

Association for Accessible Medicines GRx + Biosims Conference

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Associate Commissioner for Inspections and Investigations

Agenda

- FDA's recent reorganization
- Role of FDA's inspections and investigations
- . Well-trained inspectorate
- FDA's inspection database
- Strategic priorities for OII
- Questions





FDA Office of Inspections and Investigations (OII)



FDA Organization Chart - Office of Inspections and Investigations (OII)

Effective Oct. 1, 2024

Legend:

Directly impacted by reorganization that took effect on Oct. 1, 2024 (i.e., shifts of functions, resources and/or personnel) Department of Health And Human Services Food and Drug Administration Office of Inspections and Investigations

Associate Commissioner for Inspections and Investigations

Office of Field Operations & Response

Organizational Quality Staff

Office of Emergency Response
Office of Field Regulatory Operations†

Office of Business Informatics & Solutions Management

Division of Regulatory Business Informatics & Solutions
Division of Import Business Informatics & Solutions
Division of Solutions Planning,
Management & Governance
Division of Work Planning & Analytics

Office of Training
Education
& Development

Division of Instructional Systems & Technology
Division of Multi-Program, Leadership
& Management Training
Division of Programmatic Training

Office of Import Operations

Division of Targeting & Analysis
Division of Import Operations
Division of Analysis and Program Evaluation
Division of Southwest Imports
Division of Planning & Public Response
Division of Southeast Imports
Division of Northeast Imports
Division of Northern Border Imports
Division of West Coast Imports

Office of Criminal Investigations

Chicago Field Office Metro-Washington Field Office New York Field Office Los Angeles Field Office Miami Field Office Kansas City Field Office

Office of Management

Office of Budget, Facilities & Travel Support Office of Workforce Management

Office of Bioresearch Monitoring Inspectorate

Division of Bioresearch Monitoring Inspectorate (I-IV) Division of Bioresearch Monitoring Global Operations

Office of Biologics Inspectorate

Biologics Global Operations Staff

Division of Biologics Inspectorate (I-III)

Division of Biotechnology Inspectorate

Office of Medical Devices & Radiological Health Inspectorate

Division of Medical Device & Radiological Health Inspectorate (I-IV) Division of Mammography & Radiological

Division of Mammography & Radiological Health Inspectorate
Division of Medical Device & Radiological Health Global Operations

Office of Human & Animal Drug Inspectorate

Division of Human & Animal Drug Inspectorate (I-VI)
Division of Human & Animal Drug Foreign Inspectorate
Division of Human & Animal Drug Global Operations

Office of Animal Food Inspectorate

Division of Animal Food Inspectorate (I-II)

Office of Human Food Inspectorate[‡]

Office of Human Food East Inspectorate
Office of Human Food Central Inspectorate
Office of Human Food West Inspectorate
Office of Global & Specialty Human Food Inspectorate

†Includes Division of Tobacco Inspectorate ‡Includes specialized teams for products such as infant formula

The Role of Inspections and Investigations in Public Health

Ensure firms meet regulatory standards

Identify and address potential risks for consumers

Ensure products meet safety and quality standards, instilling confidence in FDA-regulated products

Educate regulated firms to maintain compliance





A Well-Trained Inspectorate Benefits Industry

- Clear expectations and guidelines enable compliance
- Through inspections, firms can identify potential issues early and take corrective actions, reducing costly recalls, regulatory actions, drug shortages or product delays
- Partnering with the FDA enables firms to proactively ensure products meet or exceed regulatory standards

Importance of Quality and Why it Matters

- Quality is critical to the FDA's oversight
- Directly impacts product safety and efficacy
- Poor quality could result in products that harm consumers or fail to deliver intended benefits





Commitment to Protecting and Promoting Public Health

- Every day, FDA
 employees ensure the
 safety and efficacy of
 products via informed
 decisions based on
 science and data
 - Public trust in the FDA is rooted in the expertise, commitment, and passion of our workforce

The FDA's Unique Approach: Scientific Rigor & Collaboration

- Our decisions are grounded in science, and diverse voices across disciplines ensure the best possible regulatory outcomes
- Collaboration with industry and transparent communication about regulatory standards and decisions ensure a strong partnership



FDA's Inspection Data Dashboard



Data Dashboard Home

Compliance Dashboards >

FSMA Data Search >

Resources >

FDA Data Dashboard

Compliance Dashboards

Inspections

Compliance Actions

Recalls

Imports Summary

Import Refusals

Imports Entry

FSMA Data Search

Find firm compliance and enforcement information.

Search Firm Information

LAAF Participants

TPP Participants

Approved VQIP Importers

NEW!

- Dashboard has been integrated with the <u>ORA Unified Logon</u> application. To obtain the credentials necessary to use the API, please submit authorization key requests using the online <u>ORA Unified</u> <u>Logon</u> application.
- Published 483s data is now available on the Inspections Dashboard and Firm Profiles.
- LAAF-accredited laboratory capacity and respective compliance dates have been added to the <u>LAAF</u>
 <u>Dashboard</u>.

The FDA created the Data Dashboard to increase transparency and accountability by

displaying and allowing the analysis of public FDA data through easy to use, visually

accessible, customizable, and understandable graphics.

Oll Priorities

- Continue implementing the reorganization
- . Investing in our workforce
- Modernize and update our procedures
- Broaden the narrative about regulatory coverage and inspectional outcomes
- Promote FDA's world class inspectorate





Office of Inspections and Investigations

Questions?



