The Foreign Inspection Gap: Regulatory Data Intelligence for Global GMP Oversight

Smarter Data, Safer Decisions

Research - The FDA Foreign Inspection Gap

1 ABSTRACT

Background: The majority of APIs and finished drug products entering the U.S. originate from overseas. From 2014–2024, FDA foreign GMP inspections have fallen sharply. This divergence underpins the FDA's May 6, 2025 shift toward unannounced foreign facility inspections and underscores the need to modernize global oversight.

Objectives: Examine how trends in FDA inspection quality relate to increasing import volumes of drugs into the United States by analyzing FDA-issued observations since 2014.

Methods: Ratios of import quantities and inspections were used to evaluate the FDA's effectiveness in enforcing inspections abroad, as drug imports increased from 2014 to 2024.

Results: **For every additional $1 billion of drug imports, there were 23 fewer inspections conducted (2014–2019).** While import volumes increased in leading nations, inspections declined.

Conclusion: Inspection intensity declined sharply (China: **101.8 → 18.3** per billion USD). Foreign facilities exhibited observation rates **1.3–1.8× higher** than the U.S. baseline (49.3%), with China (69.0%) and India (62.3%) showing particularly elevated rates.

2 KEY FIGURES

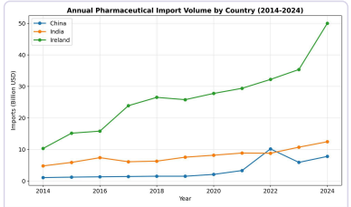


Fig. 2a — Annual Pharma Import Volume by Country

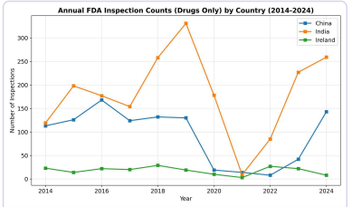


Fig. 2b — Annual FDA Inspection Counts (Drugs Only)

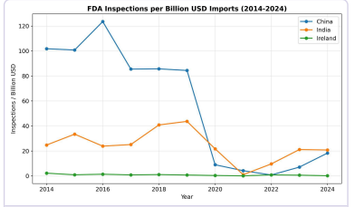


Fig. 3 — FDA Inspections per Billion USD Imports

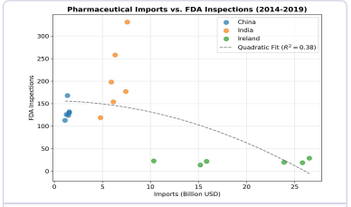
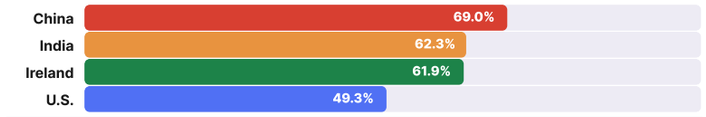


Fig. 4a — Imports vs. Inspections (2014–2019),

Inspection Outcome Rates (VAI + OAI), 2014–2024



Country	2014	2019	2024	Change
China	101.80	84.42	18.29	-82%
India	24.74	43.67	20.77	-16%
Ireland	2.22	0.74	0.16	-93%
Germany	5.56	4.41	2.68	-52%

3 CONCLUSION & DISCUSSION

Key finding: FDA foreign inspection intensity declined substantially across all major exporting nations from 2014–2024. Inspection outcome rates (VAI + OAI) remained stable despite varying volumes, averaging 62.3% for India and 69.0% for China vs. 49.3% for U.S. domestic inspections.

Policy context: The host country has an incentive to protect and promote its exporting industry. The 79-fold difference in inspection intensity between China (96.0 per billion USD) and Ireland (1.2 per billion USD) during 2014–2019 reveals significant resource allocation challenges.

Impact: These quantitative findings provide empirical support for the FDA's May 6, 2025 policy shift toward unannounced foreign inspections, addressing both volumetric gaps and integrity concerns raised by Congressional investigators. The inspections-per-billion-USD framework offers a forward-looking metric to evaluate whether policy changes translate into measurable improvements in oversight rigor.

AI & regulatory data: AI and LLM models have made text search and aggregation of regulatory data significantly easier. Using regulatory data in structured analytical workflows can support training, assessment, and compliance decision-making.

Preprint: Kwiecinski, G. (2025). The Foreign Inspection Gap: FDA GMP Oversight of U.S. Drug Imports, 2014–2024. Research Square. doi:10.21203/rs.3.rs-7849765/v1

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Company - GKS KeyPedia Applied

4 ABOUT GKS

Our mission is to improve quality and regulatory compliance and inspection readiness by providing data-driven tools that streamline the preparation for audits and inspections within the pharmaceutical industry.

20+	50K+	100K+	Real-time
Years of FDA Data	Warning Letters	483 Observations	Updates

5 HOW IT WORKS — KEYPEDIA PLATFORM

Summarize Activities
Turn large regulatory datasets into clear, decision-ready summaries.

Assess Trends
Surface recurring risks and enforcement patterns before they escalate.

Export Reports
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KEYPEDIA™

Ask about FDA regulations, compliance requirements, or regulatory processes...

- What are the areas I should focus on based on FDA current trends?
- Which FDA personnel issued the most 483s this year?
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- What's my likelihood of getting inspected in the next 6 months?

What GKS Does

- FDA & Global Updates, Inspections, Recalls, Warning Letters, and 483 Observations.
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- Export change control/CAPA evidence with clause-level provenance.

Where GKS Pays Off

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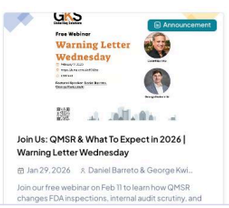

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