

# Inspections in a Post-Pandemic World

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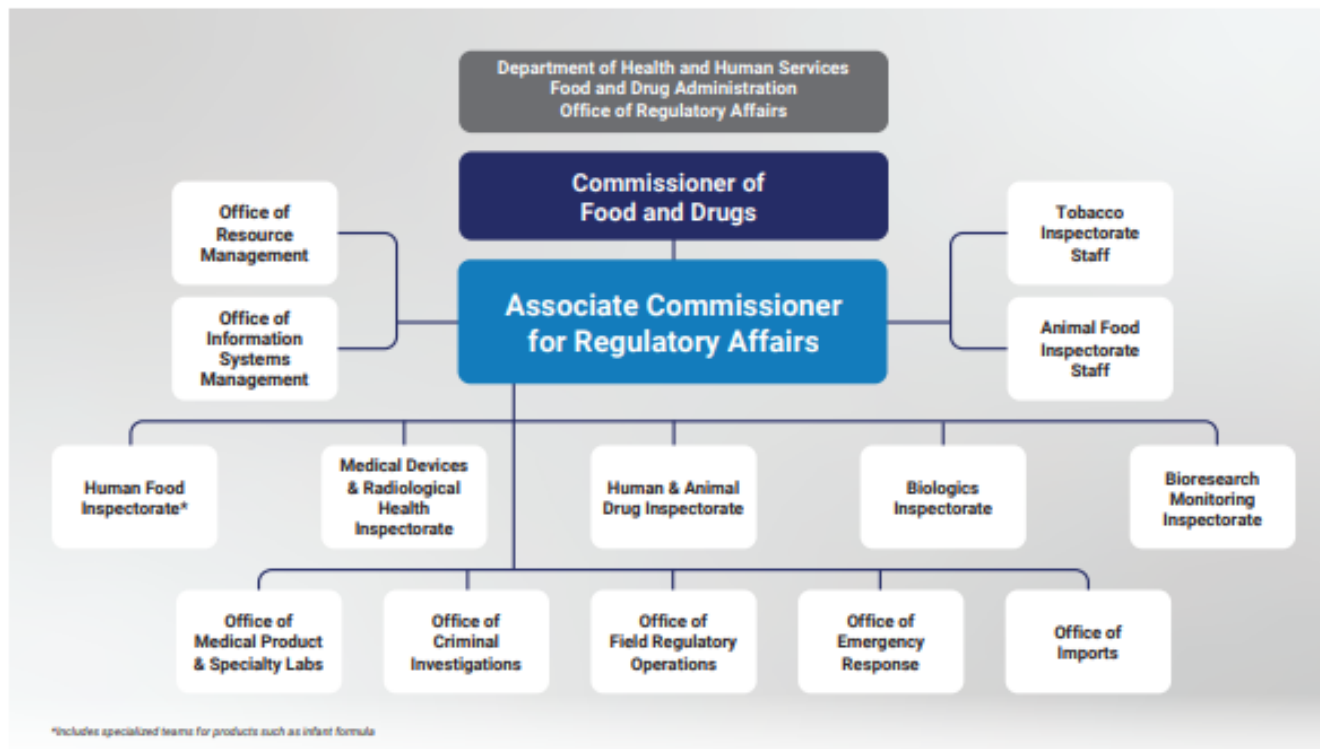
Office of Regulatory Affairs



# New Model for the Office of Regulatory Affairs (ORA)



# Proposed Office of Regulatory Affairs Organization Chart



## Descriptions of proposed ORA offices:

The **Associate Commissioner for Regulatory Affairs (ACRA)** will report directly to the FDA Commissioner with responsibility of overseeing the agency's field force who carry out inspections, investigations, and import operations in support of the FDA's product centers and programs. The ACRA will work closely with other FDA executives to ensure priorities are appropriately coordinated and advanced.



## Inspections During the Pandemic

On March 13, 2020, FDA suspended on-site inspections

- Routine ORA foreign inspection trips for rest of the world resumed in April 2022
- Routine ORA foreign inspection trips for China resumed in May 2023
- Alternative tools such as remote regulatory assessments (RRA) were also used when in-person inspections were not possible due to Covid-19 related travel restrictions.

# Alternative Tools



**Remote Interactive  
Evaluations**



**Record review authorized  
under section 704(a)(4) of  
the FD&C Act**



**Pharmaceutical  
Inspection Co-operation  
Scheme (PIC/S)**



**Bilateral Information  
Sharing**

# Remote Regulatory Assessments

## Remote Regulatory Assessments (RRAs)

RRAs are an examination of an FDA-regulated establishment and/or its records, conducted entirely remotely, to evaluate compliance with applicable FDA requirements. RRAs assist in protecting human and animal health, informing regulatory decisions and verifying certain information submitted to the agency.

### MANDATORY ASSESSMENTS

Program Areas:

- Human and animal drugs and biologics
- Foreign Supplier Verification Program for imported foods

Requests for records or other information and may include voluntary virtual interaction



There are  
2 kinds



### VOLUNTARY ASSESSMENTS

Program Areas:  
All FDA regulated commodities

Information review and/or virtual interactions such as remote interactive evaluations and video streaming



[Guidance for Industry:  
Conducting Remote  
Regulatory Assessments  
Questions and Answers](#)

# Mutual Recognition Agreement (MRA)

### FDA and the EU Expanded the scope of the MRA

- Addition of Swissmedic to MRA (human & animal drugs)
- Addition of Veterinary Pharmaceuticals (animal drugs)

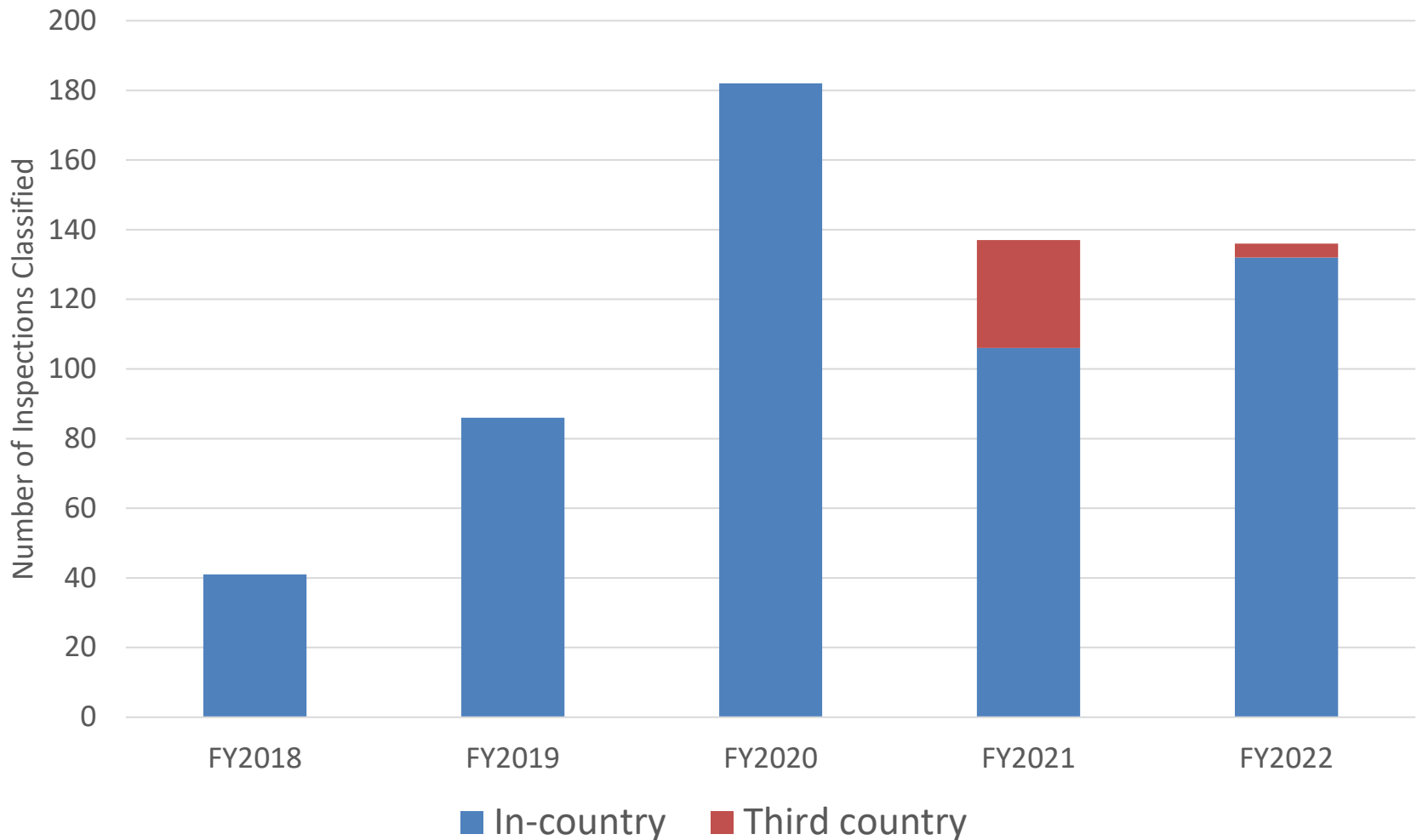
- Enhances efficiencies & avoids duplication of inspections to allow attention to areas of greater risk
- Regulatory Framework Reviews & Observing EU Audits

[FDA MRA Website](#)





# MRA Inspections Classified by Fiscal Year



# What Can Industry Do

- Ensure timely responses to Agency's requests
  - Notice of Inspection, RRAs, FDA 483 voluntary response
- Ensure all information submitted to the Agency is accurate, completed, and promptly updated when changes occur which warrant updates
  - FDA Drug Registration, submissions (e.g., 356h)
- If delayed action is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at [drugshortages@fda.hhs.gov](mailto:drugshortages@fda.hhs.gov).
- When utilizing contract manufacturers and laboratories; define, establish, and document activities of the parties involved which are subject to GMPs
  - FDA Guidance, [Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry](#)

# Final Thoughts

- ✓ ORA continues to serve as the Agency's frontline to ensure the safety and effectiveness of FDA-regulated products
- ✓ FDA has resumed routine foreign inspection travel
- ✓ ORA is making transformative changes

