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Bringing data to life

Document development is our business

Document development for drug makers is time-consuming and resource intensive.

Acumen focuses on building solutions to the myriad challenges associated with writing regulatory documents, including those critical submissions, such as INDs and NDAs/BLAs.

The brains behind the software

Acumen is a team of industry-experienced medical writers and clinical developers who provide top-tier support to drug makers.

We have harnessed our collective industry experience to develop the Smart Document Solution.

What is the Smart Document Solution?

It's a suite of software modules that integrate with Microsoft Word.

The modules include:

- eCTD Templates (integrates with Stylus)
- Stylus (document formatter)
- Electronic Style Guide
- Quality Control Module

What Does the Smart Document Solution Achieve?

Assists drug developers in writing and submitting compliant professional-level documents

Increases the speed and efficiency of writing and publishing teams

Automates time- and labor-intensive editing tasks

Quality Control (QC) Module

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The Challenges

Clean and accurate regulatory documents require informed editorial checklists.

Once developed, it can be difficult to ensure those checklists are consistently applied across all documents.

Under pressure of an audit, many companies cannot show that every document was adequately reviewed per SOP and/or adequate quality control methods.

The Solution – Acumen's QC Module

A cloud-based software available through your Microsoft Word ribbon that allows use of integrated checklists for document review.

Customers can upload their own company's SOP-driven checklists for universal compliance.

For those looking for guidance, comes with proven, best-practice editorial checklists tailored to specific documents:

- ✓ **Protocols**
- ✓ **Protocol amendments**
- ✓ **Investigator brochures**
- ✓ **Clinical study reports**
- ✓ **Manuscripts**

- ✓ **Patient narratives**
- ✓ **IND/NDA/BLA summary modules**
- ✓ **Informed consent forms**
- ✓ **Nonclinical reports**
- ✓ **Conference abstracts**

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The Solution – Acumen's QC Module

Our extensive checklists were built and refined by a team with deep editorial and QC experience within industry.

Includes tasks related to:

- ✓ **Formatting**
- ✓ **Document structure and essential elements**
- ✓ **Data QC**
- ✓ **Editorial checks**
- ✓ **Style consistency**

Acumen's checklists are customizable with the flexibility to add sections and tasks to suit your needs.

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Checklist Management

Cloud-based interface allows checklists to be centrally managed.

QC Checklists

NAME	DOCUMENTS COVERED	RELATED SOP	LAST UPDATED	MANAGE CHECKLIST			AVAILABLE TO CLIENTS	CHECKLIST	
Acumen Narratives QC Checklist	Narratives	N/A	07 Apr 2020	EDIT	CLONE	DELETE	☑	ADD TASKS	VIEW PDF
Demonstration General Checklist	Misc	N/A	07 Apr 2020	EDIT	CLONE	DELETE	☑	ADD TASKS	VIEW PDF
General Quality Control Checklist	Misc	N/A	07 May 2020	EDIT	CLONE	DELETE	☑	ADD TASKS	VIEW PDF
General Quality Control Checklist_v2	Misc	N/A	12 May 2020	EDIT	CLONE	DELETE	☑	ADD TASKS	VIEW PDF
Protocol Checklist	Protocols	N/A	17 Jun 2020	EDIT	CLONE	DELETE	☑	ADD TASKS	VIEW PDF
Name	Documents Covered	Related SOP						ADD NEW	CLEAR

EDIT

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Robust Contents

Our editorial checklists cover all essential tasks needed for a quality review.

TASK	LEVEL	MANAGE RECORD	
Style Guide	Section	EDIT	DELETE
Style Guide	Subsection	EDIT	DELETE
Style Guide and/or conventions document received from Client	Task	EDIT	DELETE
Document conforms to Client Style Guide and/or conventions document	Task	EDIT	DELETE
ADD TASK			
ADD SUBSECTION			
Key Elements Check	Section	EDIT	DELETE
Title Page	Subsection	EDIT	DELETE
Version number is correct	Task	EDIT	DELETE
Headers and footers are correct	Task	EDIT	DELETE
Confidentiality statement or disclaimer appears on title page, if applicable	Task	EDIT	DELETE
Compliance statement is present, if applicable	Task	EDIT	DELETE
ADD TASK			
Table of Contents (TOC)	Subsection	EDIT	DELETE
Documents with 5 or more pages have a TOC	Task	EDIT	DELETE
All section headings, subheadings, and appendices titles are present and listed sequentially in the TOC	Task	EDIT	DELETE
All titles are consistently formatted in the TOC	Task	EDIT	DELETE

How the QC Module Works

Once the client has selected or built their editorial checklists, they are immediately available for use within the Microsoft Word add-in.

It appears as a tab at the top for their documents.
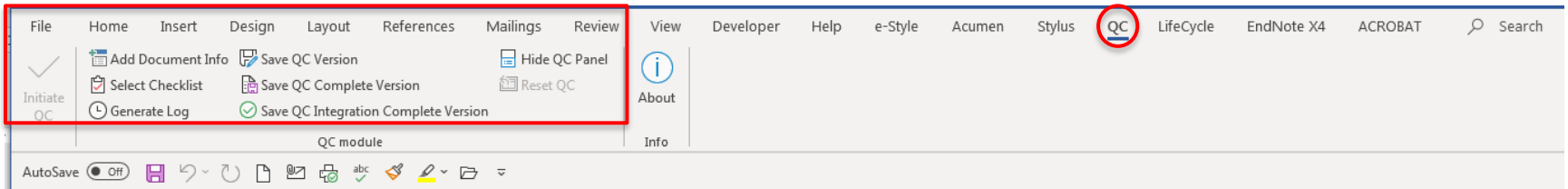
Initiating a Review

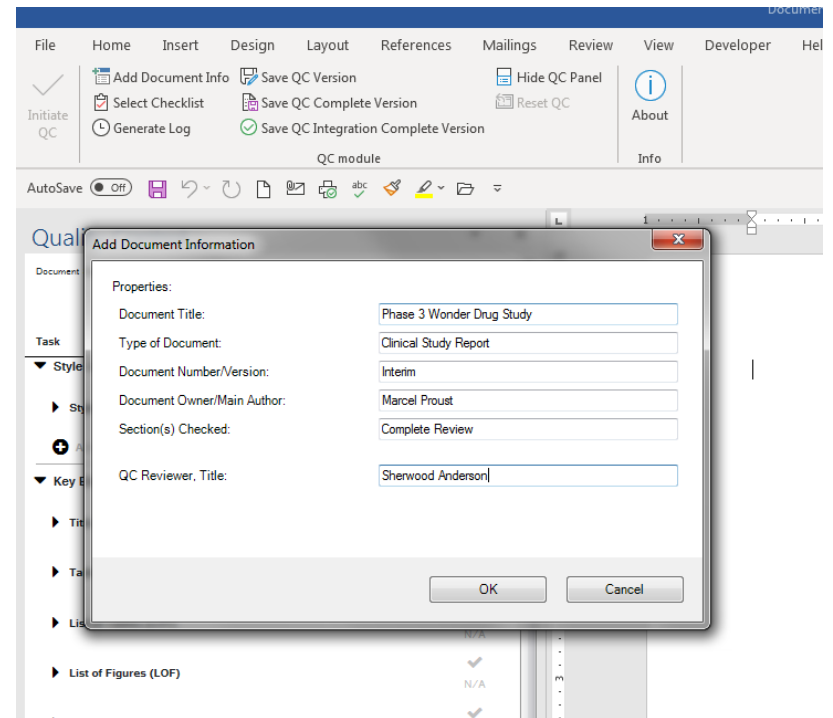**The editor or writer initiates the QC Module.**

The editor or writer then selects the appropriate checklist from a dropdown.

Document Tracking

Built-in document properties allow for a clear record of the review.

Checklist Panel

The selected checklist will then appear as a side panel to the Word document to guide the editor's review.

Checklist Features

The editor interface allows for multiple types of feedback while completing the review.

1. **A check for completed tasks**
2. N/A for anything not checked
3. **Edit icon for content that needs to be updated**
4. **Space to log comments**
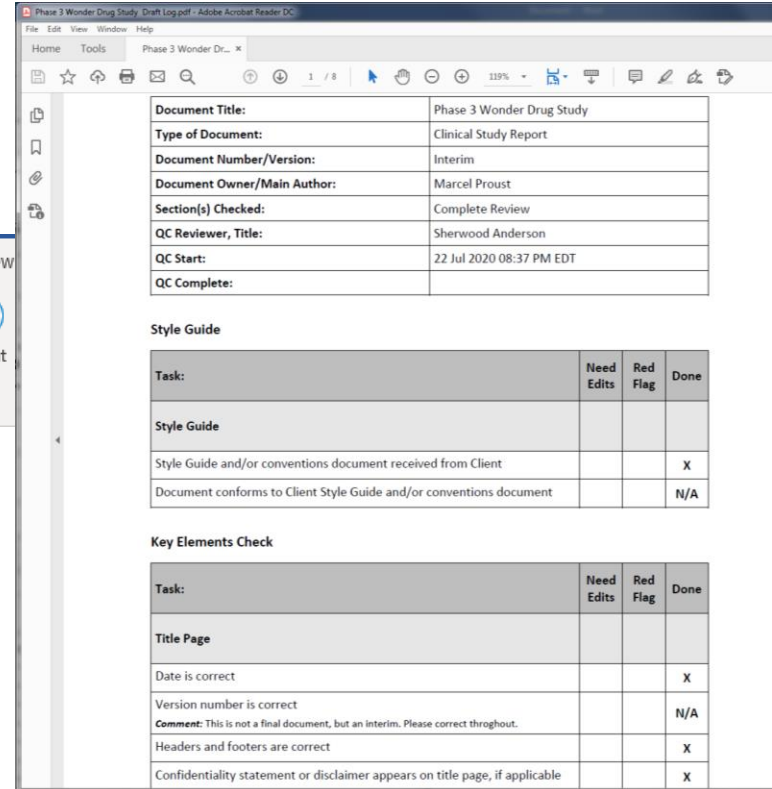5. **Red flags indicate significant findings**

Audit Trail Log

Users can export a QC log (audit trail) of all actions at any time during the QC process.
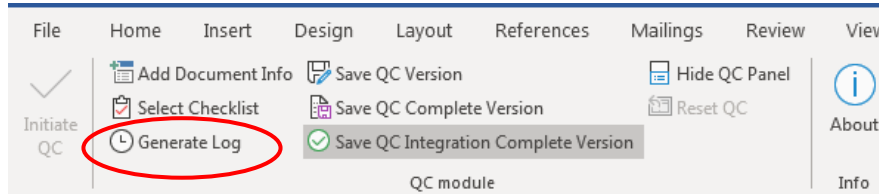
The log renders in a time-stamped PDF that shows all completed steps of the review.

A final QC log is automatically generated once the QC is marked complete.

QC Module Key Takeaways

- ✓ **Integrates with Microsoft Word and other Smart Document Solutions modules**

- ✓ **Customizable via a web interface**

- ✓ **Comes with informed document-specific QC checklists, allowing companies to jumpstart their quality processes**

- ✓ **Allows editors/QC specialists to review documents consistently and according to company SOPs**

- ✓ **Workflows ensure key versions of the document are saved**

- ✓ **Allows writers to easily manage editorial findings and make the appropriate changes**

- ✓ **Creates time-stamped audit logs in PDF for complete record keeping**

- ✓ **A COM-based MS Word add-in written in C#**

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Pricing

Monthly or yearly subscriptions are available.

Pricing designed to match your company's size and budget.

Discounts are available when bundled with other Smart Document Solutions Modules.

To purchase, contact us via our
website
or email us at
solutions@acumenmedcom.com

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