Foreword 2025

We are excited to bring you the 2025 Investigations Operations Manual (IOM). 2025 has ushered in a new era for FDA with the sunsetting of ORA and its revitalization to the Office of Inspections and Investigations (OII). This marks a new chapter for us all and your hard work and dedication during such a demanding yet rewarding time has given OII a successful start.

In addition to standing up OII, the IOM starts out 2025 completely refreshed. The IOM Refresh Project initiated in 2019 to perform a cover to cover, all-inclusive, review of the IOM to ensure the manual presented information in a clear and useful manner for field and operational staff. The 2025 IOM is the culmination of this work. The 2025 IOM includes changes to reflect the new organizational structure.

I want to express my gratitude to our entire organization as we continue to move through OII's journey together. Thanks to your mission-focused dedication, OII is prepared to keep up with the pace of change and meet the needs of the future. The work of OII, our inspections, investigations, and everything else we do, will always be fundamental to FDA's public health mission. I truly feel we are on the verge of a regulatory renaissance as we embrace opportunities to emerge stronger and more united as a world-class inspectorate.

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.

Michael C. Rogers, MS
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).

Preface 2025

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. Suggestions for the 2026 edition of the IOM including recommended changes, deletions, and additions to the IOM may be sent via e-mail to IOM@FDA.HHS.GOV. Suggestions are accepted from within the agency, our state and local partners, industry, and consumers. 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.

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