

Medical Communication

SECTION EDITOR



Lisa Chamberlain James
lisa@trilogywriting.com

Editorial

Dear all,

At the start of a medical writing career, the quality control (QC) step can fill writers with a sense of dread. Someone is holding a magnifying glass to your carefully crafted (and at this point deeply loved) document and is trying to pick holes in it! At least, that's how it can feel.

However, as writers go through the process, they should (hopefully!) see pretty quickly how much a well-executed QC can add to their document rather than detract from it, and most experienced medical writers actually love the QC step.

The eagle-eyed among you will have noted the very deliberate use of *well-executed* in front of QC in the previous paragraph. My view is that QC is like most things in life – you get as much out as you're prepared to put in. However talented and skilled the QC specialist is, a writer will only gain the maximum benefit of this person's work and wisdom by understanding the optimal way to work with such a specialist on the document.

Claire Jones is an extremely experienced QC specialist, and in this article she uses her experience in the QC world to describe the role of QC and why it is so crucial to high-quality document production. She also provides some top hints and recommendations for medical writers to be able to get the most from their QC specialists.

This insider knowledge is so valuable to writers – even if you already know and love the QC step, I'm sure there is something in this article for everyone, to allow us all to improve our day-to-day working with our QC specialists.

Bestest,

Lisa

Getting the most out of quality control specialists: Practical guidance for medical writers

Introduction

Quality control (QC) is a process that usually occurs when a document is in a near-final or final state. It involves the checking of documents by QC specialists against source data (e.g., comparing data in tables and checking that analytical statements are supported by the data presented in the document) and/or for consistency (e.g., spelling, grammar, punctuation, formatting, style, and cross-references). QC specialists might also be referred to as “data integrity reviewers”, “copy editors”, and “proofreaders”, but as my job title is “QC specialist”, I will use this term throughout.

QC is an integral part of the medical writing process and relies on clear communication between medical writers and QC specialists. As a social sciences and healthcare researcher with recent medical writing and QC experience, I have some understanding of what it is like on both sides of the fence. As a medical writer I know it can be frustrating when QC specialists send back documents with lots of comments on consistency issues or wording of particular statements that you did not want checked or if they did not change the minor issues you expected them to. As a QC specialist it can be equally frustrating if medical writers are not clear about what they want you to check and how QC findings should be addressed.

My aim in this article is to use my experiences to outline the role of QC and why it is important, as well to provide practical guidance to medical writers on getting the most from their QC specialists.

Why quality control matters

Medical writers write a range of documents that include, but are not limited to, regulatory documents, protocols, and manuscripts.¹ Medical writers are highly skilled individuals, but even the best medical writers are not infallible. It is extremely easy to add incorrect data to tables when working with source tables that are over a hundred pages long, to make an analytical statement that is not wholly supported by data, or to forget to add a period at the end of a

sentence before starting the next one. It might seem that consistency issues such as whether a space is inserted after a symbol are not as important as ensuring that data are accurate. In many ways they are not, but if a document is inconsistent in lots of the small things, and the document looks messy with no attention to detail, then it can detract attention from the key messages of the document – as Aristotle is credited as suggesting, “the whole is more than the sum of its parts”.

Ultimately, research findings will be used by regulatory agencies, medical professionals, patients, and the general public to evaluate drug efficacy and safety and to advance medicine and healthcare.¹ Findings from clinical trials may also be used to inform future studies. Therefore, it is important that data are presented accurately and clearly for their intended audience(s) and that there is a safety net to catch errors and inconsistencies in documents should they arise – QC specialists are that safety net. They provide a fresh and objective perspective on documents and ensure that they are checked for consistency, correctness, and clarity.²

Understanding quality control specialists' skills and expertise

QC specialists can do so much more than just proofread documents for spelling, grammar, and punctuation or check whether numbers are presented to the right number of decimal places. QC specialists are highly skilled in their own right and it would be a shame to under-use their abilities. For example, QC specialists understand complex medical and statistical terms, and what it means if a study is underpowered or when it is not appropriate to use p-values. Therefore, QC specialists have the knowledge to comment when an analytical statement might be too strong, based not only on what is presented in the data, but also based on the methodology of the study. QC specialists are able to identify the elements of a well-written manuscript and understand how to communicate salient messages of a study in the discussion. QC specialists might also know more



about a journal's submission requirements or how to use journal portals for submitting articles than a medical writer with limited or no former manuscript experience. If a medical writer has only recently entered the profession, QC specialists can also be a resource for regulatory guidance and the latest updates (e.g., where to find them on the internet). These are all additional benefits that skilled QC specialists offer, but what about working with them on a day-to-day basis?

Improving the efficiency and effectiveness of the quality control process

I have identified five key stages, based on my experiences both as a medical writer and a QC specialist, which I have found useful in improving the efficiency and effectiveness of the QC process (see Figure 1 for an overview of the five stages).

These stages are discussed below in more detail.

Proofread documents first

Proofreading a document before sending it for QC sounds obvious, but it is essential. If a medical writer sends a document to a QC specialist that has not been proofread beforehand, the document they receive back might contain a lot of comments and/or tracked changes making it difficult for the medical writer to see the most crucial corrections because they detract attention from the really important aspects of the document (e.g., whether the endpoints from the protocol are addressed in the results or whether conclusions on drug efficacy and safety are supported by the data).

QC is the final check of a document before it is sent to the client and then the intended audience (e.g., regulatory agencies, journals). Therefore, if the document contains lots of

consistency and data issues, it may need to be checked again once the QC comments have been addressed. This additional check increases the time spent on a project that may already be time-critical and uses more resources.

Software to aid the consistency and quality of documents is becoming an established way of supporting the medical writing process.³ In my experience, such software is relatively easy to use, can speed up the proofreading process, and can be helpful in identifying consistency issues that would take longer to identify and address if a medical writer or QC specialist were to only read through the document. An important caveat is that proofreading software does not *replace* the need for the medical writer to proofread a document because software will not identify issues with analytical statements or incorrect data, for example.

Allow a realistic amount of time

Medical writers need to be realistic about the time required for the QC process.⁴ It is not realistic for a consistency and data check to be performed in one day on a 100 page clinical study report! Any good QC specialist will always tell a medical writer if they are concerned about the timeframe or if, on starting the QC, they think that checking the document might take longer than the medical writer and/or QC specialist envisaged. That being said, QC specialists understand that deadlines can shift and sometimes medical writers need their documents back quickly. QC specialists will do what they can to help with a quick turnaround as long as it does not affect QC quality.

Be clear about what you want and how you want it done

At the start of the QC process it is essential that medical writers clarify: 1. what they want the QC specialist to check and, 2. how any QC findings should be addressed. Medical writers should never presume that a QC specialist knows either of these two factors. QC specialists should always ask the medical writer what needs to be checked and how they want QC findings to be addressed. If QC specialists understand exactly what is being asked of them, medical writers will hopefully

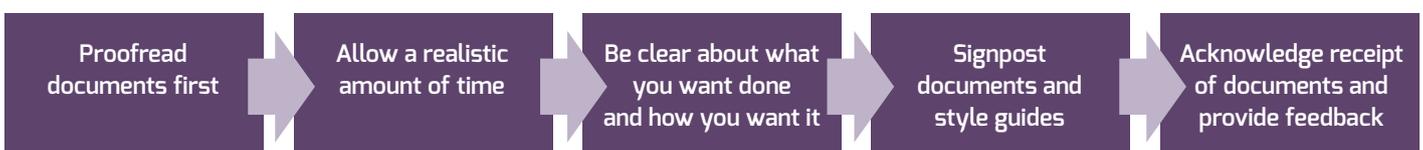


Figure 1. Five stages for improving the efficiency and effectiveness of the quality control process

receive documents that meet their expectations. Of course, there may be times when a medical writer tells a QC specialist that they do not need to check something (e.g., findings/data that have already been checked and have not substantially changed in a later draft) but if, during the course of doing the QC, the QC specialist notices that there are substantial changes (e.g., lots of new data and/or analytical statements) they should of course double check this with the medical writer concerned.

Signpost source documents and style guides

QC specialists need to know where source documents are located,⁴ if there is a system for labelling them, and if there is a style guide.⁴ Clearly labelling and signposting the source documents can save QC specialists a lot of time searching for sources and means that they are less likely to repeatedly ask medical writers where they can find a specific source. This means that clear signposting of sources improves the efficiency of the QC process because it prevents time being wasted trying to find documents and allows the medical writer to focus on writing rather than spending time answering lots of queries.

Acknowledge receipt of documents and provide feedback

QC specialists know that medical writers are often busy and possibly juggling several documents at a time. However, medical writers know how great it feels to have a client acknowledge receipt of their work and to thank them for writing a particularly tricky document or going above and beyond what they expected. Medical writers also know that having clients critique their work helps them to grow and develop as writers. QC specialists like, and need, those things too. Providing feedback – knowing what was good or helpful about a QC but also what did not work and could have been done differently – enables QC specialists to learn and to develop their skills in QC.⁵ Providing feedback to QC specialists can also boost morale because it makes them feel valued – it's showing that medical writers care enough to take the time to comment on their work. When people feel valued they become more engaged, come to work more often, are committed, and feel accountable for their performance.⁶ Thus, feedback is not just something that it is nice to do, it can be a very powerful tool for improving the QC process, which in turn leads to high quality documents.

Conclusions

QC specialists are a valuable resource for medical writers. Being aware of the added value that QC specialists contribute to medical writing, using QC specialists' skills and expertise, and incorporating the five stages of the QC process described here can enable medical writers to get the most out of QC specialists. This should improve the efficiency and effectiveness of QC and the writing of high quality, professional documents.

Acknowledgements

I would like to thank Sophie Rudert and Lisa Chamberlain James for reading the article and for their valuable feedback.

References

1. Sharma S. How to become a competent medical writer. *Perspect Clin Res.* 2010;1:33–7.
2. Tetzner R. Why Is Proofreading Important? Increase Your Chances of Publication. 2016 [cited 2018 Jul 10]. Available from <https://www.proof-reading-service.com/en/blog/why-is-proofreading-important/>.
3. Menon D. 5 useful editing and proofreading

tools. *Health Writer Hub.* 2016 Jun 14 [cited 2018 Jul 10]. Available from <https://www.healthwriterhub.com/5-useful-editing-proofreading-tools/>.

4. Haycock N. Quality Control: getting the best out of your review. *Medical Writ.* 2012;21:221–4.
5. Dignen B. Giving effective feedback is a vital part of communication, whether inside or outside the boardroom or classroom. Cambridge University Press. 2014 Mar 17 [cited 2018 Jul 10]. Available from <http://www.cambridge.org/elt/blog/2014/03/17/five-reasons-feedback-may-important-skill/>.
6. Barsade SG, O'Neill OA. Employees who feel love perform better. *Harvard Business Review.* 2014 Jan 13 [cited 2018 Jul 10]. Available from <https://hbr.org/2014/01/employees-who-feel-love-perform-better>.

Claire Jones
Quality Control Specialist
Trilogy Writing Ltd, UK
claire.jones@trilogywritng.com

