

FDA India Office: Advancing the Standard for Quality and Resilience



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11th Advanced GMP Workshop
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15+ Years Protecting Patients Through U.S.-India Engagement

FDA



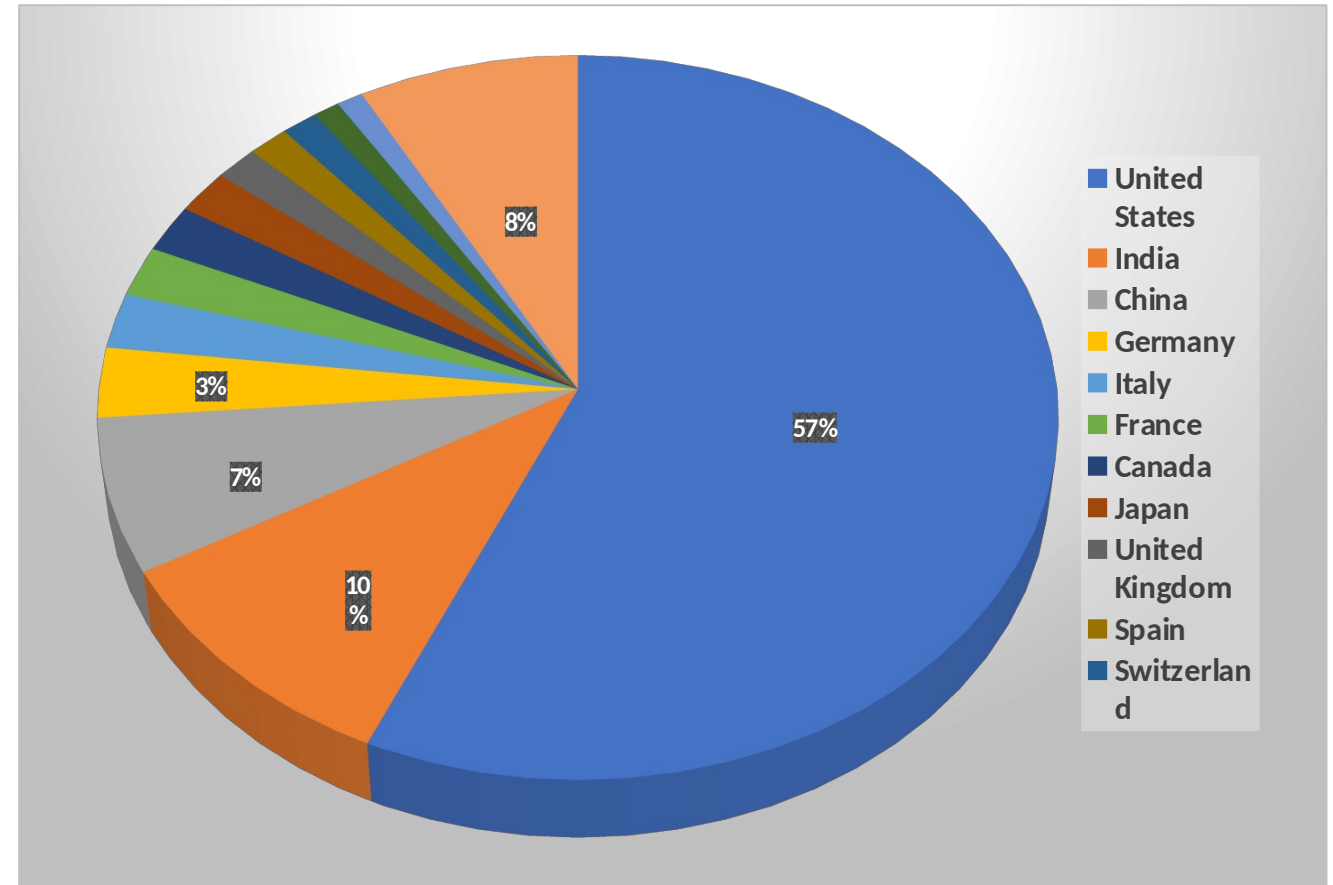
From Compliance to Resilience

The next generation of pharmaceutical quality systems must sustain a state of control—not simply demonstrate compliance at a point in time.

Why India Matters

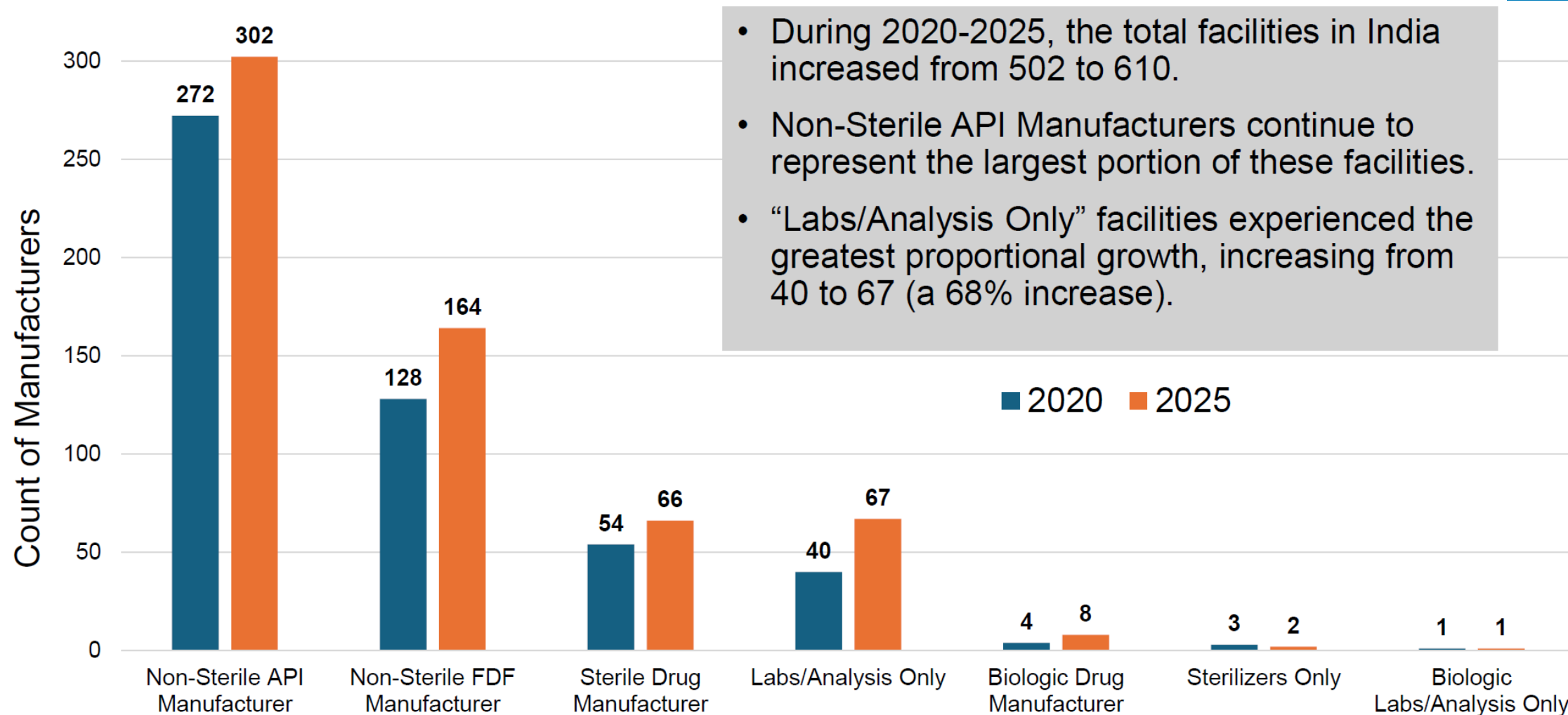


- Outside of the United States, India has the largest number of FDA-registered pharmaceutical facilities (FDA's FY2025 inventory)
- India's role in the Pharmaceutical Supply Chain Continues to Grow.



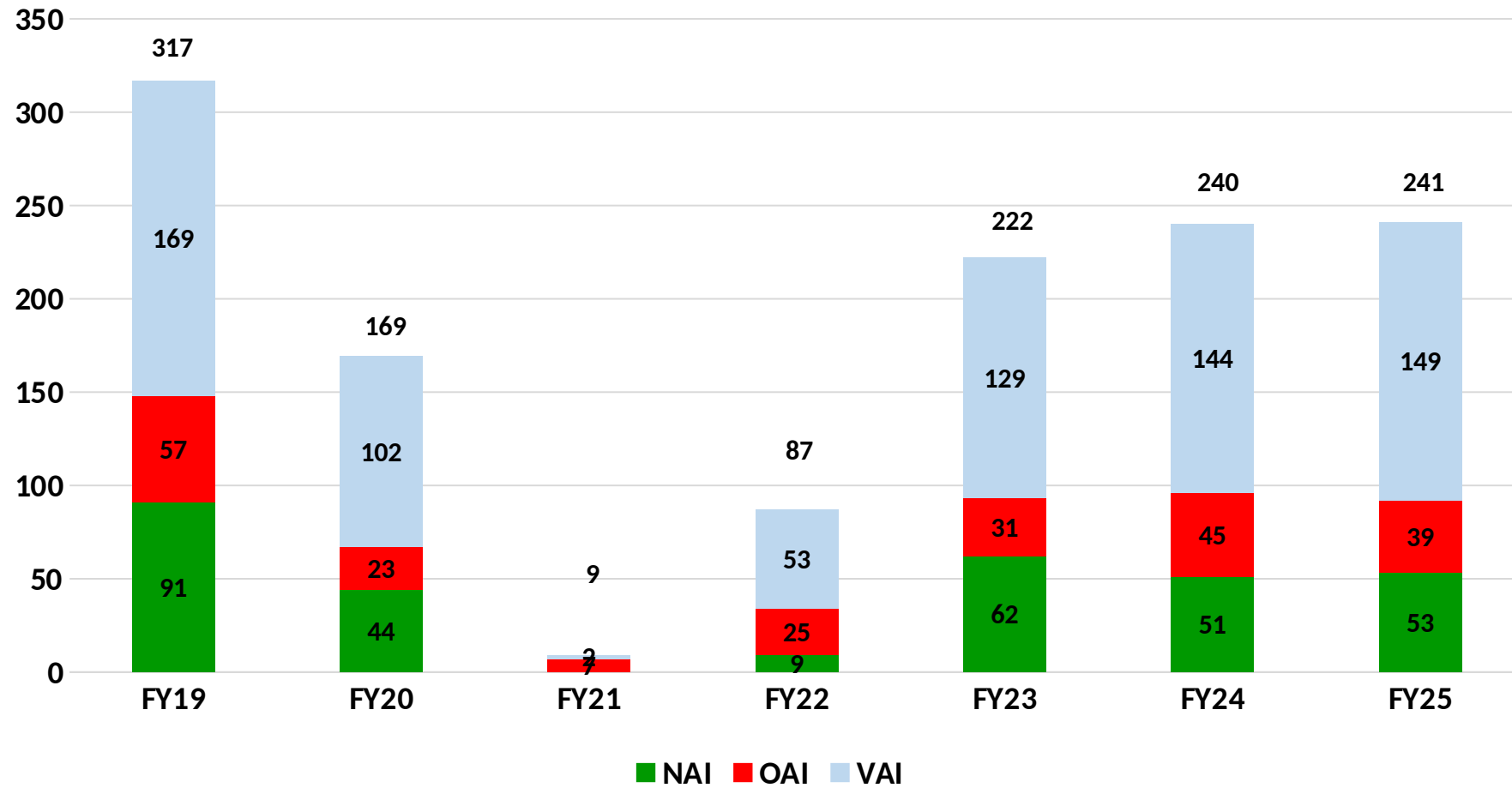
FY 2025 Pharma Manufacturing Site Distribution

India's Manufacturing Facilities Growth



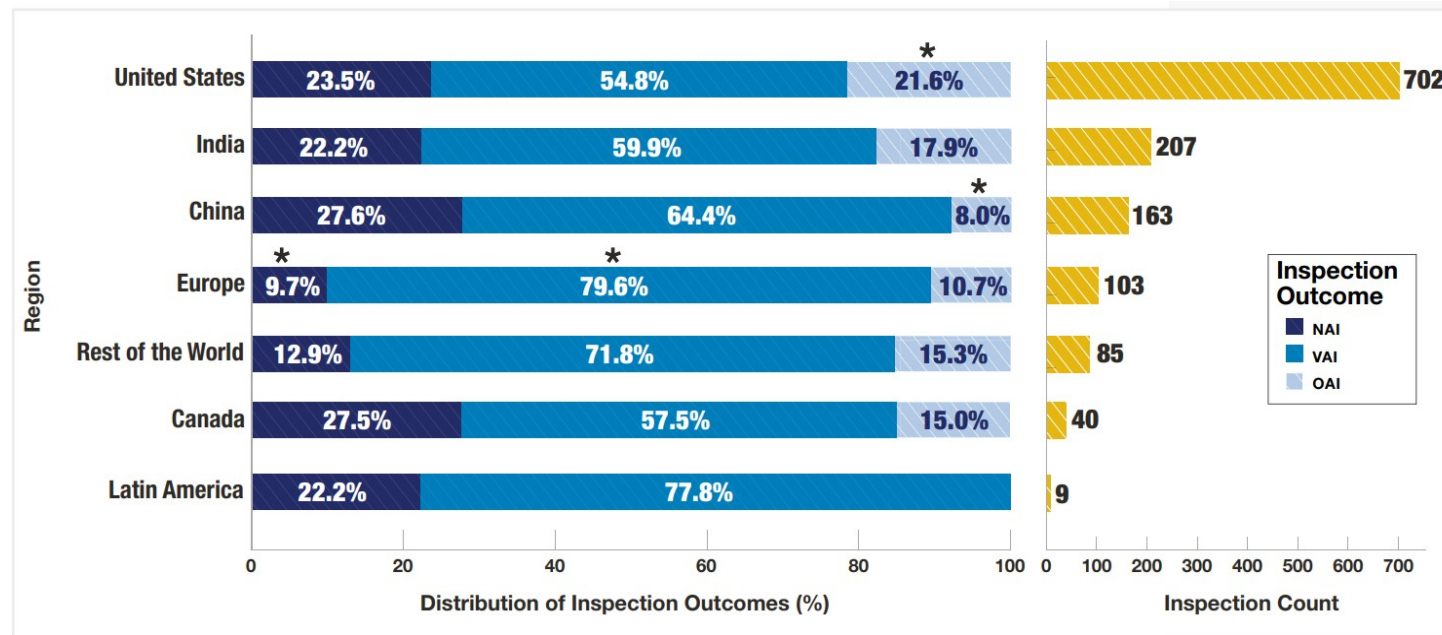
These data are based on the CDER Facilities Catalog versions for December 2020 and December 2025.

Number & Classification of Pharmaceutical Inspections in India



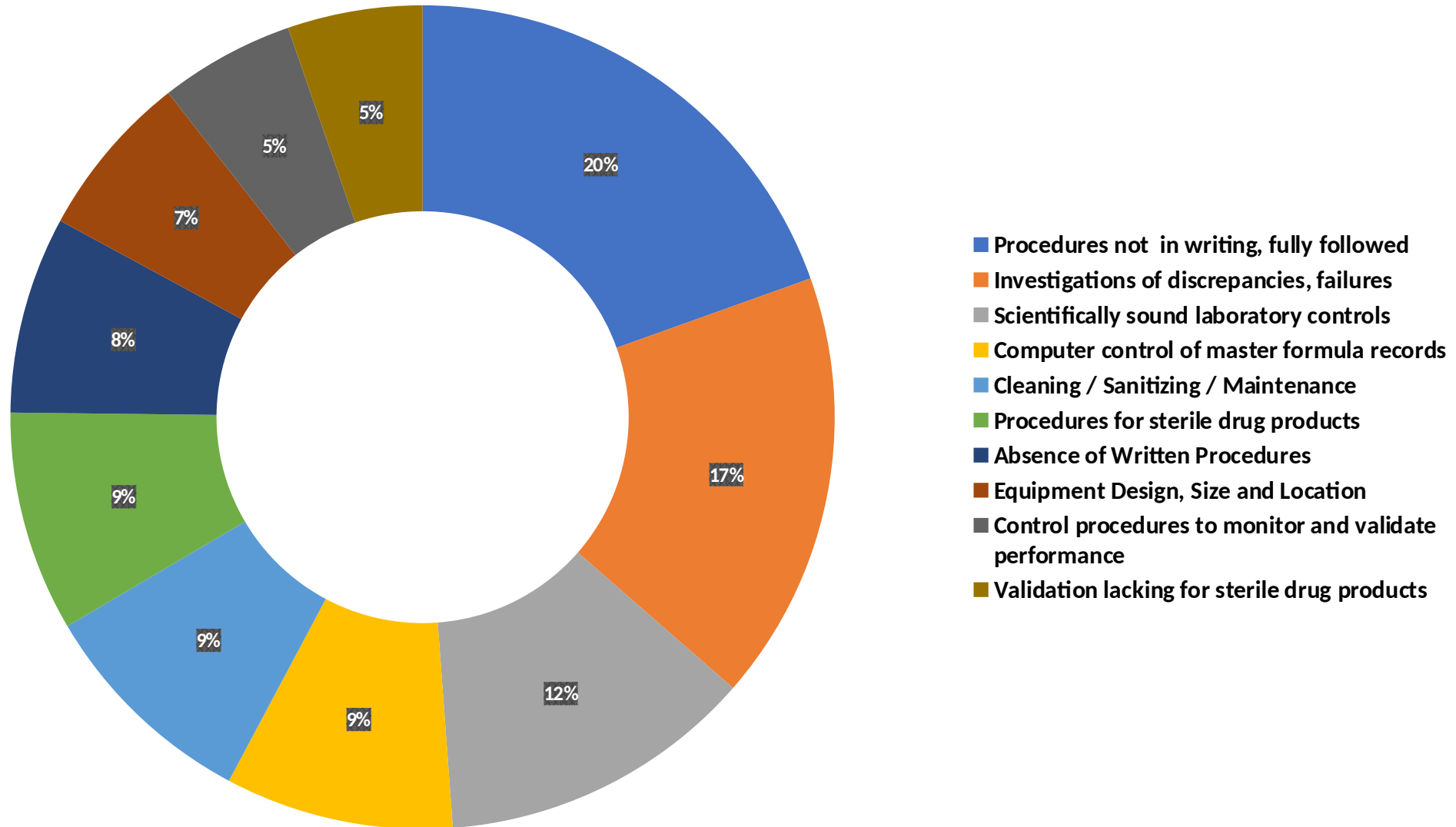
Reference: Data from OQS

FY 2025 Inspection Outcomes by Country/Region



- Global average: 22% NAI, 60% VAI, 18% OAI
- ***India's inspection outcomes are broadly consistent with the global average.***
- A statistical examination of the distributions of outcomes revealed that China had significantly fewer OAI outcomes (8.0% vs. 18% global average), while the U.S. had significantly more OAI outcomes (21.6% vs. 18% global average).
- Europe had significantly fewer NAI outcomes and more VAI outcomes than the global average.

Top 10 citations issued in India for FY 2018-2026

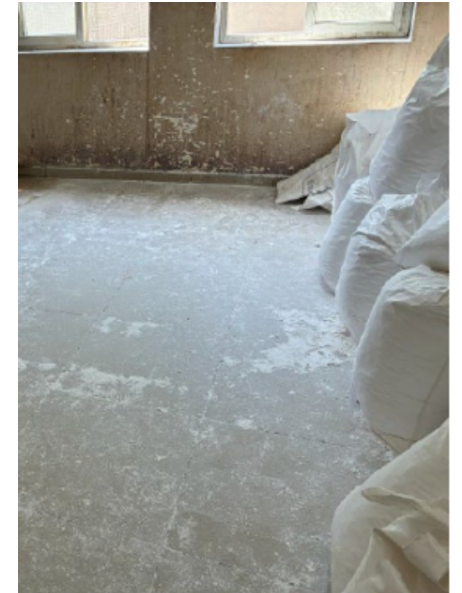


Reference: Data from OQS

Seeing the Facility as It Operates Every Day



- *Recent inspections continue to identify unacceptable, and in some cases gross, insanitary conditions.*



Reference: <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/shoolin-pharma-chem-llp>
<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/patcos-cosmetics-pvt-ltd>

Data Integrity is a Quality System Issue



Eight years after FDA issued its Data Integrity guidance, data integrity continues to remain a key

concern.

FDA cites [redacted] a large Indian generic drug manufacturer, for tossing truckloads of key documents

Data integrity is 'biggest issue' for drug, API firms during inspections, FDA official says

U.S. drug regulator flags data integrity, maintenance lapses at [redacted] India plant

Burn after reading: FDA blasts for 'cascade of failure' after investigators find heaps of shredded documents

[redacted] analyst poured acid over manufacturing docs, FDA says in scathing warning letter

Reference: <https://www.statnews.com/pharmalot/>
<https://www.fiercepharma.com/manufacturing/>
<https://www.raps.org/news-and-articles/>
<https://www.thehindu.com/business/Industry/>

<https://www.fiercepharma.com/pharma/>

Data Integrity Concerns Extend Beyond Manufacturing



FDA continues to identify significant data integrity and study conduct concerns at CROs in India—resulting in study data being deemed unacceptable and, in some cases, requiring studies to be repeated.

FDA to pharmaceutical companies: Certain studies conducted by Raptim Research Pvt. Ltd. are unacceptable

Clinical and Bioanalytical Studies Conducted by Panexcell Clinical Lab or Synchron Research Services Are Unacceptable

Reference: <https://www.fda.gov/drugs/drug-safety-and-availability/notification-pharmaceutical-companies-clinical-and-bioanalytical-studies-conducted-panexcell>
<https://www.fda.gov/drugs/drug-safety-and-availability/fda-pharmaceutical-companies-certain-studies-conducted-raptim-research-pvt-ltd-are-unacceptable>

India Office Priorities

01

Unannounced Inspections



Enhance oversight through risk-based unannounced inspections to ensure product quality and patient safety.

02

Stakeholder Engagements



Strengthen collaboration with government and industry stakeholders to advance public health goals.

03

Quality Management Maturity



Advance quality management practices beyond baseline compliance to achieve greater quality and continuous improvement.

04

Supply Chain Resilience



Support a reliable and resilient pharmaceutical supply chain to ensure continuous access to quality medicines.

Three Questions for the Next Decade

- Can your quality system detect weak signals before they become deviations, failures or shortages?
- Would your data, investigations and controls tell the same story during an unannounced inspection?
- Can your manufacturing network maintain quality and supply when something unexpected happens?

Keeping Patients at the Center

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



Engagement with Government of India (Central)



FDA-GoI Bilateral Meeting - White Oak



FDA-CDSCO-EMA Trilateral - India



DIA GAM - India Townhall -US

Engagement with Government of India (State)



**U.S. FDA-Maharashtra FDA
Regulatory Engagement**



**Andhra Pradesh
Regulatory Engagement**



**U.S. FDA-Gujarat FDCA
Regulatory Engagement**



**1st Annual U.S. FDA-Karnataka
DCD Regulatory Forum**



**2nd Annual U.S. FDA-Telangana DCA
Regulatory Forum**



**1st Annual U.S. FDA-Goa DFDA
Regulatory Forum**



**2nd Annual U.S. FDA-Guj FDCA
Regulatory Forum**

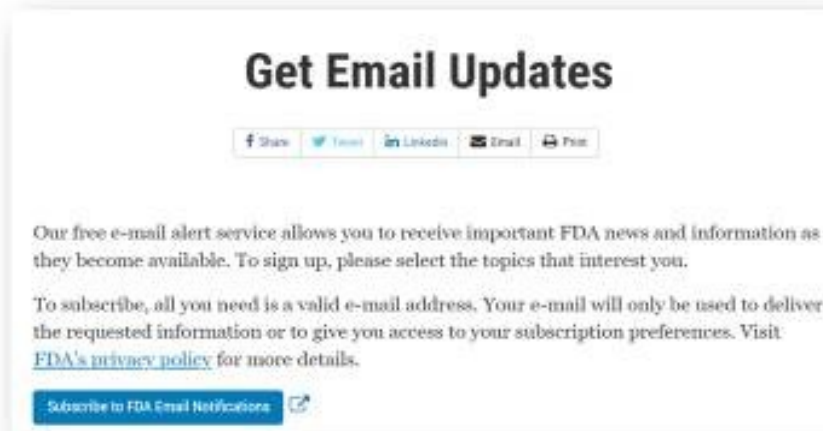
Looking Ahead to 2027



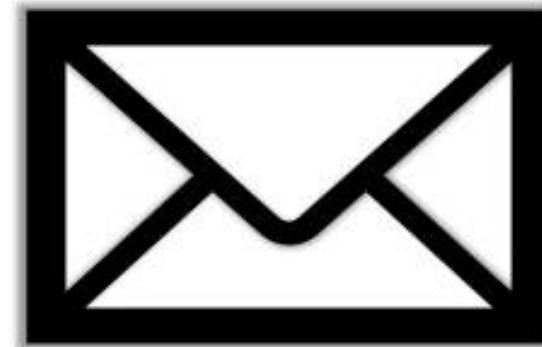
Continued Engagement on Quality and Resilience:

- Biosimilar Regulatory Roadshow
- CDER and OII Leadership Visit to India
- BA/BE and Clinical Research Discussions
- Generic Drug and Manufacturing Quality Priorities
- Quality Management Maturity (QMM)

Stay Informed!



<https://www.fda.gov/about-fda/contact-fda/get-email-updates>



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Trusted Data. Resilient Supply.