Quality control: getting the best out of your review

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Abstract

In medical writing, quality control (QC) means ensuring that a document's content, style, and format are of high quality. This does not just 'happen' but is the result of a systemic QC review. These reviews are critical because mistakes can cause the reader to question the validity of the content and may lead to errors in interpretation. QC guidance documents may be available in-house or from a client, but if not available, they can be created by combining existing guidelines and checklists. A good QC review takes time but is well worth the effort.

Keywords: Quality control, Checklist, Time

We all hear about quality control (QC), but what does it really mean? A check for typos on a rough first draft? A quick skim of a near-final document before it's finished? Neither! QC is checking a document to ensure the best possible quality of the output. It is an integral part of the production of a document rather than a one-off step in the progress from first to final draft.

Clearly, a final document should not contain errors. However, QC should be done before your reviewers even see the *first* draft. Indeed, QC is critical for making sure that every version is of the highest quality. Your reviewers are your customers, regardless of whether they are within your own company or external, and a high-quality document instills confidence that they are working with an accomplished medical writer. A poor-quality document, on the other hand, can jeopardize the chance of repeat work and may even limit your job prospects.

Who should perform the QC review?

Ideally, the QC review should be performed by somebody other than the author of the document. A fresh pair of eyes can spot errors that an author may have overlooked. Most commonly, a QC reviewer will be another medical writer within the same company. This reviewer can have less, equal, or greater experience than the author. For writers working alone, without a colleague to perform a QC review, the author may have to perform self-QC, but the principles are still the same.

Whoever is doing the QC, training on how to perform a good review is always beneficial. If QC training is not available at your place of work, you can obtain it through courses such as the Editing and Proofreading Essentials workshops (Parts 1 and 2) that are part of the Foundation Level of the EMWA Professional Development Programme. Other courses, some of which are available on line, are offered by various professional organizations such as the Society for Editors and Proofreaders (http://www.sfep.org) and the DIA (http://www.diahome.org). If you are a new medical writer or a new QC reviewer, a QC training course will give you a good start, but even an experienced medical writer can learn something new in a training course.

If a document has already undergone a review and needs subsequent QC on a later version, a review by the same person who performed the first QC review can be beneficial because they will already be familiar with the document. Some companies employ people whose main role is to perform QC reviews, which is a wonderful asset if available.

The tools of the trade – what you need to perform a QC review

Most pharmaceutical companies and contract research organisations will have their own standards for producing documents. These will be described in company-specific templates, style guides, and authoring instructions. Standard operating procedures describing the QC review process may also be available. To ensure that the quality and level of detail of a review are consistent, a QC checklist may be available. A detailed QC checklist is an important tool. It will help you cover all of the aspects of a review and will let you keep track

Table 1:   Documents to be supplied to QC reviewer

✓ QC checklist
✓ Document template
✓ Signature page (if not part of checklist)
✓ Style guide (covering text styles, punctuation, abbreviations, capitalization, number and date formats, etc.)
✓ Source documents (data tables, protocol, protocol summary, statistical analysis plan, clinical study reports, etc., depending on the document to be reviewed)
✓ Authoring instructions (covering use of company-specific authoring toolbars, document formatting, cross-referencing, in-text table format)
✓ Standard operating procedure for QC
✓ Last but not least, the document(s) to be reviewed!

Table 2:   Main topics of a QC review with examples

• Formatting
  – Styles
  – Page layout
  – Pagination
  – Headers and footers
• Consistency
  – Synopsis/summary/conclusions versus the main body of the document
  – Text and message throughout the main body of the document
  – Tabular data quoted in text
  – Specifically for protocols, the schedule of assessments table versus the text (a common one for consistency errors!)
• Tables
  – Formatting and layout
  – Consistency in style of tables throughout document
  – Clarity of presentation
  – Caption style
  – Electronic cross-references
  – Sources (correctly cited and content matches source)
• References
  – Correct citations
  – Format of in-text citations and reference list
  – Completeness of reference list
• General
  – Accuracy versus source documents/data
  – Spelling and grammar
  – Sentence construction
  – Abbreviations
  – Table of contents

of what you've checked and what's left to do. This, in turn, will help you manage your time.

The QC guidelines should be taken into account when the author is writing the document, and likewise, should be passed on to the QC reviewer. Also, the QC reviewer will invariably need the source documents (e.g. protocol or data) to verify the content of the document. A signature page should also be included as part of or separate from the QC checklist to document that the review has taken place. If you are acting as the QC reviewer, make sure that you have received as many of these documents as possible before starting your review because they will ensure maximum thoroughness. When timelines are tight, the document author may forget to provide all of the necessary documents you need, but don't hesitate to ask them to dig out the guidelines and checklist. Typical documents needed by a QC reviewer are listed in Table 1.

No QC checklist? Create your own!

Ideally, you will already have a QC checklist to work with, but if you don't, why not create your own? You can create a QC checklist specific to each type of document you review, for example, separate checklists for protocols, clinical study reports, and manuscripts. You can also create a generic checklist that contains the kind of items that should be checked in any document.

Begin constructing your checklist with a brainstorming session. Think about document formatting, style, correct use of grammar and punctuation, consistency of text and information/data in the synopsis, main body of the document, conclusions … the list goes on. The main topics that should be included in a QC checklist are shown in Table 2.

In constructing your checklist, take advantage of and combine together any guidelines or checklists you already have. Useful resources include style guides such as the AMA Manual of Style,[1] and for reporting trials and manuscripts, the CONSORT[2] guidelines and the ICMJE guidelines.[3]

Include tick boxes where the QC reviewer can check off that each item in the list has been checked. Also, include a comment box where the QC reviewer can explain why an item is not checked and in which specific findings can be described. A general comments section either at the start or end of the list is also useful, for example, for explaining that only certain parts of the document have been reviewed. In addition, include a section to state the version number and date of the reviewed document together with its title, project code, or any other identifiers, and a space to sign and date the form to record that the QC has been completed. You may also want to include space for the author to sign to document implementation of the comments or to allow the author to respond to comments. An example checklist is shown in Fig. 1.

Document title:		
Document version number and date:		
Study identifier/protocol number (if applicable):		
Document type (e.g. protocol, clinical study report etc.):		
General notes for review (guidance from author to reviewer or notes from reviewer to author):		
Item	**Checked**	**Comments (including reason if not addressed)**
Formatting		
Header and footer appears on every page	Yes ☐ No ☐ N/A ☐	
Header and footer information is correct on every page	Yes ☐ No ☐ N/A ☐	
...		

Name of reviewer: Title:
Signature: Date of review:

The comments have been addressed:
Name of author: Signature and date:

Figure 1:   An example QC checklist.

Keep your QC checklist as a living document, adding to it every time you spot something that you think will be relevant to check on future documents. You may well find your list growing, but you can always refine it to make it comprehensive but concise.

You may be involved in creating company style guides during your career. A good rule of thumb for these documents is to avoid complicated style instructions such as detailed grammar rules, so that even people who are not medical writers or who are not native English speakers can follow the guidelines.

Getting started on the QC review

Once you have all of the things you need to start your QC, it may be very tempting to dive straight in. Although QC reviews are often performed in a relatively short time due to tight timelines, take a few moments to take stock at the start of the review. This can pay dividends in the end. Make sure that you know how much you need to do and the amount of time you have to do it. Check with your author to see if any part of the document has had its QC review already and therefore doesn't need to be checked again. For example, the non-data-driven sections of a clinical study report are often reviewed before the results section of the report is written. Also, check if all of the items on the QC checklist apply to your review because your document may have already been reviewed using the checklist and therefore not everything

needs to be checked again. Clarify whether the QC review is being split between you and another reviewer.

If the timelines are very tight, the author may want two QC reviewers to work in parallel on different parts of the checklist or even on different parts of the document. If it seems that there is too much work to finish in the time allotted for the review, you may suggest at the start that another reviewer is brought on board; it's better to ask this at the start than to find yourself in a fix as your deadline approaches. You can also agree on the priority areas in case you are running out of time. Take care to look through the whole QC checklist before you start because it is easy to misjudge how much time each item will take. For example, you may find yourself speeding through the easy items, such as consistency of headers and footers or use of page breaks, and it can feel great to make such rapid progress through your checklist, but you may suddenly be slowed by an item that requires checking the entire document against its source. Reviewing your checklist before you get started can give you a better feel for how long it will take to complete and therefore which items you want to do first.

Make the most of your time

In practice, the QC probably has to fit around your other work. Try to put the other priorities aside and find some peace and quiet so that you can give close attention to the QC review. Consider

even taking a deep breath and switching off your email, if you can get away with it! Remember to take breaks to maintain your focus over long reviews as tiredness can lead to missing small mistakes. In case you have limited time, you can suggest providing comments to the author in stages if they are keen to start on revisions.

Finishing off

When you return your reviewed copy of the document and checklist to the author, ensure that your edits are clear and easy to understand. Giving a brief explanation of certain edits can also be valuable. For example, if you suggest that some text should be removed from a summary section of a document but that it should be retained in the main part of the document, explain this so that the author does not remove the text throughout the document. You can also justify stylistic changes by referring to the style guide to make it clear that you are not basing your edits on your own preferences. The QC review of a document can be a useful tool for learning (both for the author and the reviewer), so a small number of explanations with the comments can be helpful.

Conclusion

More than just a quick read-through, QC reviews are comprehensive and detailed exercises that can also be learning experiences. As a reader, we all expect high-quality documents, but this requires an organized review process. As well as QC guidance documents, a good QC checklist will contribute towards a review that is performed well and will improve the standard of the reviewed document.

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Further reading

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Author information

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