, Regulatory Information Management; STED, summary technical documentation; TFL, tables, figures and listings; ToC, table of contents.

- DocQC conducts checks on source information within the document and in other documents (eg, data sets, TFL, patient safety narratives, clinical study reports [CSRs], risk-management plans, publications) in real-time or via batch/scheduled execution options.
- It generates QC reports detailing failed checks and performance-metrics reports to track document quality and processing.

Authoring

Medical writers can also benefit from document templates and other tools that enforce standardized style and content.

DocXtools, *Litera Microsystems*, https://www.litera.com/products/life-sciences/docxtools-for-life-sciences/
This software package accelerates regulatory document drafting and review by automatically enforcing customizable standards for content, style, and format.[4]

- DocXtools automates document QC review, style, and formatting compliance; ensures approved symbol usage; inspects for portable document format (PDF) generation; and organizes/modifies all abbreviations in 1 place.
- It identifies and quickly fixes deviations from best practices and finds and fixes phrases that should be avoided.
- It offers drafting tools and automated tables of contents, appendices, cross references, figures, and tables.

Sage Submissions, http://www.sagesubmissions.com/
This product offers MS Word–based templates that enforce the global electronic Common Technical Document (eCTD) submission standard for regulatory medical writers.[5]

- The templates also support all of the US Food and Drug Administration Center for Devices and Radiological Health and Global Harmonization Task Force's Summary Technical Documentation presubmissions and submissions in electronic copy format and enable compliance with global agency guidance and specifications for PDF files.

StartingPoint, *Accenture*, https://www.accenture.com/us-en/services/life-sciences/startingpoint-submission-authoring-suite
This program is a submission authoring suite that integrates into MS Word via an "Author" toolbar for the purpose of speeding up document creation for regulatory medical writers.[6]

- StartingPoint automatically ensures documents are compliant with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and regional structure and formatting requirements.
- It offers more than 450 eCTDs and more than 100 medical-device templates.
- The design is eCTD-specific, with predefined heading styles, fonts, margins, and table formats, and offers preset validation and compliance, including advanced document validation, Physician Labeling Rule functionality, and reference management.

TransCelerate BioPharma, Inc,
https://transceleratebiopharmainc.com/
TransCelerate offers a suite of authoring templates for regulatory writers, including the Common Protocol Template (CPT), Common CSR, and Common Statistical Analysis Plan (SAP).[7]

- The CPT initiative streamlines the clinical development process across stakeholder groups, including clinical trial sponsors, regulators, institutional review boards, and ethics committees.
- Medical writers work within a MS Word ready-to-use CPT for all phases and therapeutic areas, which enhances document structure and content for easier input, review, implementation, and extraction.
- The Common CSR template integrates guidelines from key sources, including the ICH E3 guidance[8] and *CORE Reference*[9] for headings, content, and data, as well as sponsor-specific standards for appendices and TFL.
- The common SAP enables writers to create and seamlessly integrate with the CPT and focuses on information for reporting and disclosure while addressing the ICH E9 draft guidelines on estimands.[10]

Another approach to streamlining document writing is the application of natural language generation (NLG) software. Using AI, NLG tools automate the conversion of complex data sets into written narratives with speed and accuracy. Thus, NLG can be useful for generating text that does not require analysis or scientific interpretation.

Yseop, https://www.yseop.com/solutions/pharmaceuticals
This program is an AI-powered NLG application that automates regulatory report writing.[11]

- The tool offers NLG solutions for CSRs, patient safety narratives, and pharmacovigilance.
- The NLG tool frees up medical writing teams to focus on more writing that requires scientific knowledge/interpretation and strategizing.

Document Collaboration

An increasing array of tools are available to enhance document collaboration and coauthoring.

SmartDocs, *36Software*, http://www.thirtysix.net/smartdocs/features/medical

This cloud-based software integrates with MS Word and enables medical writers of all specialties to share content across documents and authors, create documents from existing content, and centralize documents using MS SharePoint.[12]

SmartDocs features document content maps, customizable document wizards, smart searching across documents and users, usage tracking, bulk publishing, and more.

Box, https://www.box.com/home
This platform helps all types of medical writing teams organize and create content via the cloud.[13]

- Users can safely share content with individuals in and outside of the organization and across any device (eg, desktop, mobile, browser).
- Box enables writers to comment and assign tasks directly within files, quickly shares content with external collaborators, and create seamless, automated workflows.
- The software integrates with more than 1,400 apps, including Office 365, G Suite, Slack, and more.

Vault-RIM, *Veeva*, https://www.veeva.com/products/vault-RIM/
Veeva recently launched Regulatory Information Management (RIM) Suite, another cloud-based collaboration tool for regulatory medical writers.[14]

- Vault-RIM unifies multiple regulatory processes and operations. Submission document management, product registration management, health authority correspondence and commitments, and submission archiving are all built into the workflow.
- This suite helps writers by streamlining stakeholder communication, disseminating the impact of new regulatory guidelines and requests, and improving data quality.

PleaseReview, *Ideagen*, https://www.ideagen.com/products/pleasereview
Ideagen offers a suite of cloud-based collaboration tools, including PleaseReview, document management software for all medical writers that features review, coauthoring, and redaction capabilities for all stages of the document life cycle.[15]

- Collaborating with both internal and external colleagues is equally secure.
- The software enables document reviews, comments, changes, and discussions documented in one place and recorded in a comprehensive reconciliation report.

Data Anonymization

Since 2015, pharmaceutical companies intending to market therapeutics in Europe have had to comply with European Medicines Agency Policy 70, which requires that clinical reports contained in Marketing Authorization Applications be made publicly available for the purposes of transparency and disclosure. Adherence to these rules requires careful data and document de-identification (de-ID), which can require considerable effort. In response, several companies have come up with solutions to automate this process.

Shadow, *GenInvo*, https://www.geninvo.com/shadow/
This software automates data and document de-ID and anonymization in regulatory writing workflows.[16]

- Shadow features risk-analysis tools (eg, determines risk for re-identification), assessment of data utility after de-ID, and generation of redaction proposals and anonymization plans and reports.
- This software stores and applies de-ID strategies in a metadata repository at multiple workflow levels and provides interactive rule application and testing, before and after views, and performance metrics to evaluate the precision/efficiency of strategy application and effectiveness of the de-ID teams.

ClinGenuity Redaction Management Service, *Synchrogenix*, https://www.synchrogenix.com/wp-content/uploads/2018/07/Redaction-Anonymization.pdf
Synchrogenix offers is an AI-enabled technology solution for automatically identifying and redacting sensitive information.[17]

- Natural language processing and natural language recognition are used to accurately identify and call out sensitive information in lengthy documents.
- Users can also benefit from access to expert consulting on regulatory policy and guidance, anonymization methodologies, reports, and agency support.

Reference Management

Finally, for reference management, a plethora of solutions are available. Leading the pack are **EndNote** (*Clarivate Analytics*, https://endnote.com/) and **Mendeley Cite** (*Elsevier*, https://www.mendeley.com/reference-management/mendeley-cite), both of which integrate with MS Word and feature customizable formatting, reference organization/storage, and search tools.

Summary

The last decade has seen immense strides in the development of automation tools for medical writers, and we look forward to the growth of additional solutions in the next decade. This software can save medical writers huge amounts of time while boosting accuracy in our work. Programs like Med-Brighter eliminate the headaches involved in document accuracy and compliance, programs such as StartingPoint ensure template compliance and validation, SmartDocs and other collaboration software streamline teamwork, reference solutions such as

EndNote take care of citations, and data anonymization tools speed up data anonymization.

Tedious, repetitive activities that are subject to error and do not require scientific knowledge or interpretation are finally being automated. These tools promote job satisfaction by freeing up medical writers to do what we do best: write.

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