

# Association for Accessible Medicines GRx + Biosims Conference

*October 27, 2025*

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Associate Commissioner for Inspections and Investigations

# Agenda

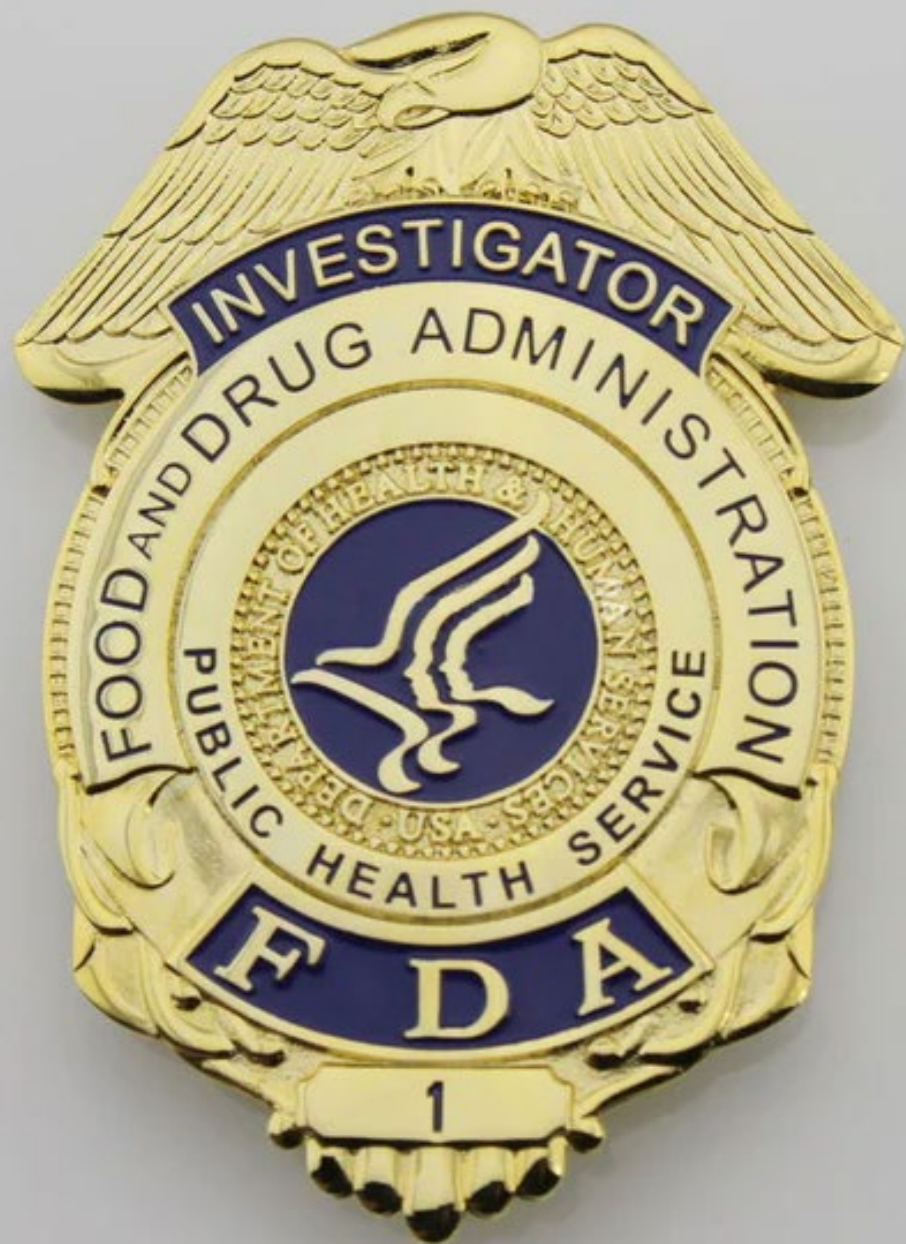
- Organizational Status
- OII Operations
- Future State





# FDA Office of Inspections and Investigations (OII)





# Lapse of Appropriations

- Risk-Based Prioritization including:
  - Inspections to safeguard human life
  - For Cause Inspections
  - Pre-Approval Inspections
  - GDUFA Funded Surveillance Inspections
  - Inspections funded by other user fee sources
  - Other investigational activities as necessary to address imminent threats to the safety of human life

# OII's Mission & Vision



This refreshed vision and mission build on the legacy of our success and the ways we'll grow as an organization.



## Mission

Our mission is to **conduct rigorous, transparent, and science-based inspections and investigations**, while providing real-time evidence and insights that are essential in empowering fact-based regulatory decisions **to protect public health**.



## Vision

Our vision is that OII's global inspections and investigations ensure FDA-regulated products are **safe, trusted, and accessible**.

OII is at U.S. borders, in International Mail Facilities, and in more than 90 countries worldwide scrutinizing the products U.S consumers rely upon, and ensuring that their production, manufacturing, and importation comply with federal law.



# Oil Core Operations



INSPECTIONS



INVESTIGATIONS



IMPORTS

# Strategic Priorities

By focusing on these priorities, we aim to better protect public health and maintain high standards in our work.



1. **Assessing and Strengthening the Workforce:** Focus on identifying inspection capacity, organizational structure and training.



2. **Optimizing Inspections:** Over the past two years, we joined colleagues across the agency to map out a new model for more effective work across the lifecycle of inspections and other core mission functions



3. **Modernizing Work Planning:** Improved governance through risk management will ensure clear accountability and streamlined decision-making, which best enables the FDA to adapt to challenges



4. **Nurturing Collaborations:** Our state, local, territorial, tribal, and international regulatory partners are crucial for keeping the public safe and helping us grow the FDA's capacity for inspectional oversight.



5. **Enhancing OII Culture:** Working to enhance OII culture by cultivating a supportive and thriving workplace environment



# OII: Where We Are Going





# Expanding Global Inspectional Reach

- Targeted inspections
- Preserve domestic oversight
- Increase inspection quality





A group of law enforcement officers and a woman in a purple suit are standing in a room with chain-link fencing and signs. The woman is on the left, looking towards the group. Several officers in blue and black uniforms are standing in the center. A man in a black shirt is in the foreground, facing away from the camera. The background features chain-link fencing with signs that read "WARNING NO TRESPASSING Restricted Area Keep Out Authorized Personnel Only" and "NOT A WARDEN PERSONNEL ONLY".

# Flexible Workforce Deployment

- Decentralization
- Maximize field coverage resource allocations
- Leveraging technology

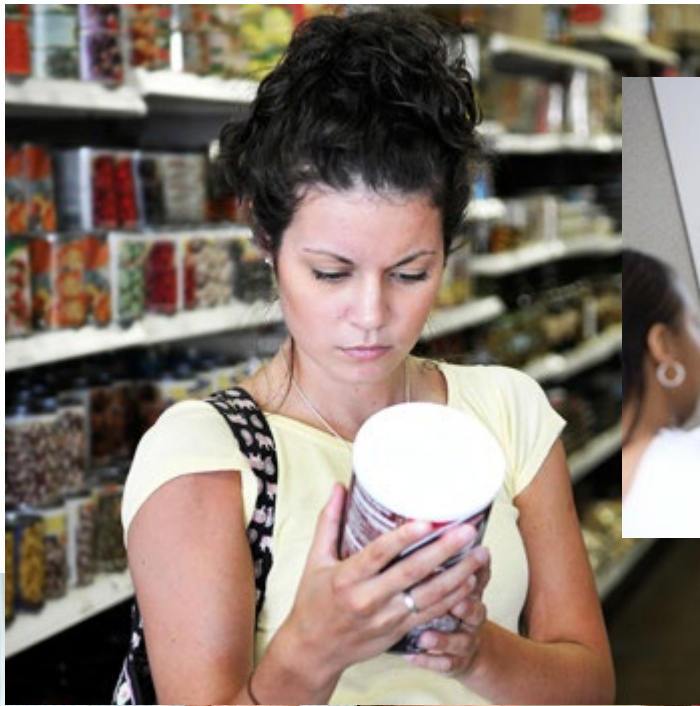


# Revolutionize Training

- . Tiered Investigator pathway
- . Modernized training platforms
- . Expanded utilization of technology
- . Continuous learning









Thank you!



**U.S. FOOD & DRUG**  
ADMINISTRATION