

Foreword 2025

We are excited to bring you the 2025 Investigations Operations Manual (IOM). The Investigations Operations Manual (IOM) is the primary operational reference for FDA employees who perform field investigational activities in support of the agency's public health mission. Accordingly, it directs the conduct of all fundamental field investigational activities. Adherence to this manual is paramount to assure quality, consistency, and efficiency in field operations.

Other FDA manuals and field instruction supplement, but do not supersede, the information in this manual. We recognize this manual will not address all situations encountered in the performance of field activities. In such cases, your management must be informed and concur with any significant departures from the IOM.

The 2025 version of the IOM contains important changes which clarify or present new information and procedures. As with each new edition of the IOM, please take time to review sections of the manual for changes which may apply to your work. Additions to the IOM are highlighted in light gray. The IOM is published hard copy annually, though updates to the IOM will continue to be performed periodically during the year to the online version. The online IOM version serves as OII's official document of record and is posted on OII's Internet Website <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual>, with all graphics included.

OII leadership is committed to continuously improving the quality and usefulness of the IOM. Suggestions for the 2026 edition of the IOM including recommended changes, deletions, and additions to the IOM from within the agency may be submitted using the IOM Change Request (ICR) Form ([FORM-000992](#)). Suggestions are also accepted from our state and local partners, industry, and consumers and may be sent via e-mail to oii-iom@fda.hhs.gov. All changes are reviewed by the IOM Committee, which is composed of a cross-functional group consisting of representatives from each commodity area in addition to imports, recalls, and policy.

Thank you for your continued exceptional work and commitment to protecting and promoting the health and well-being of the American people. It is an honor serving with you.



Elizabeth Miller, Pharm.D.
Associate Commissioner for Inspections and Investigations
U.S. Food and Drug Administration

NOTE: This manual is reference material for investigators and other FDA personnel. The document does not bind FDA and does not confer any rights, privileges, benefits or immunities for or on any person(s).

Vision

Our global inspections and investigations ensure FDA regulated products are safe, trusted, and accessible.

Mission

We conduct rigorous, transparent, and science-based inspections and investigations, providing real-time evidence and insight essential in empowering fact-based regulatory decisions to protect public health.

Ultimate Outcome

Protect consumers and patients from injury or illness from FDA-regulated products while ensuring timely access to safe and quality products.

Core Values

OII's core values define the organization's "character" and inform its actions and decisions.

Accountability

Commitment to Public Health

Communication

Integrity and Respect

Quality