

Review of: "Ensuring Quality in Clinical Research: The Impact of Quality Assurance and Quality Control in the Field of Good Clinical Practice"

Gerhard Fortwengel

Potential competing interests: No potential competing interests to declare.

I read the article with great interest. It is undisputed that QA and QC play a fundamental role in clinical trials. My comments and remarks follow the text of the manuscript.

Page 2: Key messages - bullet point 3: Is quality assurance really often forgotten? The requirement for a stable QA system with the associated operational steps has been part of ICH-GCP from the start.

Page 2, 2nd paragraph: Investigators understand the meaning and purpose of research, but it is reported that they don't understand, with some limitations, the importance of reliable data. Such a statement should be supported by a reference to avoid speculative statements.

Page 3, 2nd paragraph: Focus - past - tense!

Reliable data naturally influences monitoring and a possible inspection outcome, but the important thing is that only accurate data can answer (medical) questions about safety and effectiveness. In my view, this is an essential point that should definitely be taken into account. It is not about surviving an inspection, but about generating quality data on the basis of which decisions can be made, e.g., approval as a new product/substance.

Page 3, Section 2: Mostly redundant to the introduction. It is also important to note that no references are given. This is not permissible in this form for a scientifically correct work.

Page 3, Section 3. "as it is now referred to" - this responsibility is not new and has to be made more precise. The choice of words should be correct here so as not to give the impression that this responsibility was only "recently" defined.

Page 5, Section 4: Statements such as "audits have become more effective in several ways..." should be avoided as they are unsubstantiated statements. The following text with the references is interesting, but it is not clear why this information is given at this point. What is the purpose behind it in relation to the title of the manuscript?

Page 6 and then the following text:

It is undisputed that current information and current knowledge are necessary in order to "do good work". One possibility is to read the reports on inspections by leading authorities in order to discover clues about possible weaknesses in clinical studies. However, a total of 4 pages with long tabular overviews of findings are inappropriate for a work of this kind.

Overall, the work contains important points that should be considered, but ultimately falls short of the promise described in the last sentence of the abstract.

I would like to recommend that the authors revise the work thoroughly and give it a face of its own with precise explanations that should always be referenced. Perhaps it would be an idea to highlight individual important points that support statements in your own text instead of the large inspection overviews.

The last paragraph on page 10 is a very general statement, rather considerably basic and not very inspiring. Here, too, I recommend a revision of the content and, above all, a summary in the form of a conclusion that gives the reader "something to use" for their everyday work in clinical studies.