# Foreword 2023

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

Other FDA manuals and field instructions 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 division management must be informed and concur with any significant departures from the IOM.

The 2023 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.

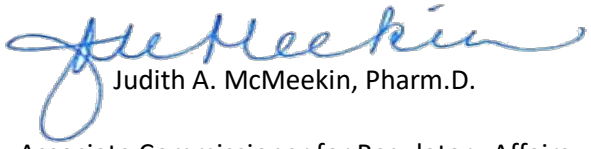
The IOM is also posted on ORA's Internet Website https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual, with all graphics included.

In 2022, the IOM Refresh Project continued its cover to cover, all-inclusive review of the IOM in an effort to ensure the manual presents information in a clear and useful manner for field and operational staff. This year saw the addition of two brand new chapters to the IOM: Chapter 1A – Notes, Records and Information and Chapter S – Safety and a refresh of Chapter 4 - Sampling. Chapter 1A updated information related to the use of electronic regulatory notes, added information about situations where CSOs are unable to take contemporaneous regulatory notes, and added a new section on records management. Chapter S serves as a tool to help employees understand, assess, and mitigate risk and hazards; an essential task to ensure the safety and well-being of all staff who meet with regulated industry. Another big change this year was the release of the Reagan-Udall reports for Foods and Tobacco. The reports show an opportunity for FDA to further evolve. ORA has always been on the forefront of evolution and 2023 will be no different. ORA stands on the edge of change and we will forge FDA's new and exciting future.

The IOM is published hard copy annually. Until the IOM Refresh Project is completed, future updates to the IOM will continue to be performed periodically during the year to the online version. The online IOM version serves as ORA's official document of record.

ORA leadership is committed to continuously improving the quality and usefulness of the IOM. Suggestions for the 2024 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.

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.



Judith A. McMeekin, Pharm.D.

Associate Commissioner for Regulatory Affairs

U.S. Food and Drug Administration, Office of Regulatory Affairs

In August 2021, ORA published its five-year Strategic Plan covering FY2022 – 2025, which outlines ORA's direction and approach to accomplish our mission and meet our vision.

## Vision

Public health is protected, promoted, and advanced.

## Mission

Protect consumers/patients and enhance public health by ensuring timely access to safe, quality FDA-regulated products.

## 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

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

*Accountability*
*Commitment to Public Health*
*Communication*
*Inclusion, Diversity, Equity, and Accessibility*
*Integrity and Respect*
*Quality*

Judith A. McMeekin, Pharm.D.

Associate Commissioner for Regulatory Affairs

U.S. Food and Drug Administration, Office of Regulatory Affairs