

"Clinical Trials Audit Preparation: A Guide for Good Clinical Practice (GCP) Inspections"

Vera Mihajlovic-Madzarevic, 2010, 246 pages, John Wiley & Sons, \$89.95

Review by Norman M. Goldfarb

"Clinical Trials Audit Preparation: A Guide for Good Clinical Practice (GCP) Inspections" is a comprehensive manual for avoiding inspections, preparing for inspections, and being inspected. It is also a useful guide for inspectors. The book covers FDA, sponsor and internal inspections of sites, sponsors, CROs and IRBs/IECs.

The book's primary messages are (a) always run in inspection-ready mode and (b) inspections can be

very comprehensive. So, if you do everything right all the time, you should be home free. If an FDA inspector does find serious regulatory violations (or problems unaddressed from a previous inspection), the focus will be on correcting the issues, rather than imposing penalties. However, if they are severe or recurrent, welcome to the meat grinder.

The core of the book is the 51-page chapter on preparing for inspections, with a focus on inspections of clinical sites. It covers the process through responding to a Form 483 and subsequent regulatory actions. The chapter reviews the documentation that should be prepared, the investigator's Form 1572 obligations, and ways to make the inspection successful. The book offers the following advice for exit interviews:

The following is what you should do during the exit interview:

- Be available for the interview.
- Listen carefully to the inspector, and take notes of his/her comments (those may be part of the internal report).
- Answer only if you really know what are you talking about.
- Answer with facts and supporting documents.
- Make sure that if you have the documents requested and noted in Form 483 you provide them to the inspector there and then and make a note that you have done so to include it in your response to Form 483.
- Ask for clarification if you do not understand the finding as to which part of the Code of Federal Regulations it refers.
- Have personnel available who may assist in the response to issues raised during the inspection.
- Be polite.

Never answer:

- *Sorry...* Sorry does not help anyone, because you have to assume your responsibilities when signing Form 1572.
- *I did not know.* As an investigator, you should know what you are doing and what is required from you. Regulatory requirements and the protocol must be adhered to at all times.
- *It is not my fault, I did not do it.* Well, basically, it is your fault because you should be personally supervising if not conducting the clinical trial.

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- *That is my coordinator's fault.* Again, it is the investigator who is responsible for all clinical trial activities at the site.
- *This is new to me.* It is true that many changes happened recently in the requirements for clinical trials (especially with electronic data handling, registrations, etc.); however, the investigator should keep him/herself updated and should not be caught by surprise.
- *"Mea culpa," yes, it is my fault.* Do not assume fault until you consult with an expert on the particular issue. The regulator is not interested in assigning you fault but correcting any violations so they do not occur in the future.
- *I do not agree with your opinion.* It is very important that the clinical investigator or representative does not become argumentative with the inspector, since the inspector may write his/her opinion on Form 483; however, the center will review the case and will reassess the findings with all the supportive documents. You always have the opportunity to express your side of the story in the written response to Form 483 to the district office.
- **DO NOT PROVIDE UNSOLICITED INFORMATION:** you may dig yourself in deeper.

The book consists of five chapters:

- Good Clinical Practice and Therapeutic Product Development
- Therapeutic Products Clinical Development in the United States
- The Inspections Preparation
- Analysis of Warning letters
- Fraud and Misconduct in Clinical Research

The report is available in bookstores.

Reviewer

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