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The FDA Compliance Program Guidance for GLPs—Inspections II

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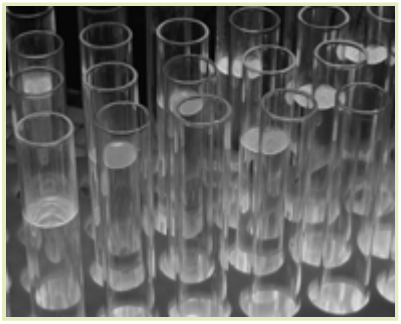

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The earlier discussion (4) ended with a discussion of the material contained in Attachment A, which is a part of the CPGM that discusses the requirements for laboratories using computerized systems. The discussion will now resume with the consideration of the requirements for the study director (21 Code of Federal Regulations [CFR] 58.33). Note that in the following, italicized sections are exact quotations from CPGM 7348.808, while material presented by the author is in normal print. STUDY DIRECTOR REQUIREMENTS d. Study director (21 CFR 58.33) 1) Assess the extent of the study director's actual...