INTERPHEX | APRIL 21-23, 2026
JAVITS CENTER, NYC

GUIDING INNOVATION FROM DISCOVERY TO DISTRIBUTION

Quick Fire: The Foreign Inspection Gap, Oversight of U.S. Drug Imports

Tuesday April 21 2026, 2:30 – 2:45pm

In the business of building businesses

Agenda

- Papers of Interest
- Foreign Inspections & FDA Inspection Process
- The Foreign Inspection Gap
- Why this Matters and What's Being Done
- Tools and Tech Tools

Papers of Interest

The Foreign Inspection Gap: FDA GMP Oversight of U.S. Drug Imports, 2014–2024

George Kwiecinski[1,2] · Kevin Yuan[3]

A Dynamic Model for GMP Compliance and Regulatory Science

Yiyi Bao[1,2] · Nicholas Buhay[2] · Qiang Zheng[1,2,3]

A Communication Effectiveness Study of the FDA GMP Warning Letters

Yiyi Bao[1,2] · Qiang Zheng[1,2,3]

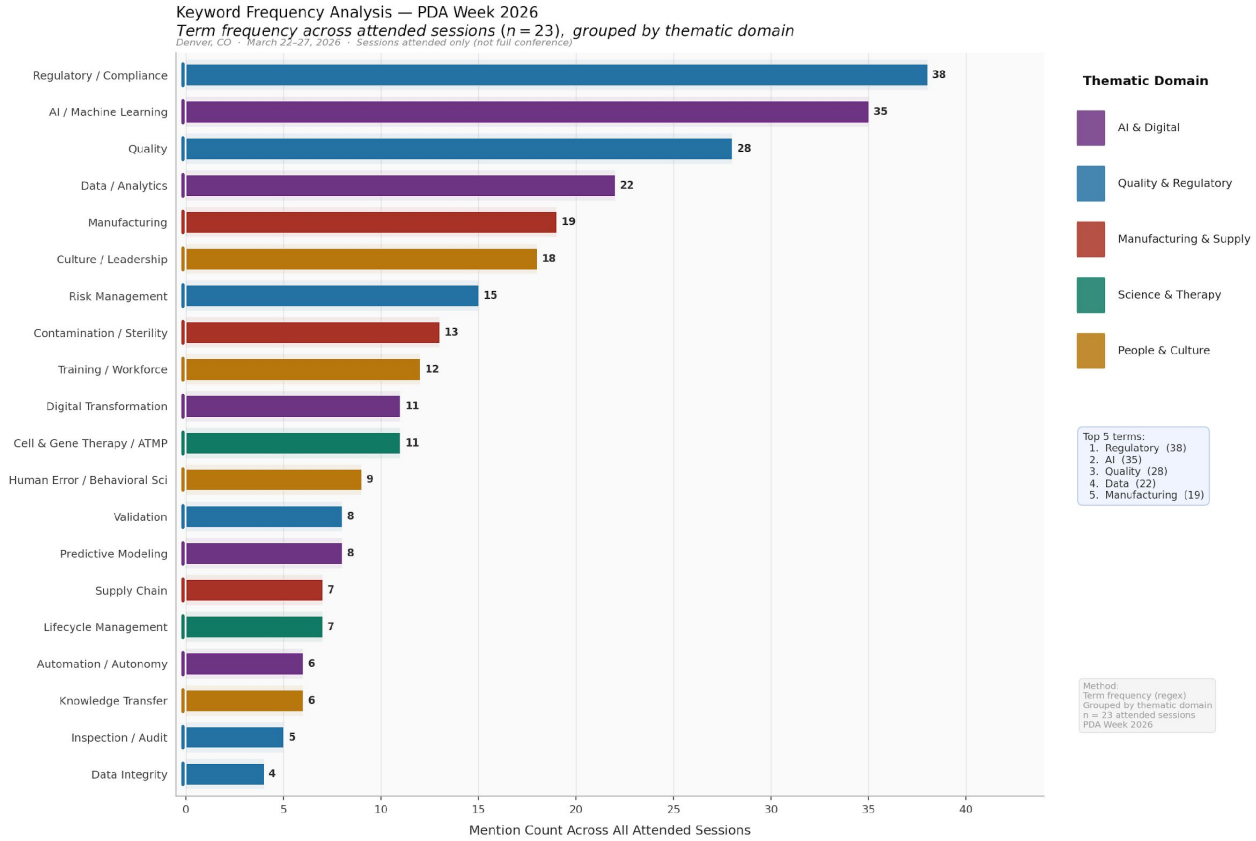
An Analysis of FDA Warning Letter Citations from 2019-2023

George Kwiecinski[1]

Unpacking the effects of adverse regulatory events: Evidence from pharmaceutical relabeling

Matthew J. Higgins[a,*], Xin Yan[b], Chirantan Chatterjee[c,d]

Why? – We can now compute what is talked about.



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The Inspection Lifecycle

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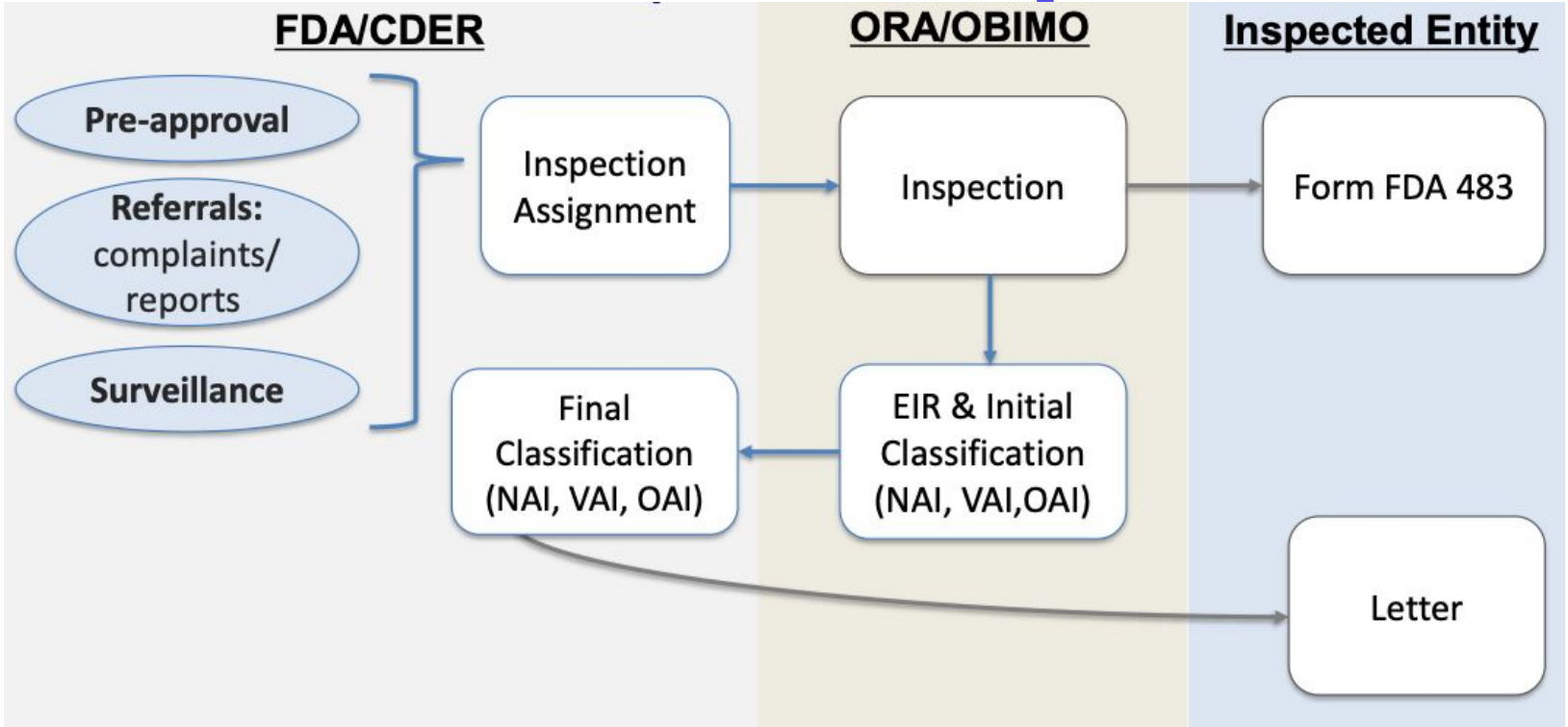
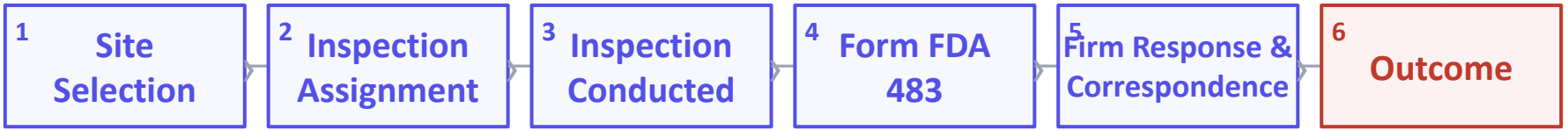
Process – Background



Process

This process is not mandatory , an investigation can lead to many types of outcomes



Routine · Pre-Approval (PAI) · For-Cause · Unannounced (2025+)

Only if objectionable conditions observed

New FDA 2026 Draft Guidance on Responses

Inspection Classifications

NAI: No Action Indicated

VAI: Voluntary Action Indicated -> 483

OAI: Official Action Indicated -> 483

Other correspondences / Escalation

- **Warning Letter**
- **Import Alert**
- **Consent Decree**
- **Criminal Prosecution**

** Import Alerts and Warning Letters may also be initiated without a prior inspection, based on foreign regulatory findings, sample analysis, or adverse event reports.*

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The Change

May, 06, 2025

https://www.fda.gov/news-events/press-announcements/fda-announces-expanded-use-unannounced-inspections-foreign-manufacturing-facilities

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FDA NEWS RELEASE

FDA Announces Expanded Use of Unannounced Inspections at Foreign Manufacturing Facilities

For Immediate Release: May 06, 2025

Today, the U.S. Food and Drug Administration announced its intent to expand the use of unannounced inspections at foreign manufacturing facilities that produce foods, essential medicines, and other medical products intended for American consumers and patients. This change builds upon the agency's Office of Inspection and Investigations Foreign Unannounced Inspection Pilot program in India and China and aims to ensure that foreign companies will receive the same level of regulatory oversight and scrutiny as domestic companies.

https://www.fda.gov/news-events/press-announcements/fda-announces-expanded-use-unannounced-inspections-foreign-manufacturing-facilities

INTERPHEX | FDA May 6

- Conduct more frequent and unannounced inspections
- Evaluate the agency's policies and practices for improvements to the foreign inspection program

"For too long, foreign companies have enjoyed a double standard—given advanced notice before facility inspections, while American manufacturers are held to rigorous standards with no such warning. That ends today. This is a key step for the FDA as part of a broader strategy to get foreign inspections back on track," said FDA Commissioner Martin A. Makary, M.D, M.P.H.

https://www.fda.gov/news-events/press-announcements/fda-announces-expanded-use-unannounced-inspections-foreign-manufacturing-facilities

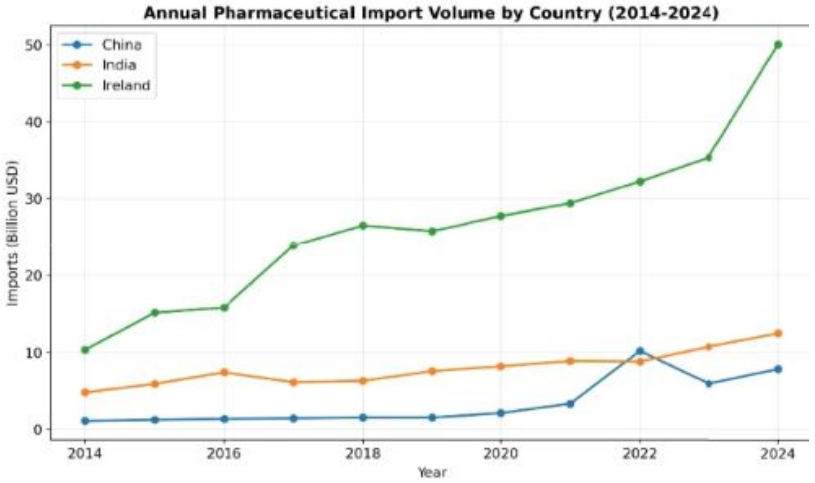
The Foreign Inspection Gap - Numbers

Background

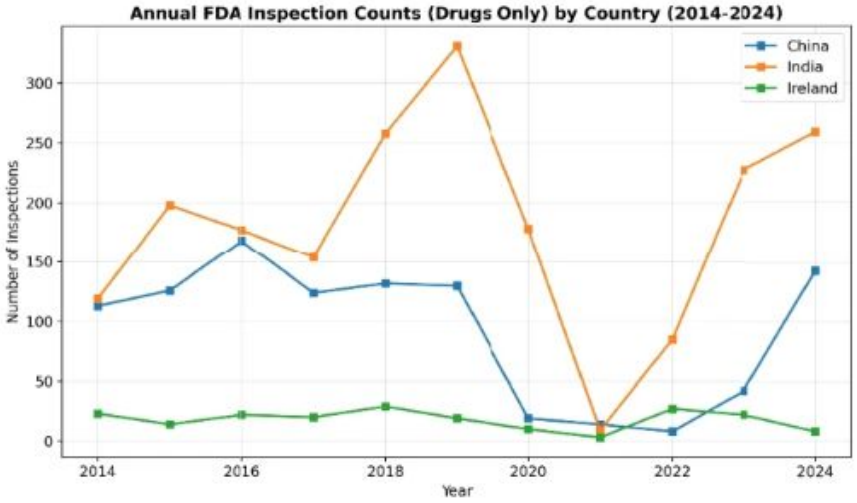
- 10-country foreign drug inspections:
- 833 (2019)
- 102 (2021)
- 674 (2024); never recovered
- Imports Increased (generally)
  - Ireland imports surged $10.3B → $50B
  - China $1.1B → $7.8B (2014-2024)
- China inspections dropped from 168 (2016 peak) to 8 by 2022

https://link.springer.com/article/10.1007/s12247-026-10406-3

The Foreign Inspection Gap - Numbers

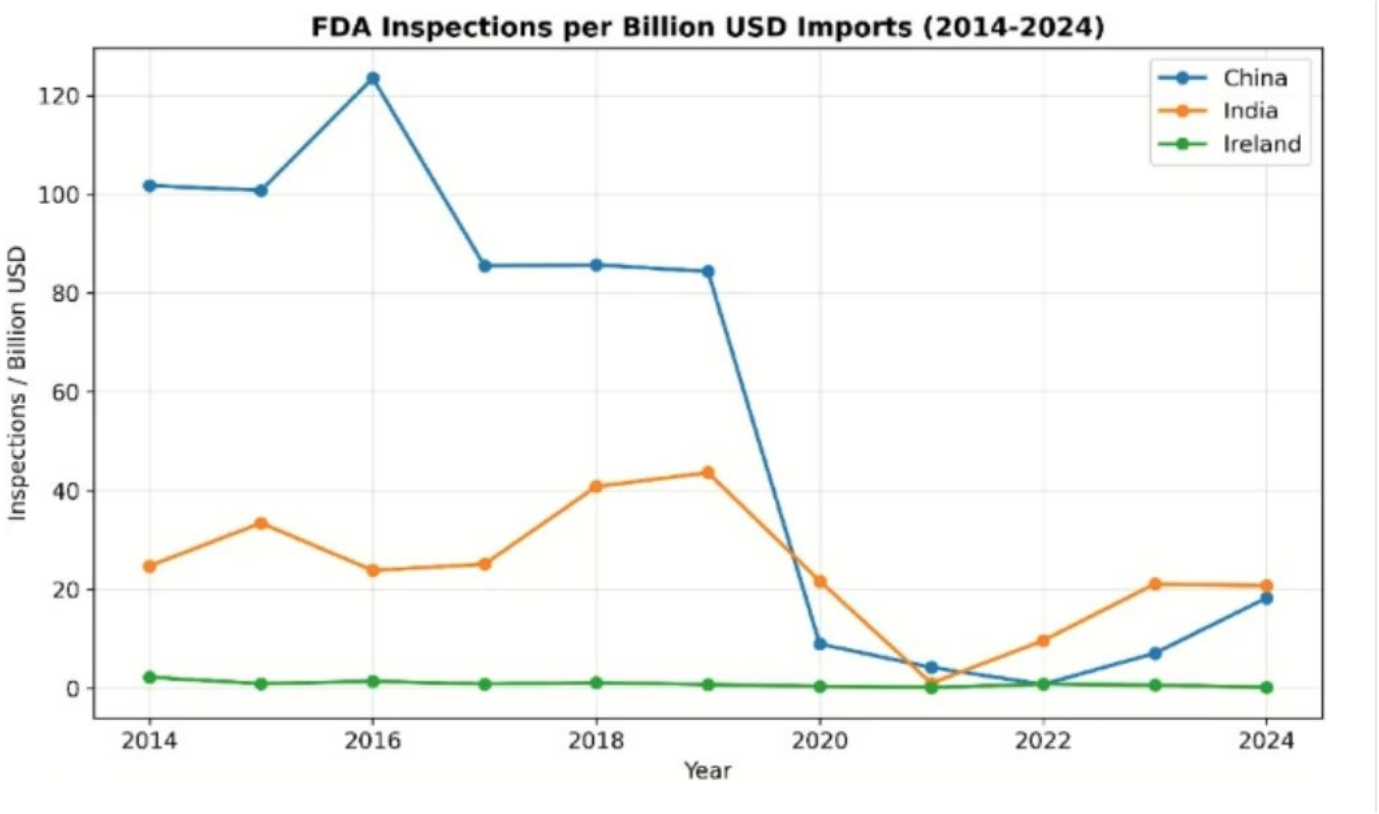


Imports (Left)



Inspections (Right)

https://link.springer.com/article/10.1007/s12247-026-10406-3



https://link.springer.com/article/10.1007/s12247-026-10406-3

The Foreign Inspection Gap - Numbers

Results

- 23 fewer inspections per additional $1B imports (2014-2019)
- China: 101.8 → 18.3 inspections per $1B imported (2014-2024)
- Ireland: 92.8% decline; imports grew fivefold simultaneously
- Foreign deficiency rate 61.9% vs. 49.3% U.S. baseline
  - Chances of (OAI+VAI) / Sum (Drugs only)

https://link.springer.com/article/10.1007/s12247-026-10406-3

The Why?

May, 06, 2025

https://www.fda.gov/news-events/press-announcements/fda-announces-expanded-use-unannounced-inspections-foreign-manufacturing-facilities

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Concluding Thoughts

- Stable deficiency rates prove gap is resources, not compliance
- Advance notice likely underestimates true non-compliance rates
  - Undermines Integrity and concludes the May 06th statements have merit
- Framework validates and benchmarks FDA's May 2025 announcement
  - Ratios of the compliance trends and outcomes from these inspections based on classifications and geography
- MRA countries receive far less scrutiny per import dollar
  - Potential Incentive discussions

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Concluding Thoughts - New Happenings

- Section 232 tariffs
- New Generic Scrutiny amongst procurement
- NDAA and Country of Origin
  - National Defense Authorization Act
  - National Drug Supply Chain Effort

Also Check out our PDA WhiteBoard Paper on CRLs

Q & A

Global Key Solutions

Thank you! Let's Connect.

GKS Researchers Publish Study on FDA's Foreign Drug Inspection Gap

Mar 9, 2026 George Kwiecinski & Kevin Y...

GKS publishes peer-reviewed research on FDA's foreign GMP inspection gap. A decade of import growth vs. declining inspections. Read the open-...

Read more →

50th International GMP Conference Days 2 and 3 Recap | GKS

Mar 6, 2026 George Kwiecinski

GKS recap of Days 2 and 3 at the 50th GMP Conference: GMP case studies, OPQ update, and fireside chat with former FDA Commissioner Califf.

Read more →

50th International GMP Conference Day 1 Recap: AI, Inspections, and the Future of...

Mar 3, 2026 George Kwiecinski

GKS recap of Day 1 at the 50th International GMP Conference. Firsthand notes on AI in FDA compliance, 483 guidance, and sterile manufacturing.

Read more →

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