FDA India Office Updates

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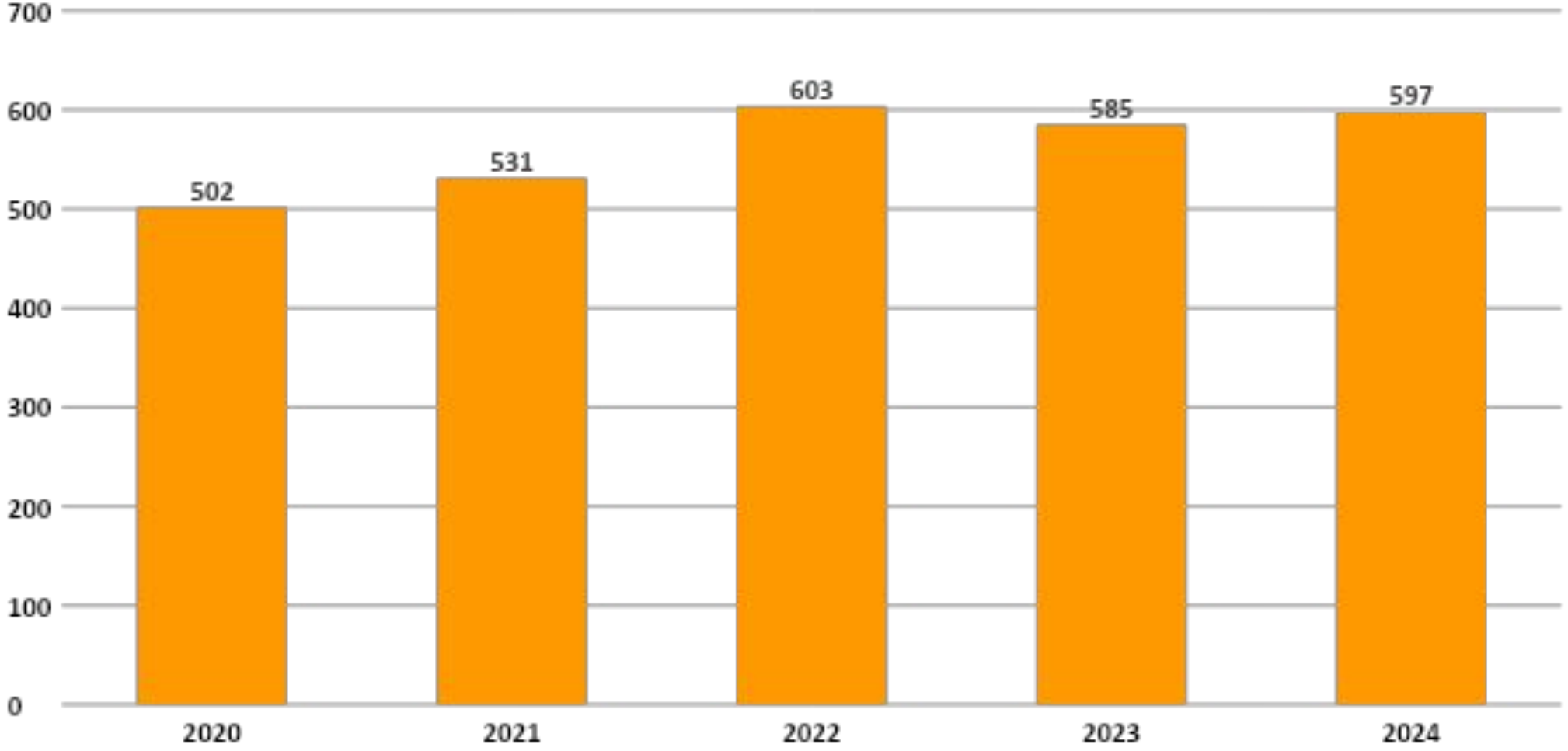
15+ Years of Service to Global Public Health

FDA Priorities

- Make America Healthy Again (MAHA) Initiative
- Accelerate cures
- Reduce drug costs
- Domestic drug manufacturing

State of Pharmaceutical Quality in India

Number of FDA Registered Pharmaceutical Firms in India



Fiscal year (FY) begins on 1st October of previous calendar year and ends 30th September of that calendar year.

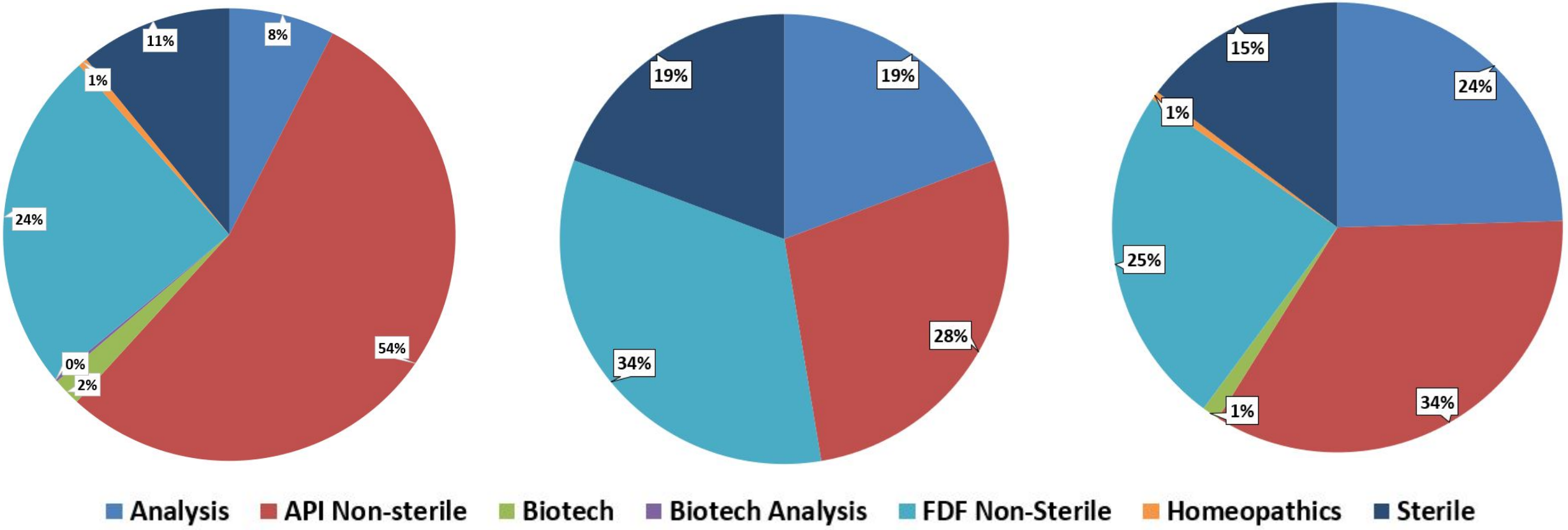
Reference: OPQ's "Report on the State of Pharmaceutical Quality"

Inventory Shift for FY2020-FY2024

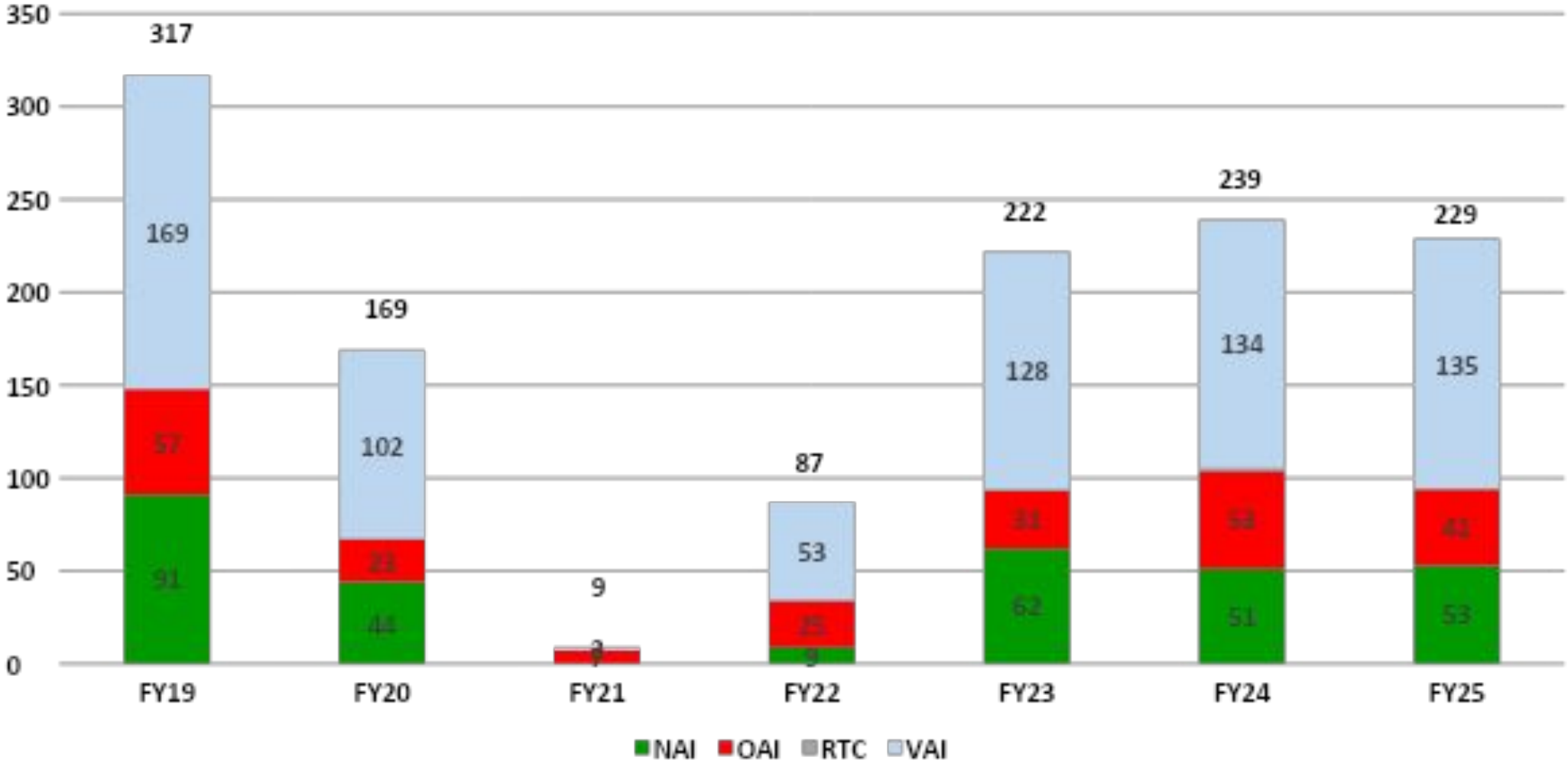
Country	Sites in FY2024 Catalog	5 Year Review of Sites in the Catalog			
		Sites Maintained	Sites Removed	Sites Added	% Net Change
United States	1,892	1,425	487	611	7%
India	**597**	**450**	**57**	**163**	**18%**
China	477	271	93	221	27%
Germany	194	151	11	47	19%

Inventory Shift for Indian Sites by Manufacturing Sector for FY2020-FY2024

450 Sites Maintained	57 Sites Removed	163 Sites Added



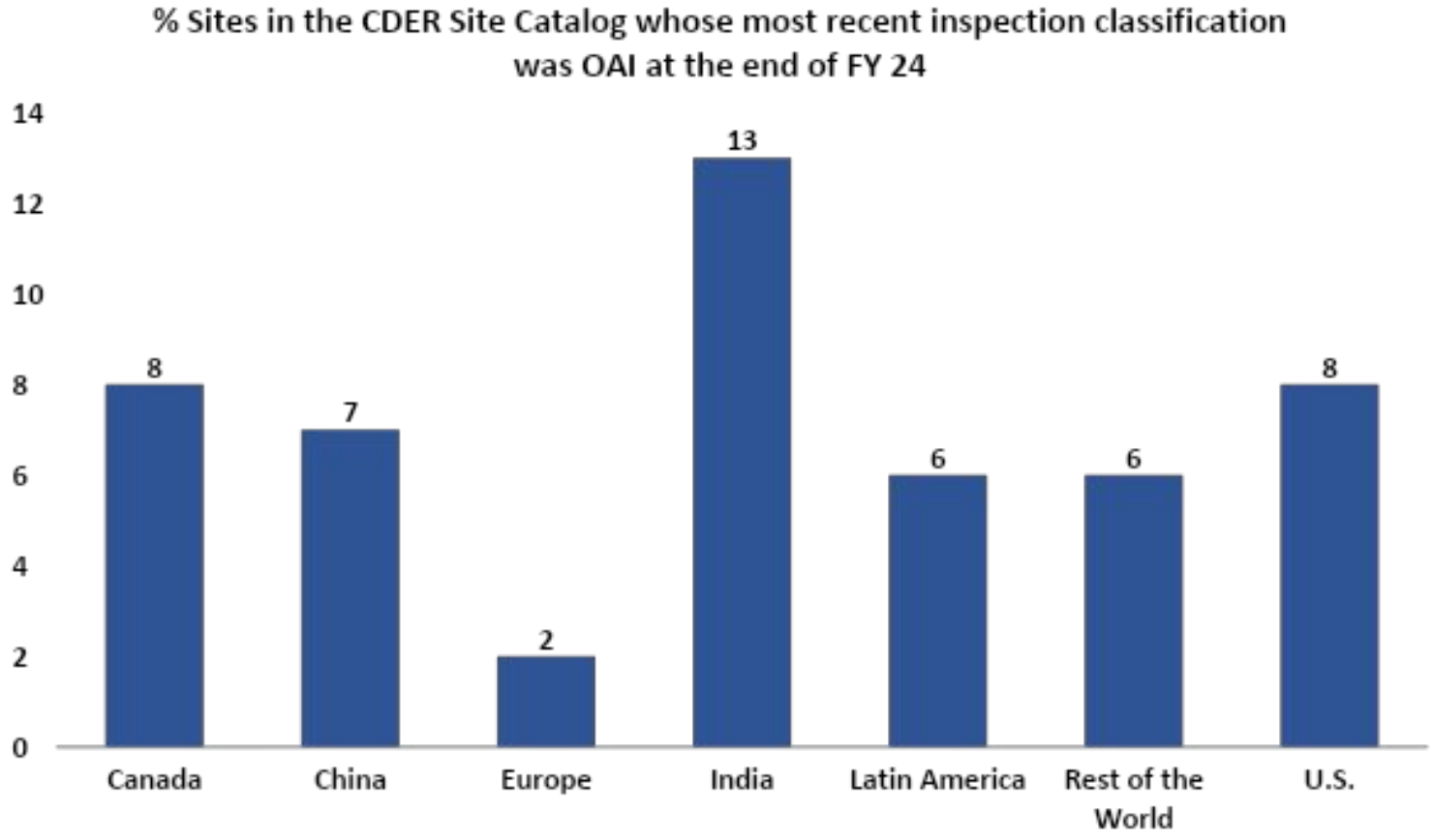
Number & Classification of Pharmaceutical Inspections in India



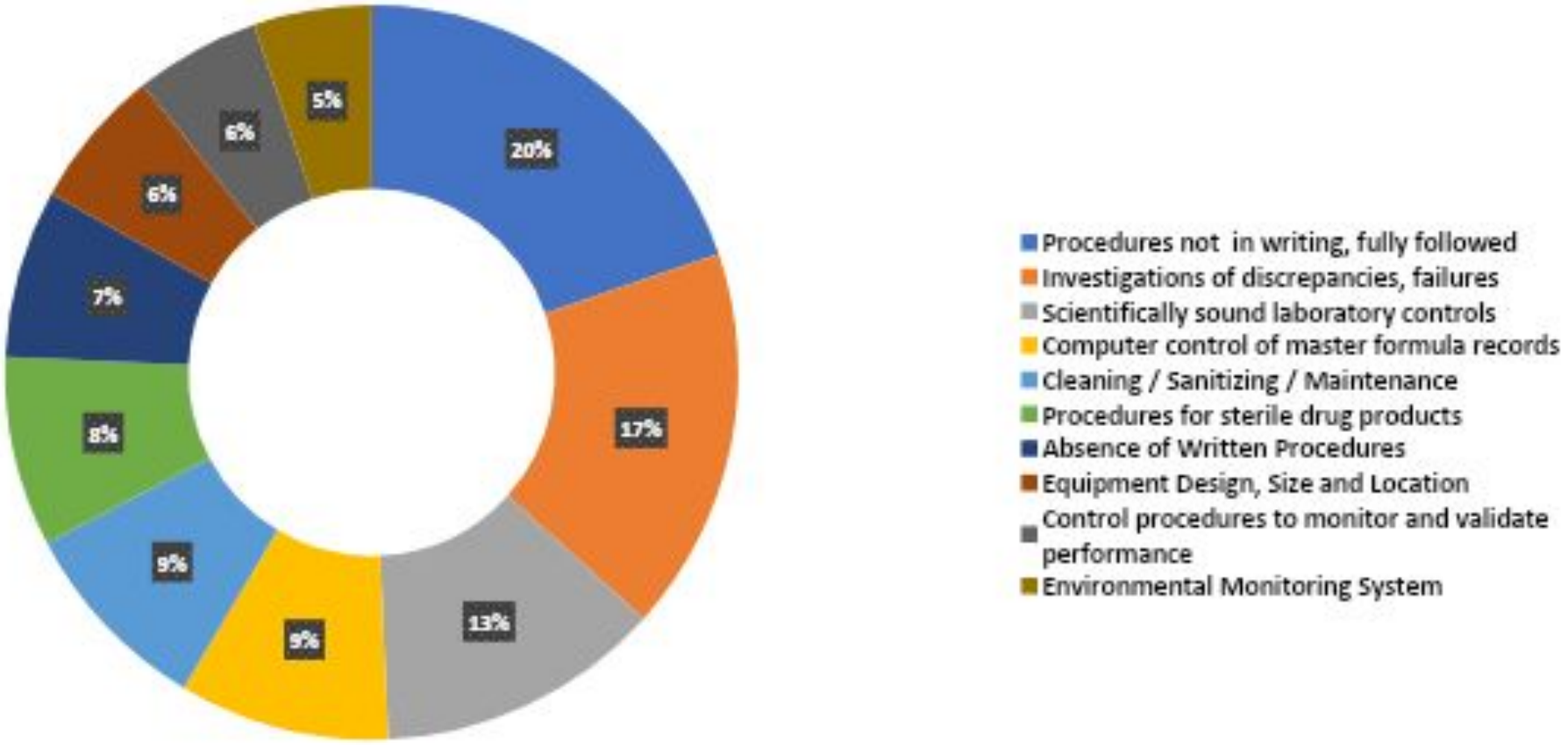
Reference: Data from OQS

Inspection Outcomes by Country/Region

- At the end of FY24, 13% of facilities in India had a most recent inspection outcome of OAI, the highest % compared to any other region.
- This is a measure of site compliance that may not equate directly with product quality.



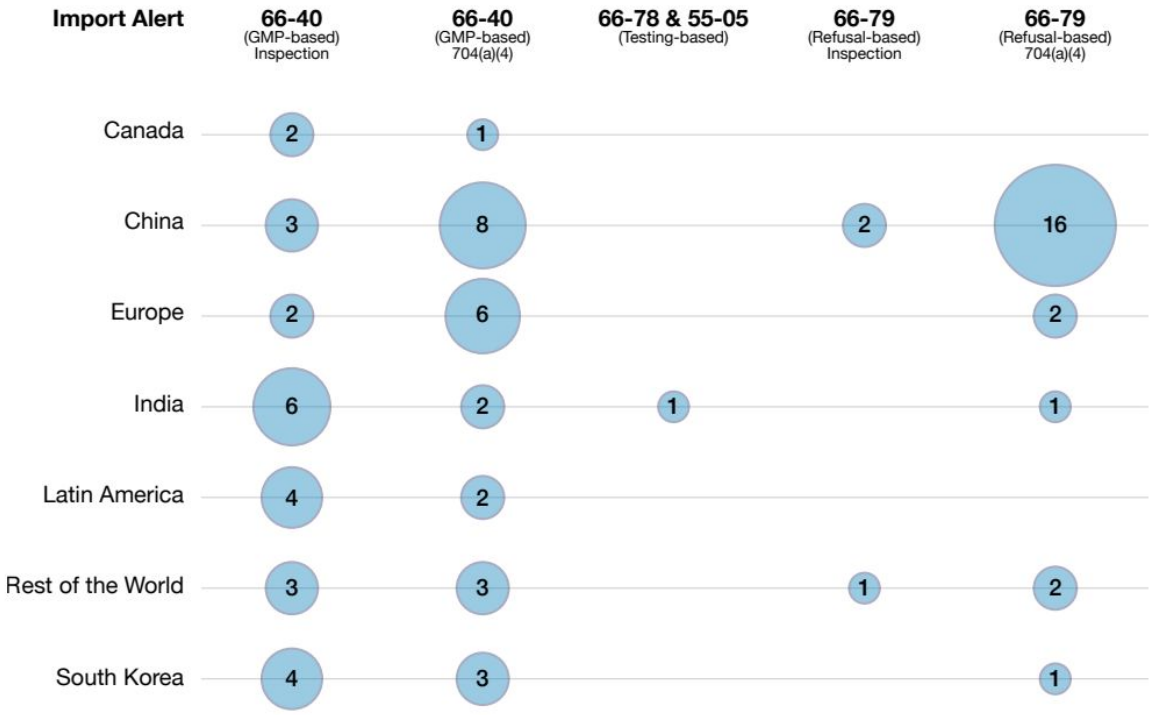
Top 10 citations issued in India for FY 2018-2025



Reference: Data from OQS

Import Alerts & Warning Letters

FY2024 Drug-Quality-Related Import Alerts Additions by Type and Region



Warning Letters by Country and Region for FY2020 – FY2024

Reference: OPQ's "Report on the State of Pharmaceutical Quality"

QMM Updates

Next Steps for the QMM Program

- Refined QMM assessment protocol based on lessons learned in 2024.
- Solicited volunteers for QMM assessments beginning in 2025:
  - Federal Register Notice soliciting volunteers was posted on April 23, 2025 and closed on June 9, 2025.
  - Nine volunteer establishments have been selected with two from India.
- Publish summary findings from the nine 2024 assessments.
- Explore additional outreach opportunities.

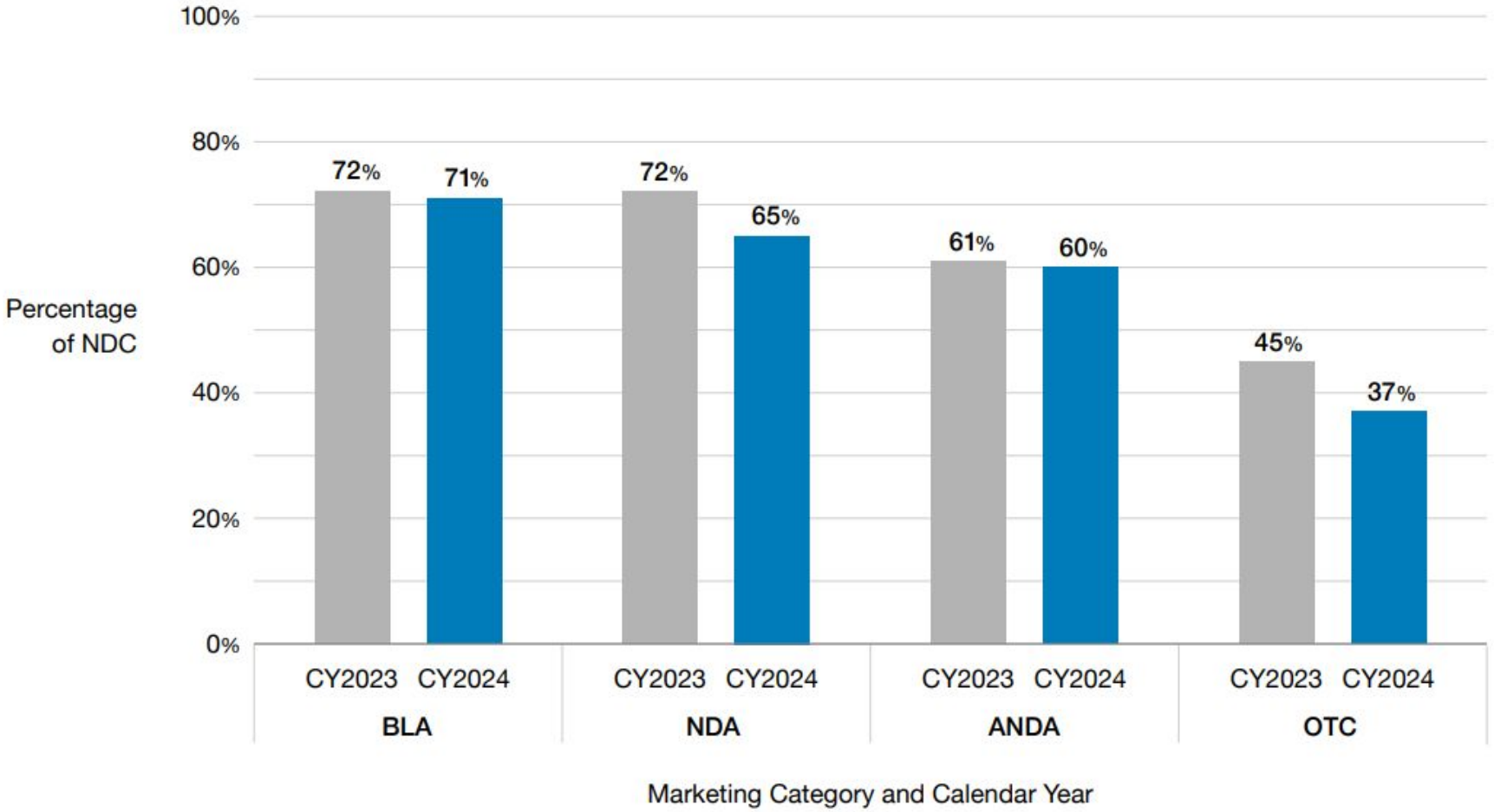
Drug Shortage Update

CARES Drug Amount Reporting

- The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) authorized FDA to enhance prevention and mitigation of possible drug shortages by augmenting its drug supply chain visibility.
- On February 26, 2024, FDA implemented the final guidance on Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act.
- It describes:
  - The recommended time frame for submitting CY reports is no later than March 31 of the following CY.
  - Reporting recommendations for drug products in finished package form, drug products not in finished package form, and APIs Reporting requirements for registrants across the drug supply chain, including contract manufacturers.
  - How FDA plans to use data from the reporting program

CARES Drug Amount Reporting

% of NDC for Active Listed CDER-regulated Drugs (excluding medical gas) for which Registrants (excluding repackers and relabelers) Submitted Drug Amount Reports, by Marketing Category



Reference: OPQ's "Report on the State of Pharmaceutical Quality"

INO Activities and Engagements

Engagement with Government of India

FDA- CDSCO BA/BE Workshop
(Sep 2024)

FDA- CDSCO Generic Drug Lifecycle Management Workshop
(Dec 2023)

1st Annual US FDA Maharashtra FDA
Regulatory Forum (Aug 2024)

FDA-CDSCO-EMA Trilateral
(Oct 2024)

1st Annual US FDA Telangana DCA Regulatory Forum
(Jan 2024)

Engagements with Industry

PDA India: 2025 Annual Meeting (Jul 25)

ICMR PGIMER Clinical Trials Workshop (Nov 2024)

IPA Global Pharmaceutical Quality Summit (Jun 2024)

PDA QMM Workshop (Sep 2024)

FDA Leadership Conversation with BA/BE study Sponsors in India (Sep 2024)

Key Messages

Ensuring patient access to critical drugs require:

1. A culture of quality
2. Practices that ensure the integrity of manufacturing and clinical data
3. Transparent quality systems that enable investment in reliable and quality producers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