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FDA Releases Final Guidance on Best Practices for Bioresearch Monitoring Inspections

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On December 18, 2025, the Food and Drug Administration (FDA) released a **final guidance** entitled "Processes and Practices Applicable to Bioresearch Monitoring Inspections." The guidance was issued to comply with the Food and Drug Omnibus Reform Act of 2022, which directs FDA to issue guidance describing the processes and practices applicable to inspections of sites and facilities inspected under FDA's Bioresearch Monitoring (BIMO) inspection program, to the extent that is not covered in already available FDA guides and manuals. The BIMO program was established to assess and monitor the conduct and reporting of FDA-regulated research as well as postmarketing activities through on-site inspections, investigations and Remote Regulatory Assessments.

The guidance largely focuses on communication between FDA and the industry before, during and after an inspection. The guidance also covers the types of records and information required to be provided and other inspections-related conduct.

Establishments engaged in FDA-regulated research should carefully review this guidance. In 2025, our practice saw robust BIMO inspection activity, with particular focus by FDA on data integrity, recordkeeping and adequacy of investigations and corrective and preventive actions (CAPAs). While FDA has publicized the agency's concern about data integrity issues at certain overseas entities conducting research and testing in particular, both foreign and domestic research establishments should prepare for ongoing scrutiny of compliance with GxP requirements.

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