
December 8, 2008. Compliance Program Guidance Manual for FDA Staff. This document is intended to provide guidance. It represents the Agency's current thinking.

Bioresearch Monitoring Program (BIMO) Compliance Programs. The regulations enforced by the bioresearch monitoring program for medical devices and responsibilities are described in the Compliance Program Guidance Manual for FDA Staff - Program 7348.808A. Compliance Programs (Program plans and instructions) directed to field personnel. Search the Compliance Program Guidance Manual Section Biologics (CBER) · Bioresearch Monitoring (BIMO) · Devices/Radiological Health (CDRH). In reviewing the Bioresearch Inspection Monitoring Compliance Guides for both FDA's bioresearch monitoring compliance program guidance manuals.

FDA/ORA Bioresearch Monitoring Information Page Compliance Programs - BIMO Guidance:


FROM Bhanu Kannan, Bioresearch Monitoring Branch, HFM-664 BLA and were conducted in accordance with FDA's Compliance Program Guidance Manual. Patricia Holobaugh, Bioresearch Monitoring Branch Chief. The inspections were conducted in accordance with FDA's Compliance Program Guidance Manual.

Compliance Program Guidance Manual - 7348.809 PROGRAM ASSIGNMENT CODES. FACTS does not require product codes for Bioresearch Monitoring Decisions (fda.gov/ICECI/Inspections/FieldManagementDirectives/).
Patricia Holobaugh, Chief, Bioresearch Monitoring Branch inspection was conducted in accordance with the FDA's Compliance Program Guidance Manual. In FDA's "Compliance Program Guidance Manual For FDA Staff - Compliance Program 7348.811 Bioresearch Monitoring: Clinical Investigators" in 2008. VA Program for Research Integrity Development & Education (PRIDE) FDA - Compliance Program Guidance Manual - Bioresearch Monitoring · FAQs - FDA. See for example, FDA Compliance Program Guidance Manual, Chapter 48 - Bioresearch Monitoring. DHHS regulations do not specify administrative actions. What is Bioresearch Monitoring (BIMO)? Compliance Program Guidance Manuals (CPGM) Inspections apply to: FDA regulated CLINICAL and non-clinical. As a result, some Web links (URLs) embedded within guidance documents are no Compliance Program Guidance Manual (CPGM) provide instructions to FDA Bioresearch Monitoring · (Retired Page) Disqualified/Restricted/Restrictions. Instead, the FDA has released an updated version of the Bioresearch Monitoring (BIMO) Compliance Program Guidance Manual for Sponsor/CRO.

FDA's bioresearch monitoring compliance program guidance manuals (CPGMs) for sponsors, CROs, and monitors (CPGM7348.810) and for CIs.


Bioresearch Monitoring Program FY2015 Program Alignment Specialization Action Plan and implemented for the FDA Bioresearch Monitoring (BIMO) program. In fact, the compliance program guidance manuals (CPGMs) for most BIMO.

Compliance Program Guidance Manual For FDA Staff - Program 7348.808 exhibits, will be sent to the assigning center bioresearch monitoring program unit. BIORESEARCH MONITORING GOOD LABORATORY PRACTICE. Compliance Program 7348.808 This document is intended to provide guidance. person and does not operate to bind Food and Drug Administration (FDA) or the public. Conducted under FDA's Bioresearch Monitoring Program (BIMO). ▫ Guide for inspections: Compliance Program Guidance Manuals. ▫ fda.gov/ICECI/.