U.S. FOOD & DRUG ADMINISTRATION

Office of Regulatory Affairs
Office of Pharmaceutical Quality Programs
Updates

Alonza Cruse, Director

Agenda

ORA
New Model

Industry Trends

Foreign
Unannounced
Inspection Pilot

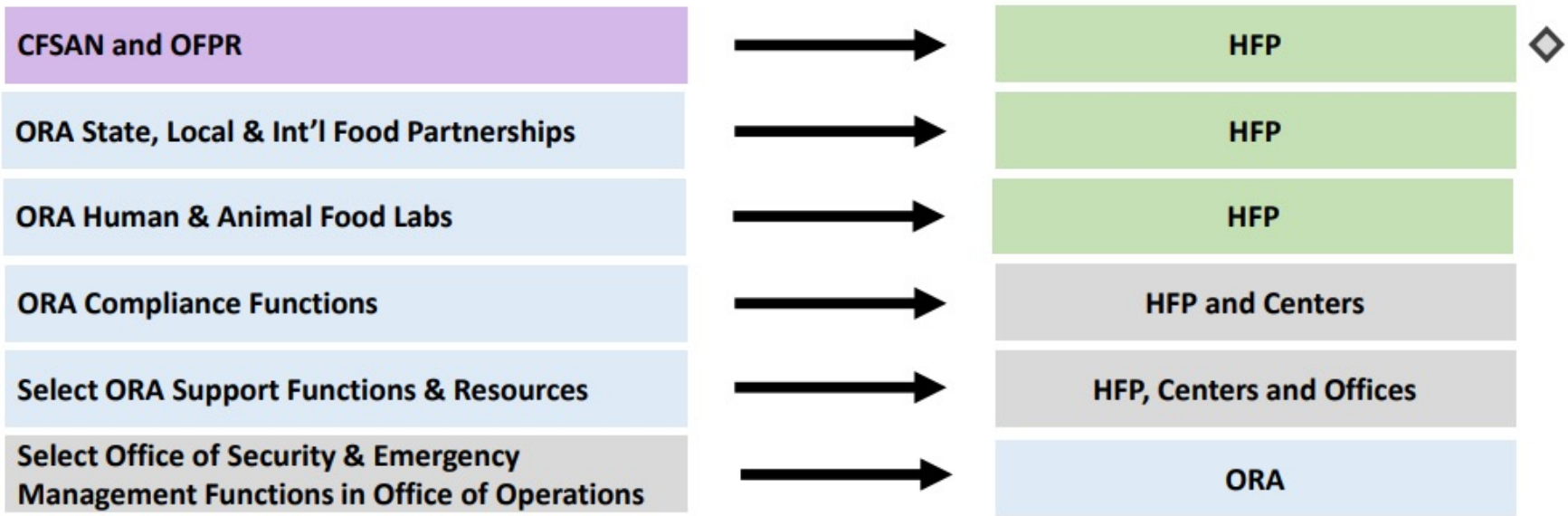
MRA/Annex 1

Staff Training

New Model for the Office of Regulatory Affairs (ORA)

New ORA Model

6/27/2023 Updates to FDA Proposal to Unify Human Foods Program / Create New ORA Model



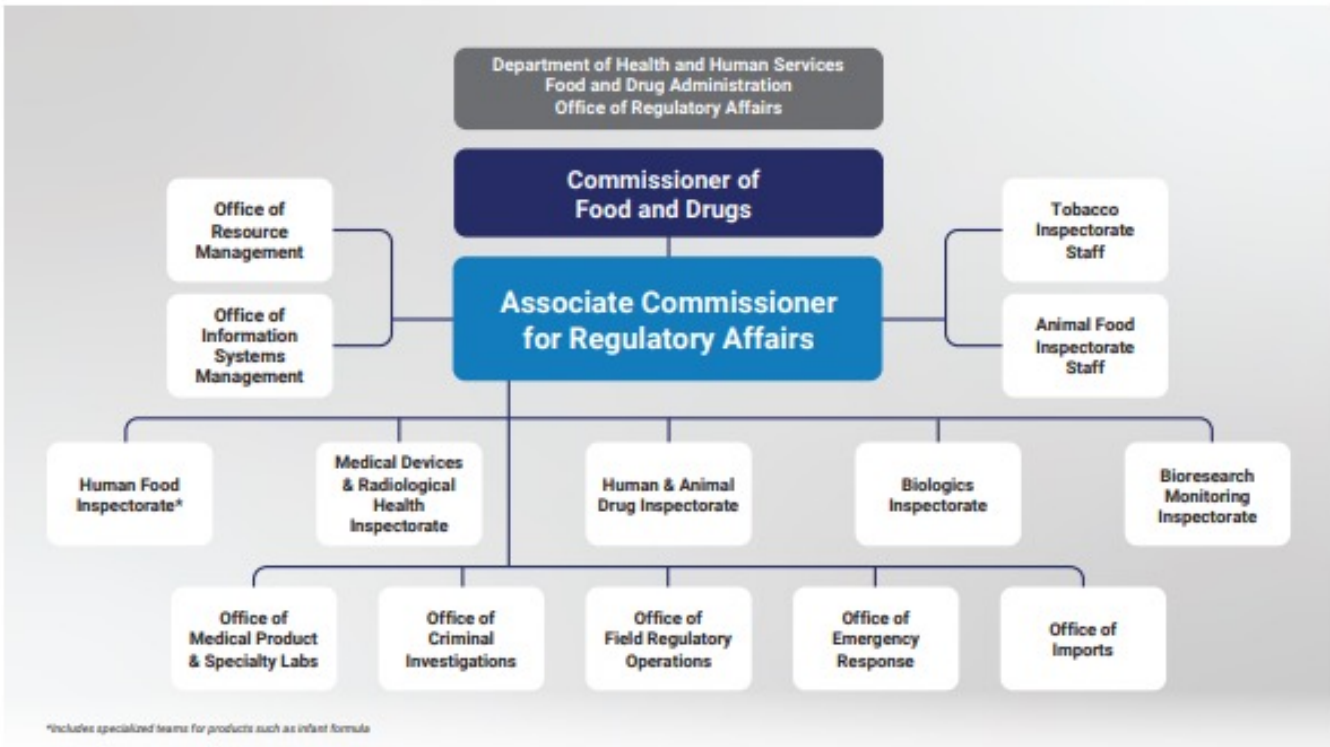
The Deputy Commissioner for Human Foods (DC) will have full authority over all components of the HFP, including human foods resources in ORA. In addition, the DC will collaborate with a senior official in ORA focused on human foods-related activities and resources. The HFP and the Center for Veterinary Medicine (CVM) will also have a clearly defined relationship. The DC will ensure robust collaboration for human and animal food laboratory research and other priorities such as scientific and regulatory pathways that support and spur innovation technologies (e.g., novel ingredients, intentional genomic alterations for agricultural products, and cell cultured foods). The DC will also work to advance all components necessary to build a truly integrated food safety system.

◇ Previously announced

LEGEND

Center for Food Safety and Applied Nutrition (CFSAN) and Office of Food Policy and Response (OFPR)	Office of Regulatory Affairs (ORA)	Human Foods Program (HFP)	Other FDA Centers and Offices

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.

Press Release
July 27, 2023

Industry Trends

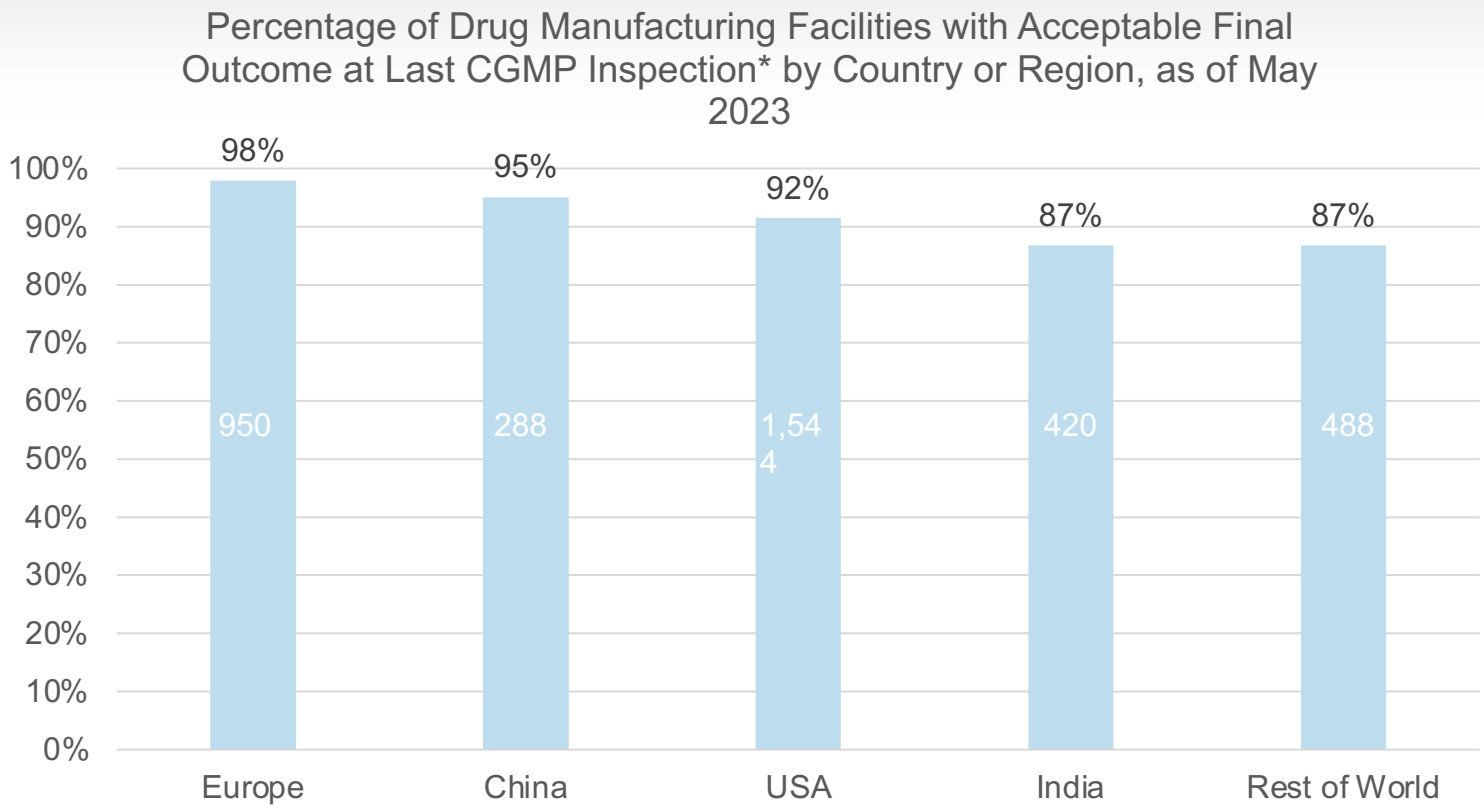
Industry Trends – FDA Data Dashboard

datadashboard.fda.gov/ora

Current Locations of Various CGMP Inspection related documents

- Below are links to various document repositories on FDA's Website
  - CDER Reading Room
    - https://www.fda.gov/drugs/guidance-compliance-regulatory-information/cder-foia-electronic-reading-room
  - ORA Reading Room
    - https://www.fda.gov/about-fda/office-regulatory-affairs/ora-foia-electronic-reading-room
  - FDA Warning Letter Page
    - https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters
  - FDA Inspections Dashboard
    - https://datadashboard.fda.gov/ora/cd/inspections.htm
  - FDA CGMP Inspection Related Import Alert
    - https://www.accessdata.fda.gov/cms_ia/importalert_189.html
  - Enforcement Reports
    - https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
  - Recalls Information
    - https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts

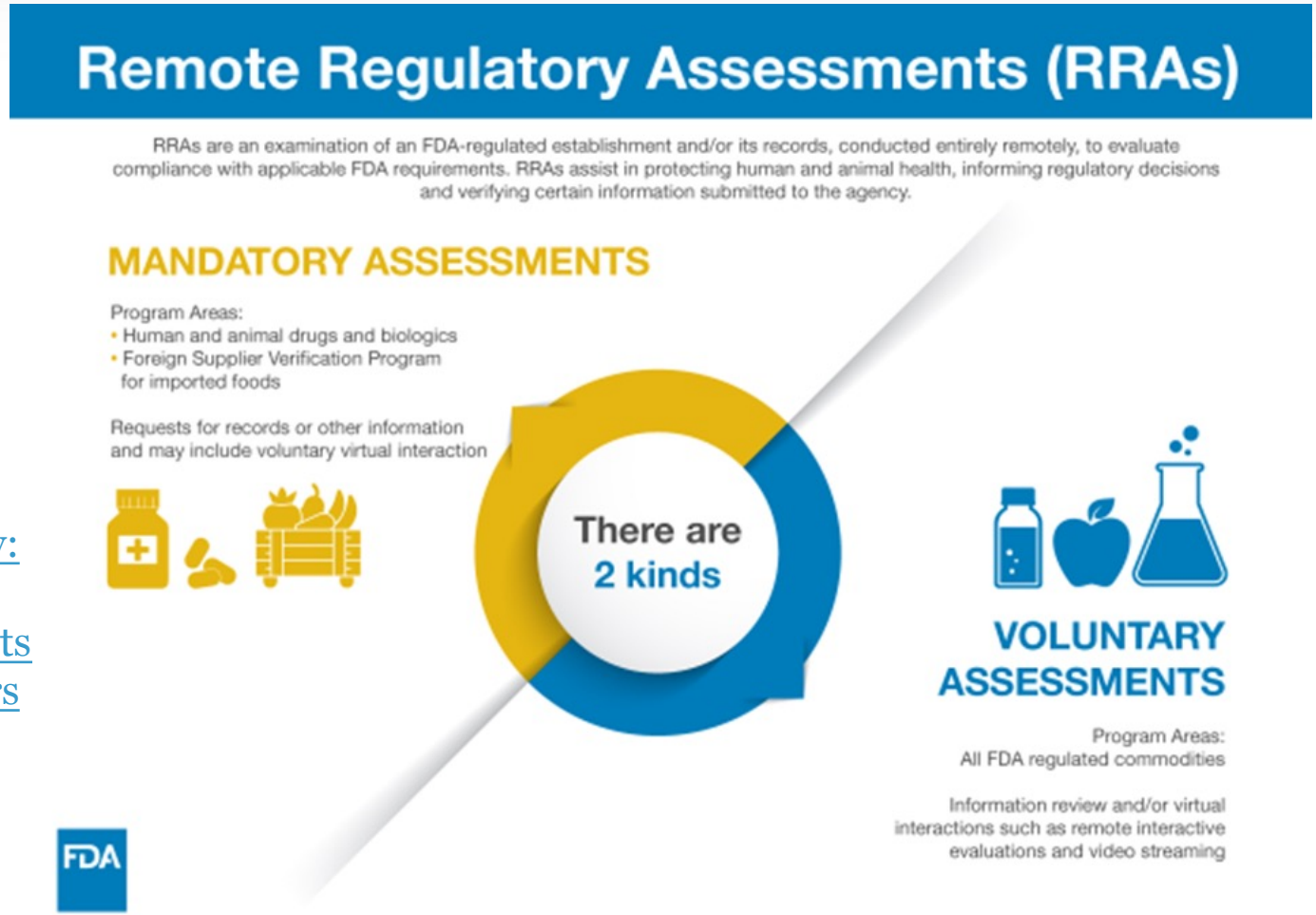
Inspection Outcomes by Region



*i.e., No Action Indicated or Voluntary Action Indicated outcomes, most recent inspection FY2000 to May 2023; number in bar represents total number of sites inspected with acceptable final outcomes

Shift in percentage of US sites: largely due to shift in US inspections for sites with higher OAI rates, for instance new hand sanitizer manufacturers that entered the inventory during the Pandemic.

Industry Trends – Remote Regulatory Assessments



Guidance for Industry: Conducting Remote Regulatory Assessments Questions and Answers

Foreign Unannounced Inspection Pilot (FUIP)

Foreign Unannounced Inspection Pilot

Pilot Background

Congress directed FDA in the FY21 & FY22 House bill language to "restart the pilot in India and establish an additional pilot in China to improve workforce development activities and include unannounced and short notice inspections."

Pilot Purpose

Evaluates intersectional outcomes resulting from inspection notification types:

- Unannounced,
- Short notice (≤ 72 hours),
- and pre-announced (≥ 8 weeks)

- Not all inspections will be unannounced.
- The inspection itself will be conducted per normal inspectional procedures and policies.
- FDA continues pilot implementation in India and recently started the pilot in China.

Mutual Recognition Agreement (MRA)

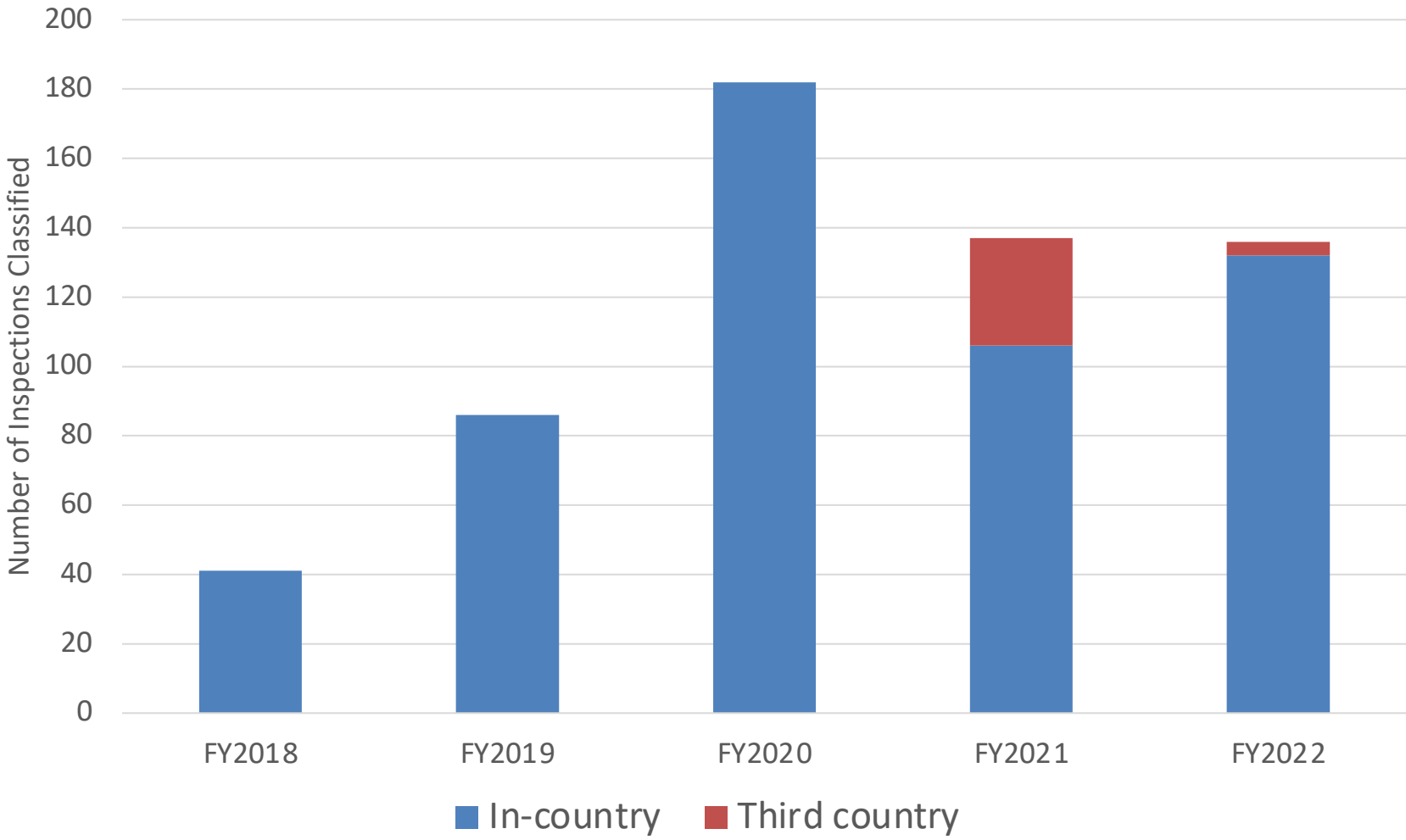
MRA Sectoral Annex for Pharmaceutical GMP

FDA and the EU Expanded the scope of the MRA

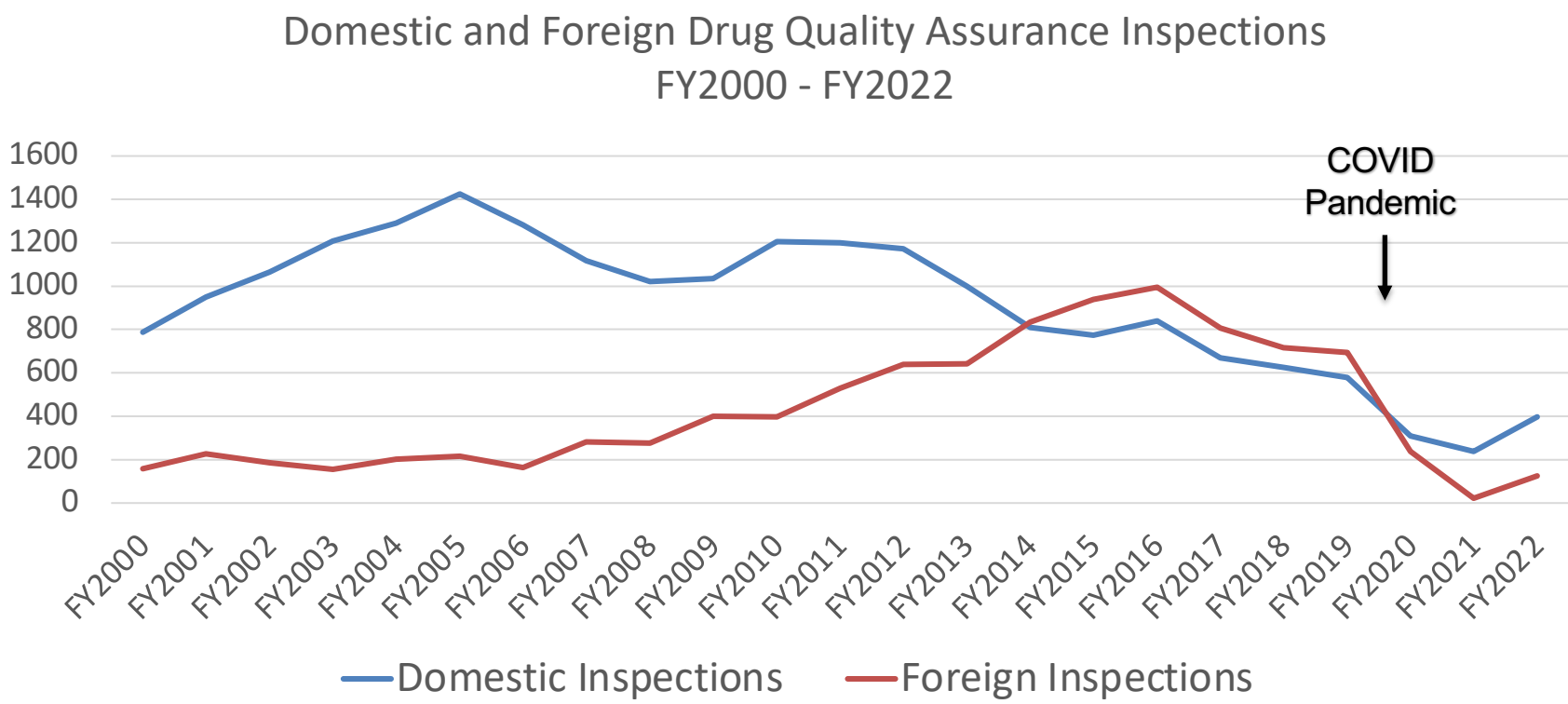
- Addition of Swissmedic to MRA (human & animal drugs)
- Addition of Veterinary Pharmaceuticals (animal drugs)
  - Enhances efficiencies & avoids duplication of inspections to allow attention to areas of greater risk
  - Regulatory Framework Reviews & Observing EU Audits
  - 16 EU Member States were found to have the capability of carrying out GMP inspections including: Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Luxembourg, Netherlands, Poland, Portugal, Slovenia, and Spain

FDA MRA Website

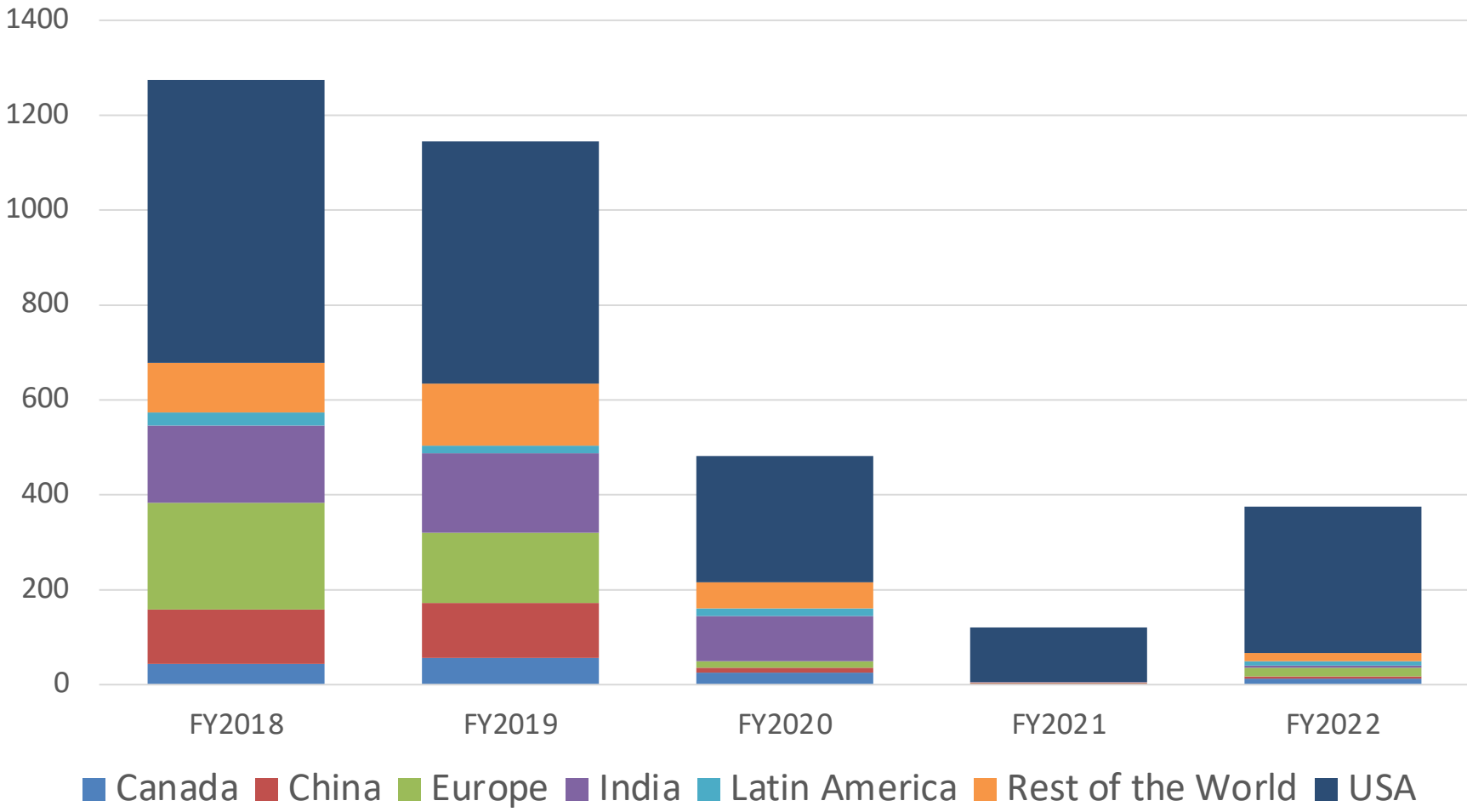
MRA Inspections Classified by Fiscal Year



Drug Quality Assurance Inspection Counts FY2000 – FY2022



Surveillance Inspections by Region



Investigator Training

Investigator Training

- On-the-job, classroom, and online
- New Hire Training Framework
  - Dedicated Training Supervisor
  - Stronger Collaboration with Peers
  - Strategic On-the-Job Training Coordination
- Continue to identify and implement strategies to provide continuous learning in an ever-changing industry

Final Thoughts

- ORA continues to serve as the Agency's frontline to ensure safety and effectiveness of FDA-regulated product
- FDA has resumed inspection travel to China
- FDA has implemented the FUIP in China & India
- It is critical firms ensure timely responses to the Agency
  - Notice of Inspection
  - RRA requests
  - 483 responses
- ORA is looking for transformative changes to enhance its efficiency and effectiveness as it contuse as an enterprise-wide organization supporting our centers and focused on inspectional activities.


FDA
U.S. FOOD & DRUG
ADMINISTRATION