Review Process (Quality checks and peer reviews)

Quality Control (QC) of Medical Writing Deliverables

- Quality control (QC) is a term that applies across many industries. Within the field of regulatory medical writing, QC refers to the process of ensuring the quality and accuracy of a final medical writing deliverable.

Why QC?

- To deliver a document of the highest quality
- It's required by the guidance set forth by the International Council for Harmonisation (ICH):
  - "The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled."

ICH E6: Guideline for Good Clinical Practice

What is QC?

- The primary purpose of QC is to verify accuracy of 100% of the data presented in the document
- A QC of any document should include:
  - 100% data QC (all data verified against a source);
  - Confirming that non-numeric information presented reflects the source (eg, protocol, statistical analysis plan);
  - Ensuring consistency of appearance and adherence to an agreed-upon style guide (whether from the Sponsor or IMPACT);
  - Checking for consistency of presentation, format, grammar, use of abbreviations (and the list of abbreviations, if present), references cited; and
  - Confirming cross-references in the document are correct

Who is Qualified to Perform QC Activities?

- The most important part of the “who” question is actually who should **NOT** QC
- The QC should never be performed by the author and should not be performed without appropriate training
- **Why not the author?** The document deserves a fresh eye. Data errors, grammatical mistakes, and formatting are often missed when an author has had the document in front of him/her for days or weeks
- Any medical writer with keen eye for details and is qualified/ trained for this task can perform QC

Points to consider as a reviewer

Stick to the facts

When you write questions or comments, try to keep your language neutral, focusing on how you think the language should change. Starting a comment with a “why are we saying” or “shouldn't this be” adds an accusatory tone that doesn't help solve the problem at hand

Points to consider as a reviewer

Explain your reason for wanting a change

To clear the air that changes you request are necessary and are not the subjective comments of a slash-and-burn reviewer, add a few words to explain your rationale. For example, “For clarity, I suggest changing to...”

Points to consider as a reviewer

Communicate clearly

Only use abbreviations and unique terminology if you know the other reviewers will understand them. In word, use track changes and review comments efficiently to mark up exact changes required. If you are marking in a format like a PDF, utilize the mark-up and commenting tools in a way that makes it clear as to which block of text you are discussing

Points to consider as a reviewer

Review your comments before sending the job along

Look over your comments before sharing the document, just to make sure they make sense. You can also use this time to delete comments that you have resolved yourself during the course of your review. Additionally, a final check will allow you to make sure you have not forgotten any key information or neglected to raise any additional questions that are on your mind

Points to consider as a reviewer

Seek consensus for complicated issues

Sequential review is a time saver only when everyone understands the issues to be resolved. If you'd like to request a change that is too involved to mention in written format, it's best to visit or call any necessary stakeholders, if time and schedules allow, to gain agreement on a solution. Similarly, if you see someone has raised a complex question, try to talk offline to resolve it, rather than add more running dialogue to the job

Peer Review of manuscripts

Manuscript peer review

- Peer review refers to the evaluation of a document by peers of authors, i.e. typically doctors and/or scientists belonging in the same area of specialisation or subspecialisation
- Peer reviewers aim to provide a critical, independent and unbiased assessment of the scientific document, and are regarded as an important extension of the scientific process
- Peer review aids in gatekeeping of what goes into the knowledge pool, and has been adopted by all major medical and scientific journals

Importance of peer review

- Research work is validated through experts
- Improvement in the quality of publications – through constructive feedback mechanism
- Publication of most important research in journals –
- Peer review process is well understood and accepted by majority of researchers

Types of review

Single blind	**Author doesn't know the identiy of the reviewer.**
Double blind	**Reviewer doesn't know the identity of the author, and vice-versa.**
Open Peer review	**The identity of the author and the reviewer is known by all participants, during or after the review process.**
Transparent Peer review	**Review report is posted with the published article. Reviewer can choose if they want to share their identity.**
Collaborative	**Two or more reviewers work together to submit a unified report. OR Author revises manuscript under the supervision of one or more reviewers.**
Post publication	**Review solicited or unsolicited, of a published paper. Does not exclude other forms of peer review.**

Single blind review

Pros

- The anonymity allows the reviewer to be honest without fear of criticism from an author
- Knowing who the author is (and their affiliation) allows the reviewer to use their knowledge of the author's previous research

Cons

- Knowledge of the author may overshadow the quality of the work - potentially leading to a lack of scrutiny, especially if it's the work of an author with a dazzling track record
- There is the potential for discrimination based on gender or nationality. Discrimination based on non-scientific criteria is clearly unacceptable,

Double blind review

Pros

- Research is judged fairly, keeping bias out of the equation
- Author and reviewer benefit from some level of protection against criticism

Cons

- Anonymity isn't guaranteed, as it could be fairly straightforward to discover the identity of the author (either because of the area of research, the references or the writing style)
- Some argue that knowledge of the author's identity helps the reviewer come to a more informed judgement - and that without this the review suffers

Open peer review

Pros

- The transparency of open peer review encourages accountability and civility, generally improving the overall quality of the review and article
- Reviewers are more motivated to do a thorough job since their names and sometimes comments appear as part of the accepted, published article

Cons

- Some reviewers might refuse to review for a journal using an open system, due to concerns about being identified as the source of a negative review
- Reviewers could be reluctant to criticize the work of more senior researchers - especially if their career depends on them. In smaller research communities and in some regions of the world this could be a significant problem

Limitations of peer review

- Time consuming process – may cause delays in the dissemination of research findings
- Effectiveness of the peer review process is debatable in detecting errors in academic papers
- Anonymity of referees is difficult in specialized research fields – very few experts available

Limitations of peer review (contd)

- Publication of poor research may not be prevented – review standards may be lower in less prestigious journals
- Reviewer's bias:
  - Conflict of Interest: Reviewers may support the findings of their own interest and oppose publication of competing ideas
  - Attitude: Unconventional ideas are not easily accepted; force editors to add their own references
  - Status: Influence of reputed institutions and scientists on reviewer's recommendations

Limitations of peer review (contd)

- Unable to uncover scientific misconduct: plagiarism, duplicate publication, fabrication of results, falsification or adjustment of data, violation of ethical standards
- Delay in the publication process: deliberate delay in decision making
- Unable to detect major flaws: examples include –
  - Fraud at the bell laboratory (1998-2002)
  - Fraud in stem cell research conducted by Korean researcher in 2005 was detected when retested by other scientists
  - Inadequacy to detect weakness in the manuscript
    - A study showed that surprisingly only 2 mistakes were detected by the 200 reviewers in a manuscript with 8 deliberated weaknesses

Ideal peer reviewer

- The reviewer should be an expert in his field and is required to render an unbiased opinion on the quality, timeliness and relevance of the document
- The reviewer has a responsibility to the author in treating each document with respect, fairness and impartiality
- He should always bear in mind that the submitted document is an intellectual property belonging to the author, and should be regarded as a highly privileged piece of communication

Ideal peer reviewer

- The reviewer should refrain from publicly discussing the contents of the document, and must not make use of knowledge of the author's work to further his own interests or for private gain
- It is recommended that the reviewer should not keep any copy of the document after completion of the review

Responding to reviewer's comments

- Take a step back and refocus on the science
- Ask yourself how you can communicate better with the intended audience (the fact that reviewer had queries indicates the communication is not happening)
- Update the manuscript and resubmit to the same or some other suitable journal

https://axial.acs.org/2020/09/17/peer-review-and-you-how-it-works-and-why-its-success-depends-on-reviewers-like-you/ accessed on 31 oct 2020

Exercise

- Review the article (anonymised) that will be provided