

The FDA Compliance Program Guidance for GLPs - General



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Courtesy of FDA

ABSTRACT

This article provides an overview of the US Food and Drug Administration's good laboratory practice guidelines found in the compliance program guidance manuals.

INTRODUCTION

The enforcement of good laboratory practices (GLPs) is often left to the BioResearch Monitoring (BiMo) program of the US Food and Drug Administration's Center for Drugs Evaluation and Research (CDER). BiMo inspections have a reputation of being very thorough and conducted by knowledgeable investigators. It is thus valuable to have some insight into the guidelines that these investigators are trained to follow. These guidelines may be found in the compliance program guidance manuals (CPGMs) that are available online at the FDA website (1).

The CPGMs are internal FDA documents that provide guidance and instructions for FDA investigators who conduct inspections. For the worker dealing with the GLP guideline, the most interesting CPGM is the one specifically covering the GLPs. This document, usually referred to as CPGM 7348.808, covers the inspection of studies that were conducted under GLP rules (2). As such, it is useful for the GLP worker to review it to be prepared for an inspection.

CPGM 7348.808 is in Chapter 48 covering bioresearch monitoring and was issued on February 21, 2001. This 37-page document is mostly devoted to administrative matters that will concern FDA personnel, but not the laboratory worker. Certain sections, however, will be of interest, and shall be discussed here.