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The FDA Compliance Program Guidance for GLPs: Inspections Part III

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In this concluding article, there will be a presentation of the protocol and conduct of a non-clinical study and a discussion of the records and reports that should result from such a study. This presentation will then end with a discussion of the data audit that an investigator is told to perform. Although this CPGM does contain more material beyond these sections, they are primarily of administrative interest to an investigator and will not concern the readership. The reader who is concerned with completeness should review the entire document as referenced above (2). Note that in the following...