Inspection Efficiency Through Regulatory Data Intelligence

Global Key Solutions: Platform for Inspection Preparation

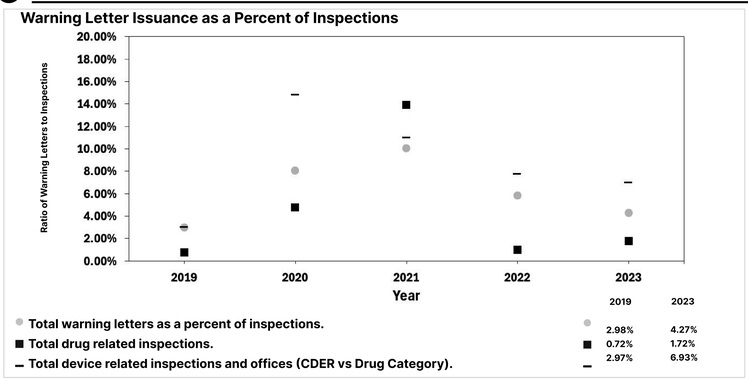
Research

An Analysis of FDA Warning Letter Citations from 2019-2023
Utilizing Classic Data Analysis Approaches

1 ABSTRACT

Purpose: This study investigates trends in the issuance of FDA warning letters from 2019 to 2023. The paper aims to assess past and present FDA statements of inspection efficiency from a quantitative and qualitative perspective.
Methods: An analytical approach combining regex filtering and web scraping was developed to log citations of law within FDA warning letters. The process included identifying recurring keywords for categorization by keyword, department, and legal reference.
Results: From 2019 to 2023, the FDA went from issuing a warning letter 2.98 times per 100 inspections to 4.27 times per 100 inspections, a 43% increase in warning letters issued per 100 inspections.
Conclusions: From 2019 to 2023, the FDA issued more warning letters more frequently when compared to inspection volume, reallocating resources and priorities throughout the COVID-19 pandemic.

2 GRAPHS



Warning Letter Issuance as a percent of inspections has increased as the agency has taken a multi-modal and reformed inspection citation approach.

The rate of change in the warning letter issuance was 43%, from 2.98 to 4.27 warning letter issuances per 100 inspections from 2019 to 2023, respectively. Additionally, the rates for devices and drugs were .72 per 100 inspections and 2.97 per 100 inspections in 2019, rising to 1.72 and 6.93 per 100 inspections in 2023, respectively.

3 CONCLUSION & DISCUSSION

Conclusion: From 2019 to 2023, the FDA issued more warning letters more frequently when compared to inspection volume, reallocating resources and priorities throughout the COVID-19 pandemic.

Discussion: These methods expand analysis beyond a simple segmentation of warning letter quantities by office or type, focusing on a deeper examination of issuance rates and content. This was done by noting both keyword and code frequencies is a way to measure content within warning letters.

Journal of Pharmaceutical Innovation (2024) 19:78
https://doi.org/10.1007/s12247-024-09879-x

ORIGINAL ARTICLE

Check for updates

An Analysis of FDA Warning Letter Citations from 2019-2023

Transforming Regulatory Data to Provide Your Firm Insights.

Journal of Pharmaceutical Innovation (2024) 19:34
https://doi.org/10.1007/s12247-024-09844-8

ORIGINAL ARTICLE

Check for updates

A Communication Effectiveness Study of the FDA GMP Warning Letters

Yiyi Bao[1,2] · Qiang Zheng[1,2,3]

Accepted: 13 May 2024

Agency Recommendations of seeking third party help.

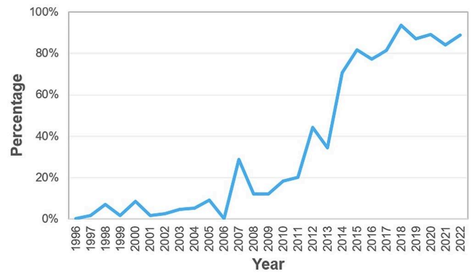
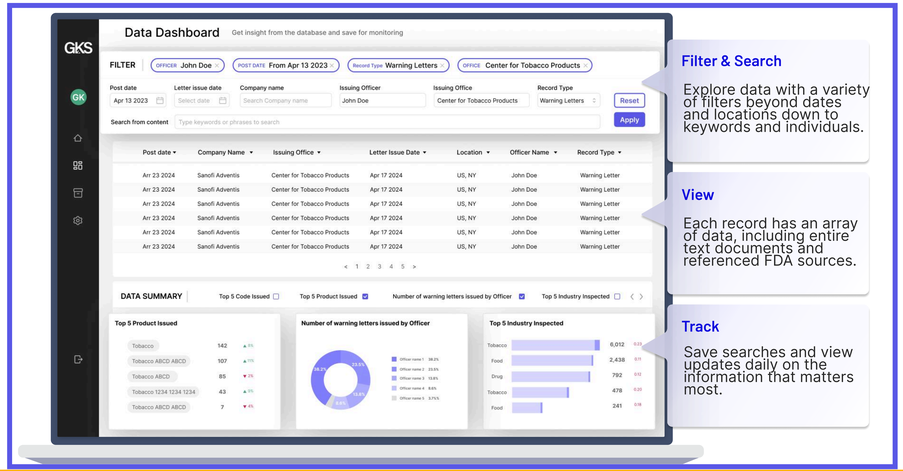


Fig. 4 The percentage of Warning Letters that Recommend Seeking 3rd Party Help



Filter & Search
Explore data with a variety of filters beyond dates and locations down to keywords and individuals.

View
Each record has an array of data, including entire text documents and referenced FDA sources.

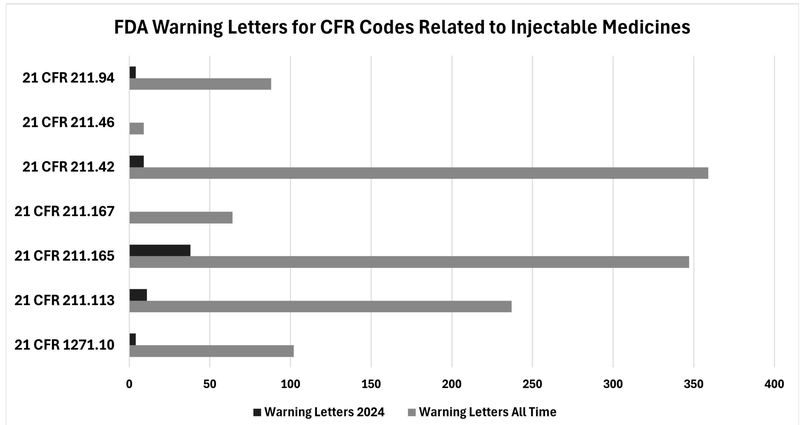
Track
Save searches and view updates daily on the information that matters most.

Company

How to utilize data

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.



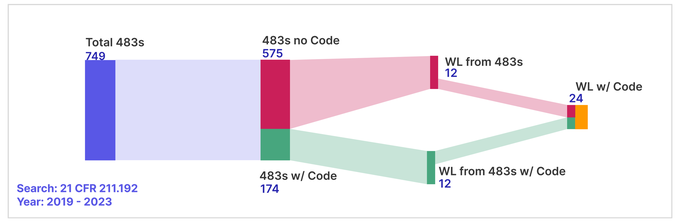
Relevant CFR Codes that relate closely to Injectable Medicines:

- 21 CFR 211.94: Design and construction features of facilities.
- 21 CFR 211.46: Environmental controls over air pressure, dust, humidity, etc.
- 21 CFR 211.42: Control of Microbiological Contamination of sterile drug products.
- 21 CFR 211.167: Special Testing Requirements
- 21 CFR 211.165: Drug Product Containers and Closures
- 21 CFR 211.113: Testing and release for distribution ensuring each batch meets appropriate specification.
- 21 CFR 1271.10: Criteria for Regulation under Section 361 of Public Health Service Act.

5 Our Process

Monitor Real Time and Historic Trends

GKS was tasked to devise a schema to make tracking 483 to warning letter content more palatable and in a manner where it can be executed for any entry.



This code's resolution rate after a 483 issuance is high, with minimal appearances in warning letters. It is also a frequent observation focus for inspectors. In this case, 40 billable hours were saved per custom search for a consulting firm.

6 Future Use

AI and LLM Models have made text search and aggregation easier.
Using regulatory data can allow for training and assessment of models.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Sections in yellow demonstrate and cite peer review research with summarized content of graphs and statements.

Sections in purple demonstrate Global Key Solution Corps Analysis, and interpretations of core methods.

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