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Review Article

Navigating USFDA Inspectional Observations: An Analysis of Trends and Compliance from Fiscal Years 2019 To 2022

Antony Sebastian Johnson[1], Balamuralidhara Veeranna[2], Saba Maanvizhi[1,*]

[1]Department of Pharmaceutics, Sri Ramachandra Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research (DU), Porur, Chennai, Tamil Nadu, INDIA.
[2]Department of Pharmaceutics, JSS College of Pharmacy, JSSAHER (DU), Mysore, Karnataka, INDIA.

ABSTRACT

The Food and Drug Administration (FDA) known for its rigorous regulatory oversight, conducts routine inspections in the pharmaceutical industry, utilizing Form 483 to highlight observed non-compliances. Inadvertent breaches of intricate FDA criteria can lead to unsuitable conditions. Substantial violations triggering the issuance of Warning Letters (WL) serve as official notifications of federal law non-compliance, necessitating timely and effective responses to avoid severe consequences such as import denial, refusal, memoranda, or legal actions. Adherence to FDA's regulations is imperative for ensuring product quality and public safety and navigating the complex landscape of pharmaceutical compliance. The study delves into cumulative trends in FDA inspection citations related to Good Manufacturing Practices (GMP) from FY2019 to FY2022 and the impact of the COVID-19 pandemic on FDA's inspection process on drug manufacturers. Understanding the evolving GMP compliance landscape is crucial for industry stakeholders, given the FDA's continuous refinement of inspection protocols to ensure pharmaceutical product quality and safety. The analysis comprehensively examines the top GMP-related citations during the specified timeframe, identifying recurring themes and patterns. This research provides insights into the regulatory landscape, potential areas of industry improvement and emerging challenges faced by pharmaceutical manufacturers. In conclusion, this abstract emphasizes continuous monitoring, adaptation to evolving regulatory standards and a nuanced understanding of cumulative GMP citation trends. Upholding compliance, enhancing product quality and contributing to public health and safety remain paramount objectives in the dynamic regulatory environment of the pharmaceutical industry.

Keywords: Code of Federal Regulations-CFR, Fiscal Year-FY, Form 483 observation, Inspection protocol, Regulatory oversight.

Correspondence:
Dr. Saba Maanvizhi
Professor, Department of Pharmaceutics, Sri Ramachandra Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research (DU), Porur, Chennai, Tamil Nadu, INDIA.
Email: sabamaanvizhi@sriramachandra.edu.in

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INTRODUCTION

The Food and Drug Administration is the primary regulatory body of the United States that is in charge of ensuring the efficacy, safety and quality of pharmaceuticals. A vital component of this objective is the FDA's routine inspection program for facilities, which examines organisations involved in the production, handling or storage of regulated products. A vital tool for assessing adherence to the stringent guidelines set out in the Federal Food, Drugs and Cosmetics Act (FD&C Act) and related regulations is the inspection process.

A crucial part of the inspection procedure is the issue of Form 483, often known as the "Notice of Inspectional Observations." This form is an essential tool that FDA investigators use to record observations of situations or behaviours that could be against the law. Every observation listed in the Form 483 alerts the inspected organizations to possible areas of concern and highlights situations in which remedial action is necessary to address compliance issues.

Understanding FDA 483 observations is crucial for regulated associations because they provide valuable information regarding areas that require corrective action to maintain regulatory compliance. Furthermore, for professionals, regulatory advisers and stakeholders, a full grasp of FDA 483 compliances gives precious insights into existing compliance difficulties and growing trends in regulated industries.[1,2]

The purpose of this article is to explore the complex meaning behind FDA 483 observations, clarify what they mean for regulated organizations and provide advice on how to deal with and lessen compliance problems that are found during FDA inspections. A thorough grasp of FDA 483 observations and their implications may help stakeholders maintain the highest levels of

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quality and safety for medical items on the market and strengthen their efforts to comply with regulations.

Inspection

The FDA inspects and surveys regulated facilities to see if firms comply with all applicable rules and laws. The FDA inspects manufacturing facilities, clinical testing sites, laboratories that perform animal or microbial studies and imported controlled goods. Inspections are also carried out at overseas sites that produce or process FDA-approved items for export to the US. Figure 1 provides a detailed overview of the FDA inspection process.

Ensuring safety: USFDA's domestic and foreign inspections

The U.S. Food and Drug Administration conducts inspections of both domestic and foreign drug manufacturing facilities to ensure compliance with regulatory standards and to safeguard public health. However, the COVID-19 pandemic significantly impacted these inspection activities.

Domestic inspections

Domestic inspections by the FDA are critical for maintaining drug safety and effectiveness. During the pandemic, the FDA initially postponed routine inspections but continued with mission-critical inspections, such as those related to drug shortages or COVID-19 treatments. Despite these challenges, the FDA managed to conduct prioritized domestic inspections once conditions allowed, using alternative tools such as remote interactive evaluations and record reviews to maintain oversight when on-site inspections were not feasible.

Foreign inspections

Foreign inspections have historically presented unique challenges for the FDA, such as logistical difficulties and reliance on translators provided by the inspected facilities, which could compromise the accuracy of the inspections. The pandemic exacerbated these challenges, leading to a significant reduction in foreign inspections. From March 2020 to March 2021, the FDA conducted very few inspections abroad, focusing primarily on mission-critical activities.

The decline in foreign inspections has raised concerns about the quality and safety of drugs imported into the U.S. Before the pandemic, foreign inspections had been increasing, but they dropped sharply due to travel restrictions and safety concerns. Even as the FDA resumed some inspections, the backlog and reduced frequency of foreign inspections persisted, highlighting the need for better resource allocation and strategic planning.

Recently, three prominent US lawmakers have raised concerns over the FDA's foreign drug inspection program in India. Inconsistencies in inspection results between January 2014 and April 2024 were brought to light in their report. While some inspectors identified problems in virtually every inspection, others reported no problems in nearly every inspection. The lawmakers drew attention to these disparities and demanded an inquiry to guarantee thorough and uniform inspections.[4-7]

Figure 2 illustrates "Foreign and Domestic Inspections" showing the number of inspections conducted in fiscal years 2019, 2020, 2021 and 2022. The inspections are categorized into two regions: Domestic and Foreign.

Domestic inspections

1. There is a significant decrease from 1,401 inspections in 2019 to 793 in 2020.
2. The number slightly decreased to 777 in 2021.
3. There is an increase to 943 inspections in 2022.

Foreign inspections

1. A sharp decline is seen from 1,210 inspections in 2019 to 510 in 2020.
2. This downward trend continues with a drop to 183 inspections in 2021.
3. There is a recovery to 432 inspections in 2022.

FDA inspection classification

The U.S. Food and Drug Administration categorizes its inspections of drug manufacturing facilities based on the findings of compliance with regulatory standards. Figure 3 depicts the classification of inspection on drug manufacturers during the FY 2019-FY 2022, which help to determine the next steps in terms of regulatory actions and corrections. Here are the three primary classifications:

No Action Indicated (NAI)

Definition

This classification is given when an inspection does not uncover any significant deviations from regulatory standards.

Implication

Facilities receiving an NAI classification are considered compliant with FDA regulations. No further action is required, though the facility is still expected to maintain compliance.

Voluntary Action Indicated (VAI)

Definition

This classification is assigned when an inspection identifies some issues, but they are not severe enough to warrant immediate regulatory action.

Implication

Facilities are advised to voluntarily correct the identified issues. While these findings do not typically lead to enforcement actions, they are expected to address the problems to avoid future escalations.

Official Action Indicated (OAI)

Definition

This classification indicates that significant regulatory violations were found during the inspection.

Implication

Facilities with an OAI classification may face enforcement actions from the FDA. These actions can include warning letters, seizure of products, injunctions, or other regulatory steps to ensure compliance and protect public health.[8]

Analysis of trends

The number of NAI inspections started at 1,233 in 2019, dropped sharply to 453 in 2021 and slightly rebounded to 594 in 2022.

Starting at 1,214 in 2019, VAI inspections also saw a significant decline to 397 in 2021 before recovering to 628 in 2022.

OAI inspections showed a decrease from 197 in 2019 to 80 in 2020, but then increased again to 162 by 2022.

FDA Form 483 observation

Form 483 "is issued to firm management after an inspection when an investigator (s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related acts," as stated on the FDA website. Thus, if an investigator finds anything that may not comply with the FD&C Act throughout the course of the audit, you will likely obtain a 483.

Total number of Form 483 issued between Fiscal Year 2019-2022

Manufacturers receive Form 483 observations from the U.S. Food and Drug Administration when investigators find any circumstances that can be considered breaches of the Food Drug and Cosmetic Act (FD&C) and associated laws. These observations highlight areas where the facility's processes or products may not comply with current Good Manufacturing Practices (cGMP).

Table 1 provides the total number of 483 observations issued between the FY 2019-FY 2022 which has seen fluctuations, especially influenced by the COVID-19 pandemic. The pandemic led to a reduction in on-site inspections, which consequently affected the number of Form 483s issued. From March 2020 to March 2021, there was a significant decrease in foreign inspections, resulting in fewer 483 observations compared to

Table 1: Total number of FDA FORM 483 issued between (FY 2019-FY 2022).[1]

Fiscal year	Drugs	Medical devices	Biologics	Veterinary medicine
2019	779	822	116	229
2020	349	422	28	100
2021	215	191	17	105
2022	466	538	61	124

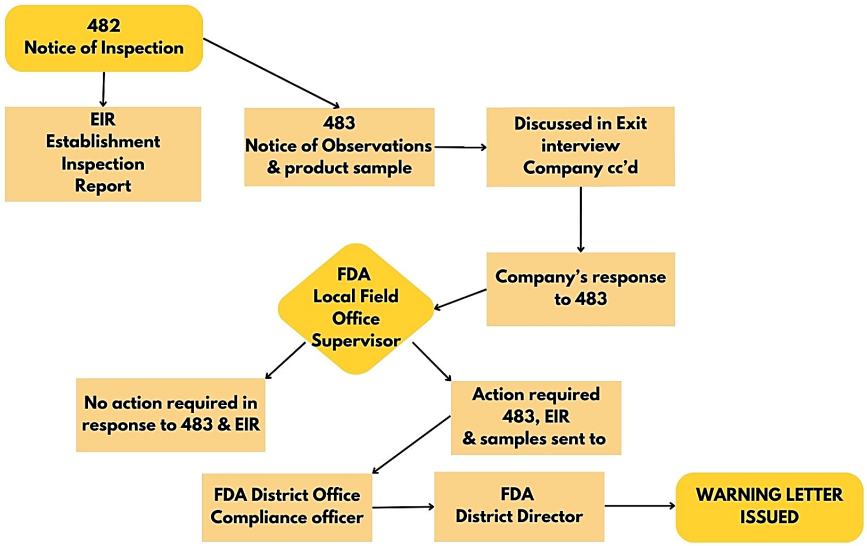

Figure 1: FDA Inspection process.[3]

previous years.[9,10] Figure 4 provides a graphical illustration of Total number of FDA 483 issued between FY 2019-FY 2022.

Most cited CFR violation between the Fiscal Year (2019-2022) for drug products

The annual statistics published by the FDA on inspectional observations provide valuable information about the main sources of these observations. Table 2 provide the top 10 program area-citations between FY 2019-FY 2022 and Figure 5 displays the frequency of the top 10 citations between FY 2019-FY 2022 for drug products. In the field of drug development, potential breaches of 21 CFR Part 211 are often highlighted in Form 483s. These forms report various compliance issues observed during inspections.

Remedial action

To address common CFR violations, manufacturers should develop and document comprehensive Standard Operating Procedures (SOPs) and ensure staff training and regular audits. Accurate submission of Form FDA-1572 and thorough training on protocol compliance are essential. Establishing robust systems for investigating discrepancies, maintaining detailed laboratory controls and ensuring complete case history records are critical. Rigorous testing protocols and quality control programs must be implemented. Validating computer systems for master formula records and ensuring appropriate equipment design, size and location are also vital. Regular reviews, updates and audits across all processes will help maintain compliance and improve operational standards.[11]

Most cited CFR violation between the Fiscal Year (2019-2022) for medical devices

Between fiscal years 2019 and 2022, the most frequently cited violations of the Code of Federal Regulations (CFR) for medical device manufacturers were primarily related to the FDA's

Table 2: Top 10 citations between (FY 2019-FY 2022) for drug products.[1]

Program area-citations	Frequency
Drugs-21 CFR 211.22(d)-Procedures not in writing, fully followed.	406
Bioresearch Monitoring-21 CFR 312.60-FDA-1572, protocol compliance.	301
Drugs-21 CFR 211.192-Investigations of discrepancies, failures.	257
Drugs-21 CFR 211.160(b)-Scientifically sound laboratory controls.	226
Drugs-21 CFR 211.100(a)-Absence of Written Procedures.	189
Drugs-21 CFR 211.67(a)-Cleaning/Sanitizing/ Maintenance.	160
Bioresearch Monitoring-21 CFR 312.62(b)-Case history records- adequate or inadequate.	158
Drugs-21 CFR 211.165(a)-Testing and release for distribution.	134
Drugs-21 CFR 211.68(b)-Computer control of master formula records.	133
Drugs-21 CFR 211.63-Equipment Design, Size and Location.	123

(*Not all inspections are included in the database. Inspections conducted by states, pre-approval inspections, mammography facility inspections, inspections waiting for a final enforcement action and inspections of nonclinical labs are not included).

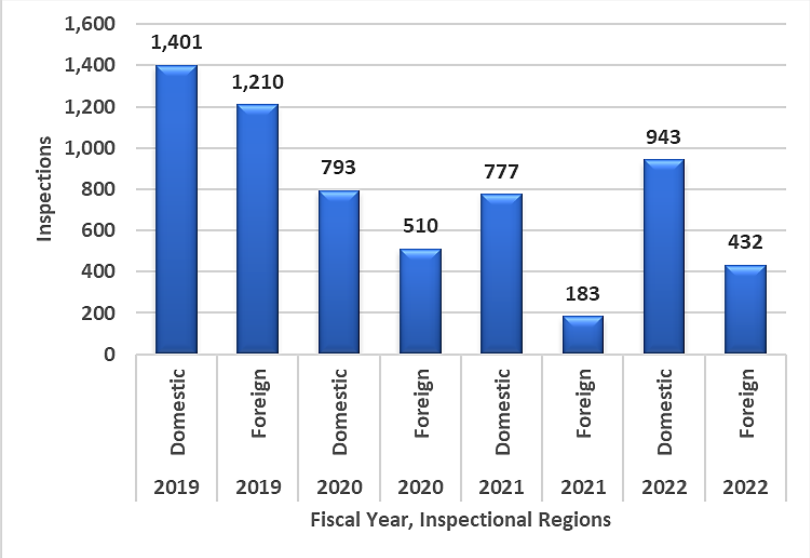

Figure 2: Foreign and Domestic inspections by USFDA on drug manufacturers (FY 2019-FY 2022).[8]

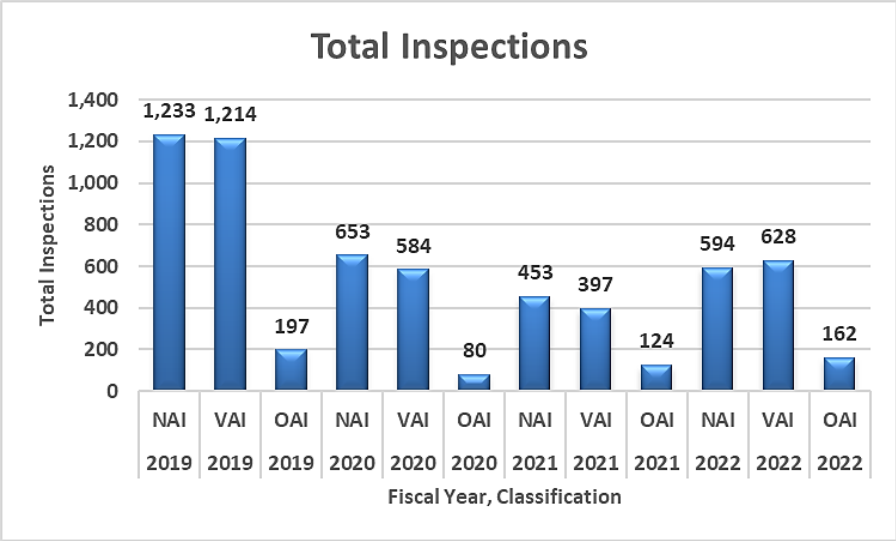

Figure 3: Classification of inspection on drug manufacturers (FY 2019-FY 2022).[8]

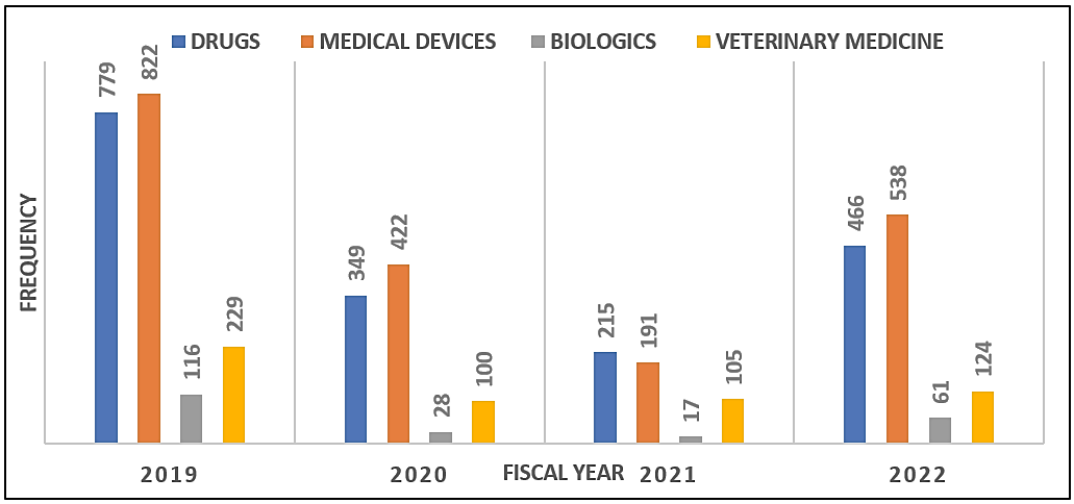

Figure 4: Total number of FDA 483 issued between (FY 2019-FY 2022).[1]

Quality System Regulation (QSR) found in 21 CFR Part 820. Table 3 displays the top 10 program area-citations between FY 2019-FY 2022 and Figure 6 illustrates the frequency of the top 10 citations between FY 2019-FY 2022 for medical devices. These regulations oversee the procedures, facilities and controls used in the design, production, labelling, packing, storage, installation and maintenance of all finished devices intended for human use.[12]

Remedial action

Medical device manufacturers should create extensive corrective and preventative action procedures (21 CFR 820.100(a)) and ensure comprehensive training on these protocols to handle FDA violations. Strict purchase controls (21CFR 820.50) and comprehensive complaint handling procedures (21 CFR 820.198(a)) must be put into place. In addition, organizations need to follow strict Medical Device Reporting (MDR) guidelines (21 CFR 801.17) and manage non-conforming products (21 CFR 820.90(a)). It is important to have robust process validation, as per 21 CFR 800.100(b). Compliance will be further improved by establishing robust procedures for design modifications (21CFR 820.30(i)) and creating stringent acceptance standards (21CFR 820.80(a)). Maintaining regulatory compliance and enhancing overall quality management requires regular training, internal audits and continuous improvement projects.[13]

Most cited CFR violation between the Fiscal Year (2019-2022) for biologics

The FDA issued many 483 observations to biologics manufacturers and human tissue transplantation facilities between the fiscal years 2019 and 2022 for violating the Code of Federal Regulations (CFR). Table 4 provides the top 10 program area-citations between FY 2019-FY 2022 and Figure 7 highlights the frequency of the top 10 citations between FY 2019-FY 2022 for biologics. These citations reflect critical areas where compliance is essential to ensure the safety and efficacy of biological products.

Remedial action

Manufacturers need to take significant corrective actions to resolve FDA violations related to biologics manufacturing and human tissue transplantation. These include 21 CFR 1271.75(a)(1) strengthening risk assessment and clinical evidence recording; 21CFR 1271.47(a) strengthening testing, screening and donor eligibility process; and 21CFR 606.100(b) strictly adhering to Standard Operating Procedures (SOP). Precise conclusions grounded in communicable disease agent prevention methods (21CFR 127.180(a)) and screening and testing (21CFR 1271.50(a)) are crucial. Manufacturers are required to implement core Current Good Tissue Practice (cGTP) protocols (21CFR 1271.180(a)) and uphold rigorous documentation (21 CFR 606.160(b)). Enacting effective procedures to prevent microbiological contaminations in sterile drug products (21CFR 211.113(b)), conducting a thorough evaluation of failures and discrepancies (21CFR 211.192) and adhering to the eligibility warning label requirements (21CFR 1271.190(c)) are all crucial. It is also necessary to provide frequent training, internal audits and continuous process improvements to ensure compliance with regulations and the efficacy and safety of the biological products.[14]

Table 3: Top 10 citations between (FY 2019-FY 2022) for medical devices.[1]

Program area-citation	Frequency
Devices-21 cfr 820.100(a)-lack of or inadequate procedures.	681
Devices-21 cfr 820.198(a)-lack of or inadequate complaint procedures.	527
Devices-21 cfr 820.50-purchasing controls, lack of or Inadequate procedures.	298
Devices-21 cfr 803.17-lack of written mdr procedures.	283
Devices-21 cfr 820.90(a)-nonconforming product, lack of or Inadequate procedures.	238
Devices-21 cfr 820.75(a)-lack of or inadequate process validation.	227
Devices-21 cfr 820.22-quality audits-lack of or inadequate Procedures.	173
Devices-21 cfr 820.100(b)-documentation.	147
Devices-21 cfr 820.30(i)-design changes-lack of or Inadequate procedures.	122
Devices-21 cfr 820.80(a)-lack of or inadequate procedures- Acceptance activities.	118

(*Not all inspections are included in the database. Inspections conducted by states, pre-approval inspections, mammography facility inspections, inspections waiting for a final enforcement action and inspections of nonclinical labs are not included).

Most cited CFR violation between the Fiscal Year (2019-2022) for veterinary medicine

Between fiscal years 2019 and 2022, the FDA's regulatory oversight of veterinary medicine manufacturers highlighted several critical areas of non-compliance with the Code of Federal Regulations (CFR). Table 5 displays the top 10 program area-citations between FY 2019-FY 2022 and Figure 8 visualizes the frequency of the top 10 citations between FY 2019-FY 2022 for veterinary medicine. These violations were primarily identified during routine inspections and were documented in Form 483 observations. The most frequently cited violations underscored systemic issues within the industry, particularly related to quality control, production processes and laboratory practices.

Table 4: Top 10 citations between (FY 2019-FY 2022) for biologics.[1]

Program area-citation	Frequency
Human Tissue for Transplantation-21 CFR 1271.75(a)(1)-Risk factors, clinical evidence.	107
Human Tissue for Transplantation-21 CFR 1271.47(a)-Testing, screening, donor eligibility procedures.	72
Biologics-21 CFR 606.100(b)-Establish, maintain and follow manufacturing SOPs.	70
Human Tissue for Transplantation-21 CFR 1271.50(a)-Determination based on screening and testing.	46
Human Tissue for Transplantation-21 CFR 1271.85(a)-Infection with communicable disease agents.	40
Human Tissue for Transplantation-21 CFR 1271.180(a)-Procedures to meet core cGTP.	27
Biologics-21 CFR 606.160(b)-Required records.	27
Human Tissue for Transplantation-21 CFR 1271.90(c)-Eligibility not required--warning labels	25
Drugs-21 CFR 211.192-Investigations of discrepancies, failures	24
Drugs-21 CFR 211.113(b)-Procedures for sterile drug products	24

(*Not all inspections are included in the database. Inspections conducted by states, pre-approval inspections, mammography facility inspections, inspections waiting for a final enforcement action and inspections of nonclinical labs are not included).

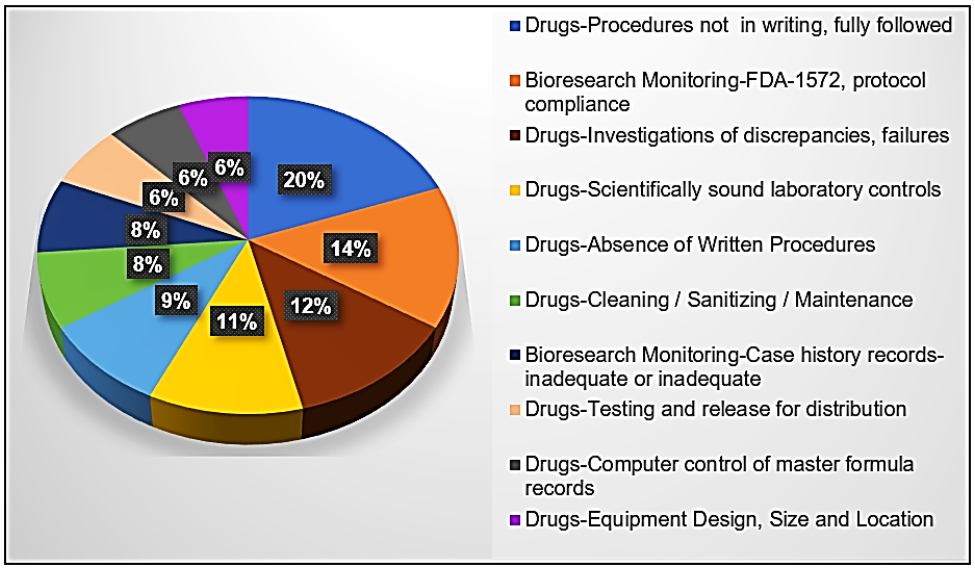

Figure 5: Frequency of top 10 citations between (FY 2019-FY 2022) for drug products.[1]

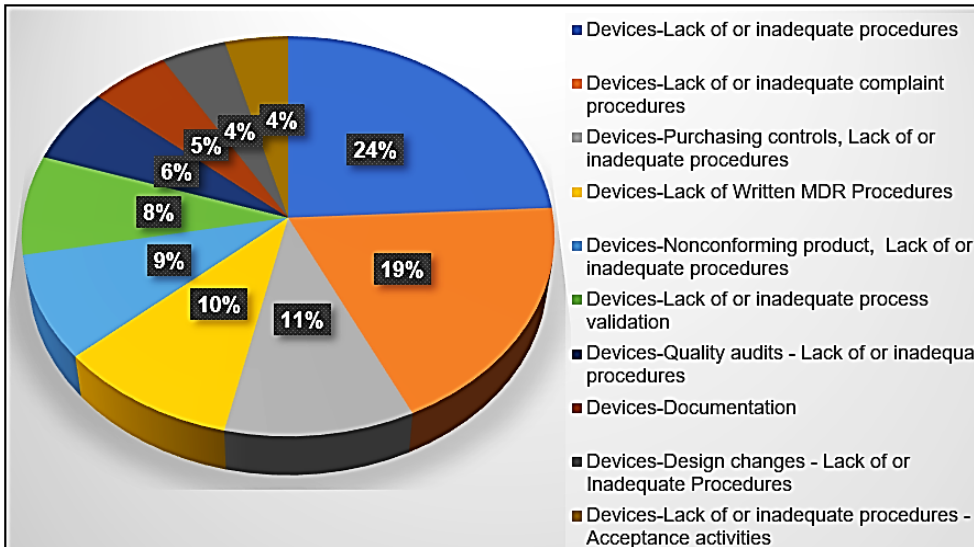

Figure 6: Top 10 citations between (FY 2019-FY 2022) for medical devices.[1]

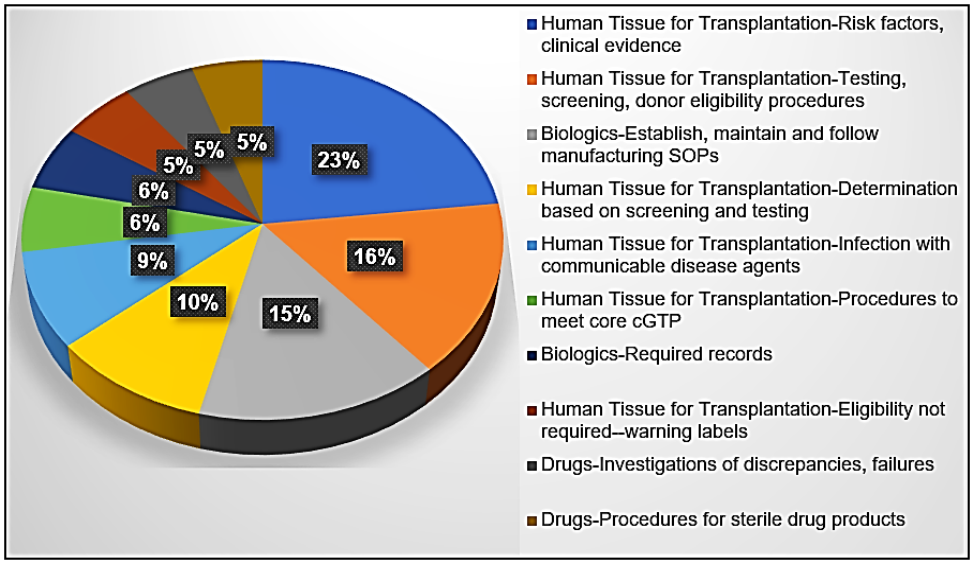

Figure 7: Top 10 citations between (FY 2019-FY 2022) for biologics.[1]

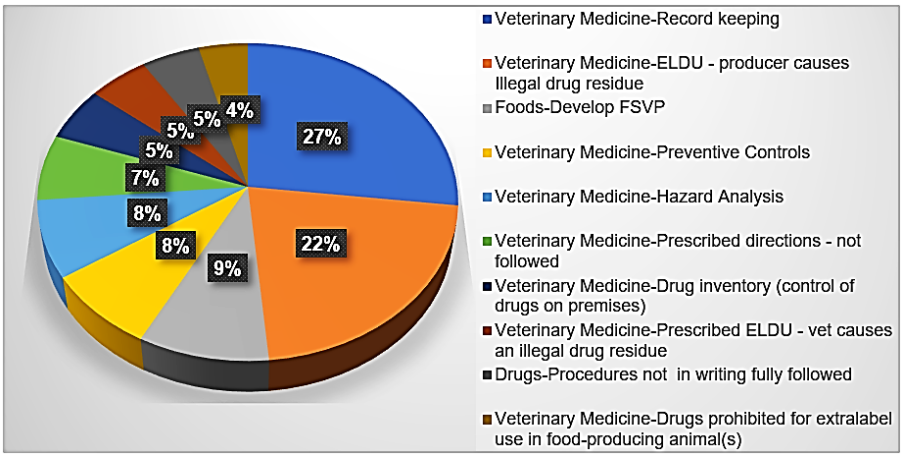

Figure 8: Top 10 citations between (FY 2019-FY 2022) for veterinary medicine.[1]

Table 5: Top 10 citations between (FY 2019-FY 2022) for veterinary medicine.[1]

Program area-citation	Frequency
Veterinary Medicine-FDCA 402(a)(4)-Record keeping.	201
Veterinary Medicine-21 CFR 530.11(d)-ELDU-producer causes Illegal drug residue.	162
Foods-21 CFR 1.502(a)-Develop FSVP.	69
Veterinary Medicine-21 CFR 507.34(a)(1)-Preventive Controls.	60
Veterinary Medicine-21 CFR 507.33(a)-Hazard Analysis.	59
Veterinary Medicine-21 CFR 530.11(a)-Prescribed directions-not Followed.	50
Veterinary Medicine-FDCA 402(a)(4)-Drug inventory (control of drugs on premises).	41
Veterinary Medicine-21 CFR 530.20(a)(2)(iv)-Prescribed ELDU-vet causes an illegal drug residue.	38
Drugs-21 CFR 211.22(d)-Procedures not in writing, fully followed.	37
Veterinary Medicine-21 CFR 530.41(a)-Drugs prohibited for extra label use in food-producing animal(s).	31

(*Not all inspections are included in the database. Inspections conducted by states, pre-approval inspections, mammography facility inspections, inspections waiting for a final enforcement action and inspections of nonclinical labs are not included).

Remedial action

To deal with non-compliances, firms ought to improve their record-keeping (as per FDCA 402(a)(4)), offer comprehensive training on appropriate drug administrations (as per FDCA 530.11(d)), establish a robust Foreign Supplier Verification Programme (FSVP) (as per Foods 21CFR 1.502(a)), establish preventive controls (as per 21CFR 507.34(a)(1), carry out thorough hazard analyses (as per 21CFR 507.33(a)), make sure that prescribed medication directions are followed (as indicated in Veterinary Medicine-FDCA 402(a)(4)), impart training on Extra-Label Drug Use (ELDU) protocols (as per Veterinary Medicine-21 CFR 530.20(a)(2)(iv), maintain written procedures for manufacturing (as per Drugs-21 CFR 211.22(d) and educate stakeholders. The goal of these steps is to ensure continued adherence to regulatory requirements.[15,16]

DISCUSSION

The U.S. Food and Drug Administration plays a crucial role in ensuring the safety and efficacy of pharmaceutical products through rigorous inspection and regulatory oversight of manufacturing facilities. The impact of the COVID-19 pandemic on FDA inspection activities, particularly the stark reduction in both domestic and foreign inspections, underscores the importance of these regulatory processes and the challenges posed by global health crises.

Impact of COVID-19 on FDA inspections

The pandemic significantly disrupted FDA's ability to conduct routine inspections, with domestic inspections plummeting from 1,401 in 2019 to 793 in 2020 and foreign inspections dropping from 1,210 in 2019 to just 510 in 2020. This reduction persisted into 2021, with foreign inspections declining further to 183. Despite these challenges, the FDA prioritized mission-critical inspections related to drug shortages and COVID-19 treatments, utilizing alternative tools such as remote evaluations and record reviews to maintain oversight when on-site inspections were not feasible.

CONCLUSION

The FDA's rigorous inspection processes and the issuance of Form 483 observations play a critical role in maintaining compliance within the pharmaceutical, medical device, biologics

and veterinary medicine industries. The analysis of inspection trends and citation data from Fiscal Years 2019 to 2022 highlights the dynamic and challenging nature of regulatory oversight, particularly under the constraints imposed by the COVID-19 pandemic.

Compliance with FDA regulations is not merely a procedural obligation but a cornerstone of ensuring product quality, safety and efficacy, which are fundamental to public health. The decline in both domestic and foreign inspections during the pandemic underscores the importance of adaptability and innovation in maintaining regulatory oversight, such as through remote evaluations and record reviews.

In conclusion, the ongoing monitoring and analysis of FDA inspection trends and Form 483 observations are vital for industry stakeholders. By understanding these trends and proactively addressing compliance challenges, manufacturers can enhance their operational standards, contribute to public health and safety and navigate the complexities of the regulatory landscape more effectively. Continuous improvement and adherence to evolving regulatory standards remain paramount in achieving sustained compliance and ensuring the highest levels of product quality.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

FDA: Food and Drug Administration; **GMP:** Good Manufacturing Practices; **CFR:** Code of Federal Regulations; **FY:** Fiscal Year; **NAI:** No Action Indicated; **VAI:** Voluntary Action Indicated; **OAI:** Official Action Indicated; **QSR:** Quality System Regulation; **SOPs:** Standard Operating Procedures; **MDR:** Medical Device Reporting; **cGTP:** Current Good Tissue Practice; **FD&C Act:** Federal Food, Drugs and Cosmetics Act.

SUMMARY

This study analyses FDA inspection trends and citations related to Good Manufacturing Practices (GMP) from FY2019 to FY2022, highlighting the impact of the COVID-19 pandemic on inspection activities. The pandemic led to a significant decline in both domestic and foreign inspections, which affected the number of Form 483 observations issued to pharmaceutical manufacturers. The research identifies recurring GMP citation themes, emphasizing the importance of adherence to FDA regulations to ensure product quality and public safety. The study underscores the need for continuous monitoring, adaptation to evolving regulatory standards and proactive remedial actions to address compliance issues, thereby safeguarding public health in the dynamic pharmaceutical regulatory environment.

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