



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DRUG EVALUATION AND RESEARCH

Fiscal Year 2022 Report on the State of Pharmaceutical Quality



June 2023



Introduction

The Office of Pharmaceutical Quality ([OPQ](#)) in the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research ([CDER](#)) ensures that drugs legally marketed in the U.S. are safe and effective, and meet quality standards. For FY2022¹, the fifth annual Report on the State of Pharmaceutical Quality presents key data that characterize drug and manufacturing site quality. This report was produced by OPQ's [Office of Quality Surveillance](#) as part of its vision to be the global benchmark of pharmaceutical quality surveillance. It covers FDA-registered drug manufacturers² and drugs, including biological products, regulated by CDER³ to inform stakeholders about the quality of the U.S. drug supply.

This report presents analyses that reveal insights about pharmaceutical manufacturers and their products. In addition, this report highlights several ongoing initiatives that employ state-of-the-art approaches to surveil, characterize, and advance quality: the New Inspection Protocol Project (NIPP), the Quality Management Maturity (QMM) program, and the CARES Act⁴ Drug Amount Reporting Program. Through these initiatives, data from inspections, assessments, and drug industry production amounts can provide more effective knowledge management and better supply chain transparency. This information will enable FDA to better prevent and mitigate quality issues that may lead to drug shortages and supply chain vulnerability. Furthermore, these initiatives will advance quality surveillance by engaging industry and encouraging their continual improvement. Overall, this report provides a comprehensive picture of the state of pharmaceutical quality for U.S. consumers and patients who have the expectation for safe, effective, and high-quality medicines.

1. Fiscal Year 2022 (FY2022) is from October 1, 2021 to September 30, 2022.

2. A "manufacturer" is anyone engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug.

3. This report covers CDER-regulated products and excludes products regulated by FDA's Center for Biologics Evaluation and Research (CBER), e.g., blood, vaccines, tissues, and certain other biological products.

4. The [Coronavirus Aid, Relief, and Economic Security Act \(CARES Act\)](#) was enacted on March 27, 2020 to aid response and ease economic impacts of COVID-19.



Manufacturing Site Demographics

Key Takeaways

The number of surveillance inspections of human drug sites tripled from FY2021 to FY2022.

CDER's Site Catalog has more than 4,800 manufacturing sites⁵ with over 40% in the U.S.

The FY2022 CDER Site Catalog (as of October 2022)⁶ includes 4,814 drug manufacturing sites (**Table 1**), a 12% increase over FY2018. This excludes manufacturers that only produce alcohol-based hand sanitizers and registered during the COVID-19 public health emergency (PHE). Of all FY2022 drug manufacturing sites, 40% are in the "No Application" sector, indicating that all products manufactured at those sites can be legally marketed in the U.S without approved FDA applications. This sector includes [over-the-counter \(OTC\) monograph products](#), marketed [unapproved prescription drug products](#), and [homeopathic products](#). The remaining 60% of sites manufacture at least one application product, including:

- Biological products licensed under Biologics License Applications (BLAs)⁷
- Innovator products approved under New Drug Applications ([NDAs](#))
- Generic products approved under Abbreviated New Drug Applications ([ANDAs](#))

The top five countries based on the number of sites in the catalog (U.S., India, China, Germany, and Canada) all had net increases in the number of manufacturing sites over the past five years, based on new registrations and removals⁸. FDA uses these site locations and their trends to allocate resources and plan surveillance and outreach activities.

5. Although they meet the definition of "manufacturer," medical gas manufacturers (based on existing CDER Site Catalog policy), [registered outsourcing sites](#) (under section 503B of the Federal Food, Drug, and Cosmetic Act), and sites exclusively manufacturing alcohol-based hand sanitizers that registered after March 2020 are excluded from the count and analyses presented in this report.

6. The CDER Site Catalog is the curated inventory of registered manufacturing sites, vetted by FDA as legally manufacturing human drugs for the U.S. market. Hence, not all registered human drug sites qualify as "manufacturers" for the CDER Site Catalog.

7. See FDA's webpage for further explanation of which [therapeutic biological products are regulated by CDER](#) per the original transfer and those subsequently [deemed to be BLA products](#).

8. FDA removes sites from the CDER Site Catalog if they are not currently engaged in the manufacture of human drugs for the U.S. market and therefore are not subject to routine surveillance inspection. This commonly occurs when sites deregister or are no longer active in an approved application.

Table 1. Inventory Shift Over FY2018–FY2022 for Countries with Greater Than 50 Sites

| Country | Sites in FY2022 Catalog | 5-Year Review of Sites in the Catalog | | | |
|----------------|-------------------------|---------------------------------------|---------------|--------------|--------------|
| | | Sites Maintained | Sites Removed | Sites Added | % Net Change |
| United States | 2,019 | 1,427 | 437 | 694 | 13% |
| India | 603 | 448 | 59 | 162 | 17% |
| China | 430 | 296 | 110 | 143 | 8% |
| Germany | 187 | 156 | 17 | 31 | 7% |
| Canada | 158 | 142 | 27 | 39 | 8% |
| Italy | 149 | 125 | 10 | 9 | -1% |
| France | 141 | 115 | 13 | 28 | 11% |
| Japan | 134 | 113 | 25 | 24 | -1% |
| United Kingdom | 105 | 84 | 18 | 22 | 4% |
| South Korea | 100 | 45 | 46 | 56 | 10% |
| Spain | 88 | 68 | 11 | 24 | 15% |
| Switzerland | 82 | 62 | 10 | 21 | 13% |
| Mexico | 64 | 45 | 14 | 19 | 8% |
| Ireland | 59 | 51 | 7 | 9 | 3% |
| All Others | 495 | 350 | 83 | 161 | 16% |
| Total | 4,814 | 3,527 | 887 | 1,442 | 12% |

With the COVID-19 PHE continuing through FY2022, FDA continued its use of alternative tools while resuming inspections as travel restrictions eased. To strengthen its use of alternative tools, FDA published a draft guidance on “[Conducting Remote Regulatory Assessments \(RRAs\)](#),” including use of requests under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA’s use of multiple surveillance tools allowed the agency to be agile and resilient throughout the PHE and will continue to do so. During FY2022, FDA accomplished 328 [surveillance inspections](#), 129 inspection classifications under [Mutual Recognition Agreements \(MRAs\)](#), and 49 surveillance systems-based assessments using information from 704(a)(4) requests. The number of surveillance inspections was nearly triple the amount (115 inspections) accomplished in FY2021, demonstrating progress in returning to pre-PHE inspection levels.

Site Inspection Score (SIS)

- Range: 0–10, with higher scores indicating better CGMP compliance
 - Used as a proxy for compliance with CGMP requirements⁹
 - Based on classifications of FDA drug quality inspections over the prior ten years¹⁰
-

For FY2022, the median Site Inspection Score (SIS) for all sites (7.00) was similar to past years. As a group, the median SIS for sites in the U.S. were slightly higher (7.17) than foreign sites (7.00).

9. Adherence to the CGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers adequately control manufacturing operations (FD&C Act 501(a)(2)(B) and [21 CFR 210.1](#)).

10. This includes inspections classified under the MRA program.



Drug Product Demographics

Key Takeaways

- CDER's Product Catalog contains over 140,000 application and non-application products.
- Nearly 90% of essential medicine, medical countermeasures and critical inputs (EM) products have at least one domestic finished dosage form manufacturer; however, 52% of EM products are completely reliant on foreign sites for active pharmaceutical ingredient manufacturing.
- Field Alert Reports decreased by 15%, due in part to a decline in the use of injectable products related to COVID-19.

The CDER Product Catalog is an inventory of all registered products, consisting of application products (NDAs, ANDAs, and BLAs) and non-application products (including OTC monograph products, marketed unapproved prescription drugs, and homeopathic products). For FY2022, the Product Catalog comprised 12,835 ANDAs, 3,538 NDAs, and 325 BLAs. Some of these applications may include multiple products of different strength, concentration, or packaging size. The Product Catalog contains 123,532 non-application products with a unique National Drug Code (NDC).

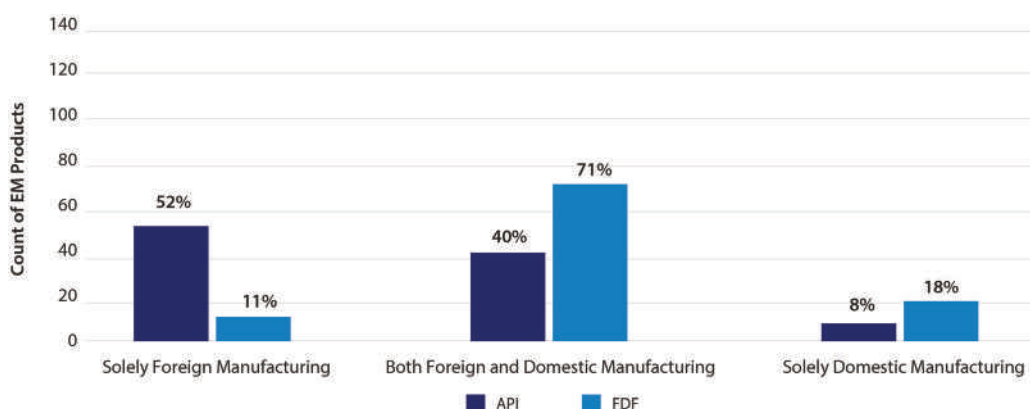
Essential Medicines

Pursuant to [Executive Order 13944](#), FDA continues to carefully monitor supply chains for the 227 drug and biological products contained in its October 2020 [List of Essential Medicines, Medical Countermeasures, and Critical Inputs](#) (EM). Of the 227 EM products named, 168 are CDER-regulated drug products, with the remainder being products such as vaccines and plasma products that are regulated by CBER. These CDER EM products include over 1,800 approved applications (1,467 ANDAs, 347 NDAs, and 33 BLAs) and over 1,900 OTC monograph NDCs that are manufactured at more than 1,100 sites. As is the case for non-EM products, the majority of EM manufacturing sites are located outside of the U.S. As of October

2022, 82% of active pharmaceutical ingredient (API) manufacturing sites and 57% of finished dosage form (FDF) manufacturing sites of EM products are foreign. Note that this analysis is based on manufacturing site counts because manufacturing volumes remain uncertain. In the future, drug amount reporting under the CARES Act will provide a source for amounts manufactured.

Although there is a heavy reliance on foreign manufacturing for EM products (**Figure 1**), 48% of products have at least one domestic API manufacturer and nearly 90% have at least one domestic FDF manufacturer. These data provide important information about current manufacturing as the U.S. seeks to establish and strengthen domestic supply chains for EM and other key drug products.

Figure 1. Domestic vs. Foreign Manufacturing for the 168 CDER-Regulated EM Products



Product Quality Defects (PQDs)

FDA receives, evaluates, and monitors post-market quality reports. FDA’s post-market regulations, [21 CFR 314.81\(b\)\(1\)](#), require that application holders notify FDA about significant PQDs in marketed products within three working days for [Field Alert Reports](#) (FARs) and 45 days for [Biological Product Deviation Reports](#) (BPDRs). Voluntary reports of [MedWatch](#) (MW) and [consumer complaints](#) (CC) can be submitted by consumers, patients, and healthcare professionals when product quality fails to meet expectations. During FY2022, CDER received 12,353 quality-related MW reports¹¹ (7% increase from FY2021), 3,502 FARs (15% decrease from FY2021), 259 CC (5% decrease from FY2021), and 196 BPDRs (4% decrease from FY2021). The recent decrease in FARs is due, in part, to a recent decline in the use of injectable products following an abrupt increase in demand at the beginning of the COVID-19 PHE. As the demand for injectable products rose and fell, so did the number of FARs. In particular, in FY2021 there were three injectable firms that, in total, submitted 534 more FARs than they did in FY2022.

11. Quality-related MW reports are voluntary post-market reports from health professionals, patients, and consumers concerning product quality issues (not adverse events), such as defective components, contamination, poor packaging, and suspected counterfeit products.



Import Alerts, Recalls, and Warning Letters

Key Takeaways

- FDA records requests produced the majority of import alerts related to drug quality due to sites that refused to respond and those with CGMP deficiencies that were identified through record review.
- 37% of recalled products were associated with four specific events (see text for details).
- 31 warning letters were issued to hand sanitizer manufacturers, including 14 for methanol impurities detected by FDA testing.

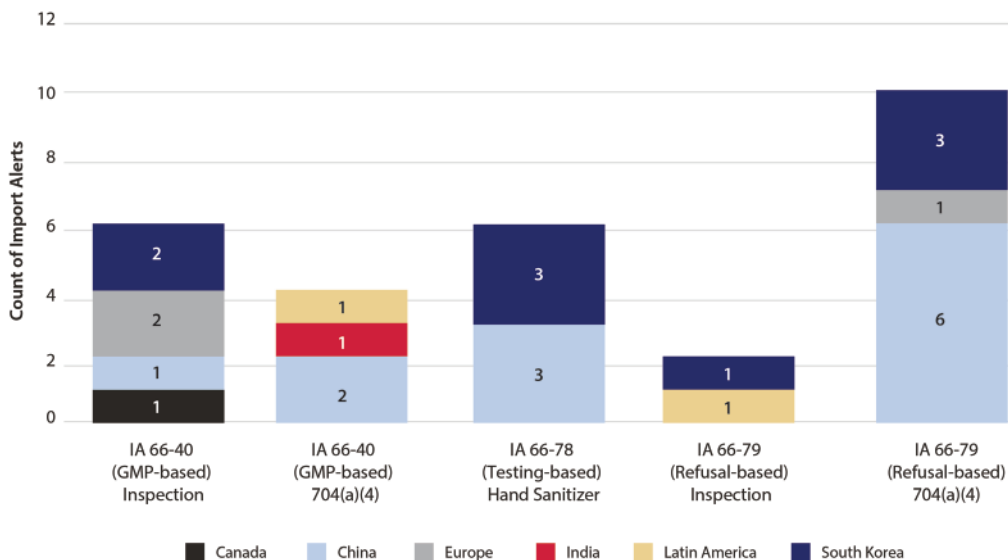
Import Alerts

During FY2022, FDA issued 28 [import alerts](#) to sites for reasons related to drug quality (**Figure 2**)¹². Most of the sites (89%) placed on import alert produced non-application, non-sterile, finished drug products. 82% of the import alerts related to drug quality were for sites manufacturing hand sanitizer. The largest number of import alerts related to drug quality issued in FY2022 were for sites that refused to respond to FD&C Act 704(a)(4) record requests, or for current good manufacturing practice (CGMP) deficiencies that were identified through record review. This demonstrates the ability of records requests to identify sites with deficiencies in CGMP compliance or those sites unwilling to provide evidence of CGMP compliance. Sites in China and South Korea accounted for most import alerts, 43% and 36%, respectively. As a point of comparison, China and South Korea represent only 15% and 4%, respectively, of foreign sites in the catalog. Consistent with import alerts related to drug quality in general, 86% of the import alerts for China and South Korea were for hand sanitizer manufacturing sites.

12. The subset of import alerts reported here are for 66-40 (GMP-based) 704(a)(4), 66-40 (GMP-based) Inspection, 66-78 (Testing-based) Hand Sanitizer, 66-79 (Refusal-based) Inspection, and 66-79 (Refusal-based) 704(a)(4).



Figure 2. FY2022 Drug-Quality-Related Import Alerts by Type and Region

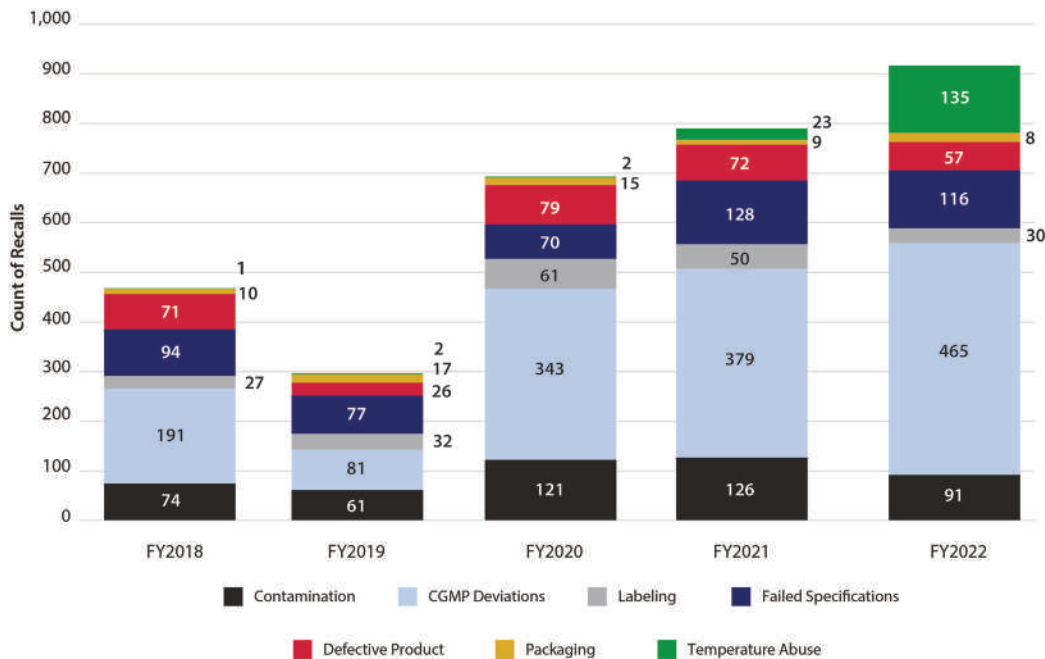


Recalls

In FY2022, 166 sites generated 912 [recalls](#)¹³, the highest number of recalls in five years (**Figure 3**). As in prior years, the largest defect group for recalls continued to be CGMP deviations. During FY2022, 37% of recalled products were associated with four specific events: 1) [130 recalls](#) were attributed to temperature abuse, 2) [100 recalls](#) were attributed to product held outside appropriate storage temperature conditions, 3) [56 recalls](#) were attributed to CGMP deviations, and 4) [51 recalls](#) were attributed to manufacturing with contaminated excipient that was recalled from the excipient supplier.

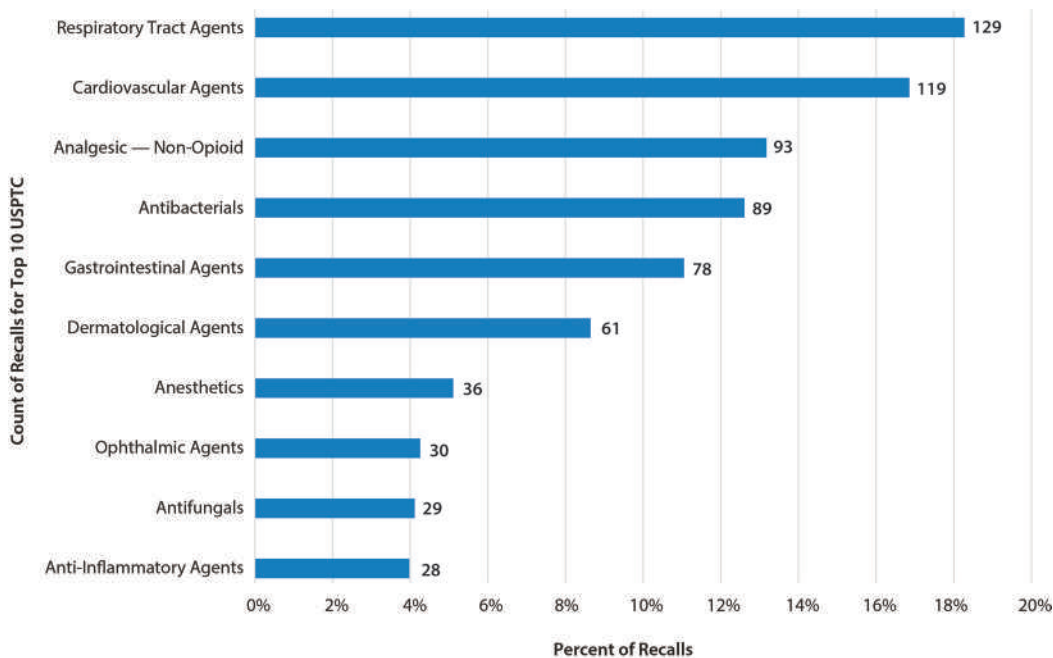
13. Recalls can be analyzed by product NDC numbers recalled (recall number) or by recalling event. Multiple product NDC numbers and lot numbers may be listed within a single recall event. All recall classes (I, II, III) are included in this analysis. Recalls of drug products not in the CDER Product Catalog (e.g., compounded drugs and those marketed without an approved application) are not included in this analysis.

Figure 3. Recalls by Defect Group for FY2018-FY2022



In FY2022, the [United States Pharmacopeia Therapeutic Category \(USPTC\)](#) Respiratory Tract Agents had the most recalls (**Figure 4**). In addition to the data analyzed, 28 recalls were attributed to unapproved drug products marketed in the U.S. without conforming to an OTC monograph or receiving FDA approval. These unapproved drugs are not included in the CDER Product Catalog.

Figure 4. Top Ten Recalls in FY2022 by USP Therapeutic Category





Notably, the median SIS of the manufacturing sites with more than one FY2022 recall event is lower (4.96) than the median SIS for sites with one or fewer recall events in FY2022 (7.00). This continues to suggest a correlation between low site inspection scores and potential recalls.

The non-proprietary names of the five most recalled drug products are acetaminophen-containing drug products (tablets, liquids, suspensions), losartan with and without hydrochlorothiazide (tablets), fexofenadine/pseudoephedrine (tablets), oxymetazoline hydrochloride (nasal solution), and magnesium citrate (oral solution). Most of these products were recalled due to temperature abuse or improper storage conditions in warehouses. A product could degrade under such conditions and negatively impact the shelf-life, safety, or effectiveness of the drug product. This emphasizes the need to maintain labeled storage conditions and monitor those conditions throughout the drug supply chain.

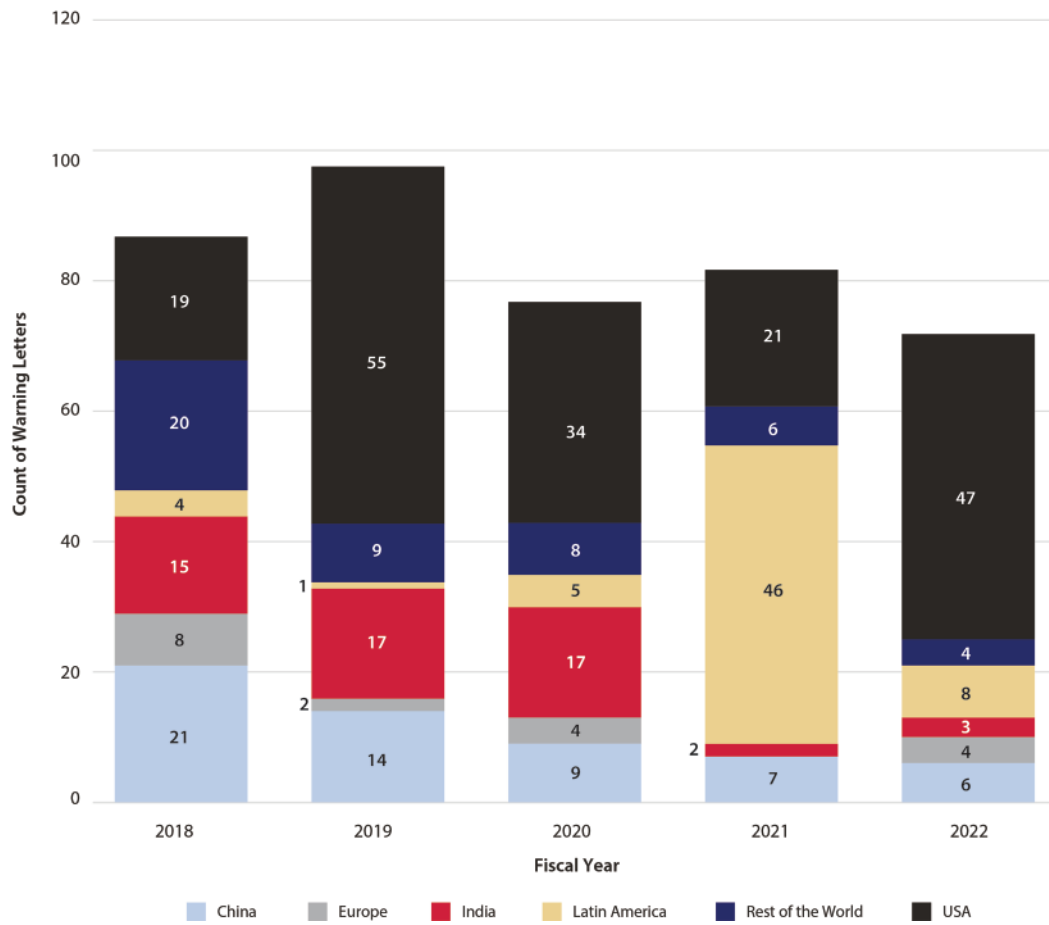
Warning Letters

FDA issued 72 CGMP-related [warning letters](#) to pharmaceutical manufacturing sites in FY2022 (**Figure 5**). Most of the sites that received warning letters (68%) were FDF manufacturers of non-sterile, non-application products, even though these sites represented only 30% of FY2022 inspections. Thirty-one warning letters were issued to hand sanitizer manufacturers, and of these, 14 were issued solely based on methanol impurities detected during FDA's testing. An increased proportion of warning letters issued to domestic manufacturers, as compared to the prior two years, is attributable to an increased percentage of domestic inspections due to ongoing travel restrictions, as well as a significant drop in hand sanitizer-related warning letters issued to sites in Latin America.

The most cited FY2022 CGMP issues by FDA across all warning letters were related to the quality control unit, production record review/investigations, written procedures/deviations, equipment cleaning and maintenance, and testing/release.¹⁴ Details about FDA's warning letters are available through a searchable [database of warning letters](#).

14. These observations are aligned with the CGMP regulatory requirements in 21 CFR 211.22, 21 CFR 211.192, 21 CFR 211.100, 21 CFR 211.167, 21 CFR 211.165, and 21 CFR 211.84.

Figure 5: Warning Letters by Region for FY2018-FY2022





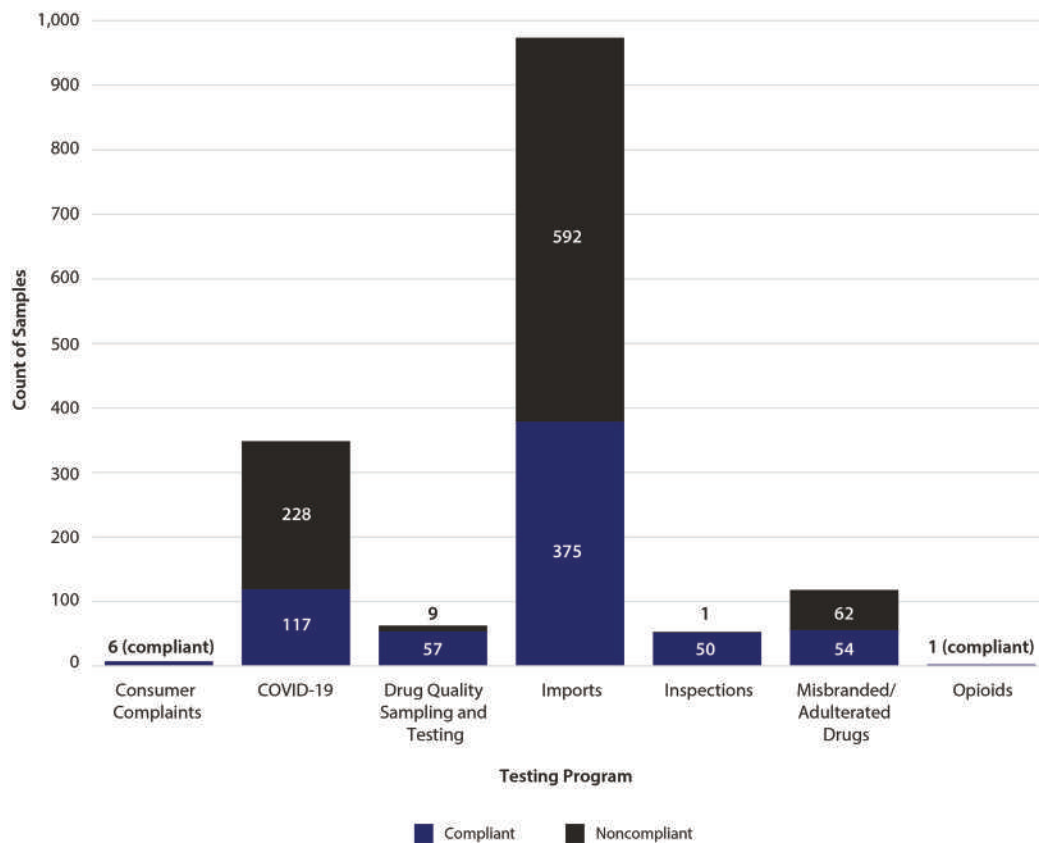
Sampling and Testing

Key Takeaways

- FDA's sampling and testing program uses risk-based analytics to target potentially noncompliant products and found 892 of 1,552 samples (57.5%) to be noncompliant.
- CDER is conducting a statistically-designed sampling and testing strategy to better understand the risk of benzene contamination.

To assure the quality of marketed drug products, [FDA samples and tests selected products every year](#). Sample selection uses data analytics and post-market quality data to identify products with potential quality risks. This targeted, risk-based approach results in a relatively high rate of noncompliant products that does not represent the quality of marketed products in general. In FY2022, FDA found 892 of 1,552 samples tested in FDA laboratories to be noncompliant. As shown in **Figure 6**, these samples were analyzed as part of several FDA testing programs. The imports-based testing program found 592 of the noncompliant samples, primarily from drugs that included undeclared drugs or ingredients shipped in small quantities directly to consumers. The testing program that focused on products related to the COVID-19 PHE found 228 of the noncompliant samples, all for hand sanitizer products that lacked potency or had unacceptable levels of impurities. The misbranded/adulterated testing program found noncompliant samples with undeclared ingredients and noncompliance with product specification limits.

Figure 6. Count of Compliant and Noncompliant FY2022 Laboratory Samples by Testing Program



Commitment to Quality

Key Takeaways

- NIPP is enhancing the collection and use of inspection data to improve future inspections.
- CDER is working with stakeholders to build a program for assessing QMM at drug manufacturing sites to strengthen quality systems and promote supply chain resiliency.
- CARES amount reporting will provide data that strengthen drug quality surveillance.
- NIPP, QMM, and CARES amount reporting are creating a more agile and robust pharmaceutical quality landscape.

New Inspection Protocol Project (NIPP)

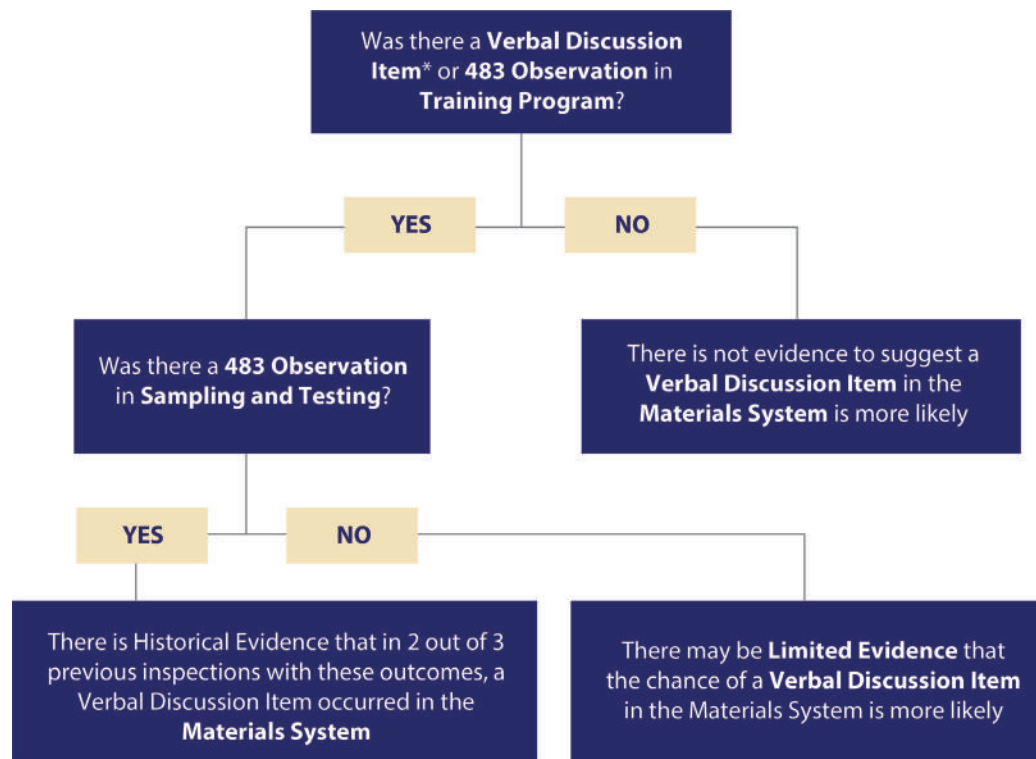
NIPP is modernizing FDA's inspections program by improving how data from surveillance and pre-approval inspections are recorded, assessed, and reported. In FY2022, NIPP evolved by enhancing the inspection protocols (for sterile and non-sterile manufacturing) based on investigator feedback. The non-sterile protocols provide coverage for multiple dosage forms including tablets, capsules, creams, ointments, solutions, suspensions, and transdermal delivery systems. These NIPP enhancements are aligned with broader FDA enterprise projects to conduct end-to-end inspections within a single platform. NIPP's data management and analytical capabilities are being improved with automated data pre-processing and advanced predictive tools.

A new internal training program was designed to be consistent with current protocols and to capitalize on NIPP data analytics. It will empower investigators to be efficient, accurate, and comprehensive when documenting pre-approval and surveillance inspections. The training focuses on how NIPP creates a better means for evaluating the state of quality, identifying policy needs, informing regulatory flexibility decisions, and enabling predictive capabilities. Concurrently, a systems analysis documented current pain points and future needs. The NIPP process seeks integrated planning between inspection protocols, FDA Form 483, inspection reports, and regulatory notes.

Figure 7 illustrates an example logic path that was created with NIPP data. It shows how experience from prior inspections can inform logic rules that provide insights for upcoming inspections. Using the attributes of a site that is planned for inspection, algorithms can draw associations from prior inspections and identify inspection areas that merit focus and those of lesser concern. As more NIPP data become available, the output of these algorithms should become more robust. In this example, an algorithm, built with data from prior inspections, uses outcomes

from the current inspection (observations for “Training Program” and “Sampling and Testing”) to forecast the likelihood of an outcome in the “Materials System.”

Figure 7. Illustrative NIPP Logic Flowchart that Supports Inspection Preparation



*An observation by the investigator that was not included as an observation on FDA Form 483.

Quality Management Maturity (QMM)

Through public outreach and published research, CDER continued its development of a [QMM program](#) for sites to promote the availability of high-quality drugs. CDER collaborated with Dun & Bradstreet and the University of St. Gallen to publish the results of a study on [Benchmarking the Quality Practices of Global Pharmaceutical Manufacturing to Advance Supply Chain Resilience](#). The study provided objective insights into the positive relationship between indicators of QMM, supply reliability, and manufacturing performance. In March 2022, two CDER contractors completed pilots that assessed QMM for eight domestic FDF and seven international API manufacturers, all voluntary participants. A summary of the lessons learned from the pilots was recently published ([Lessons from CDER’s Quality Management Maturity Pilot Programs](#)). Following completion of these pilots, CDER issued a white paper ([Quality Management Maturity: Essential for Stable U.S. Supply Chains of Quality Pharmaceuticals](#)) describing how QMM can improve supply chain resiliency and reduce supply chain disruptions. In May 2022, CDER convened a public [QMM Workshop](#) in collaboration with stakeholders. The 2,000 attendees learned about the potential impacts of QMM ratings and lessons from CDER’s

QMM pilots. Then, in November 2022, CDER presented the merits of a QMM program before the [Pharmaceutical Science and Clinical Pharmacology \(PSCP\) Advisory Committee](#) and received unanimous (9-0) support for establishment of a QMM program.

CDER's proposed framework for a QMM program includes five practice areas:

- management commitment to quality
- business continuity
- technical excellence
- advanced pharmaceutical quality system
- employee engagement.

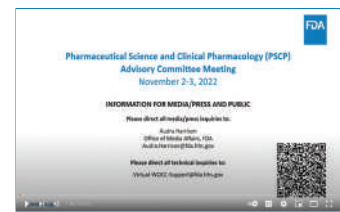
To establish a robust and successful QMM program, CDER will continue to engage with stakeholders including pharmaceutical manufacturers, purchasers, payors, healthcare providers, pharmacies, and patients/consumers. Several operational elements are currently under consideration including eligibility criteria for participation, whether FDA or a third party will conduct assessments, and whether assessments will be remote, virtual, or use a hybrid approach.

Additional intramural and extramural research continue to support the design of a robust QMM program. To facilitate QMM implementation, CDER applied systems analysis to characterize impacted parties and explore potential unintended consequences. This highlighted the importance of incentives for program success. The FDA-funded Center of Excellence in Regulatory Science and Innovation at the University of Maryland ([M-CERSI](#)) provided an economic analysis of the potential effects of quality ratings on the pharmaceutical industry. The [study](#) concluded that "quality ratings should incent manufacturers to invest in quality processes with an aim toward reducing drug shortages."

CARES Drug and Biological Products Amount Reporting

The CARES Act included authorities to enhance FDA's ability to identify, prevent, and mitigate possible drug shortages by, among other things, improving FDA's visibility into drug supply chains. Section 3112(e) of the CARES Act added section 510(j)(3) to the FD&C Act establishing a new reporting requirement for FDA-registered manufacturers. These establishments must now report annually to FDA the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed for commercial distribution.

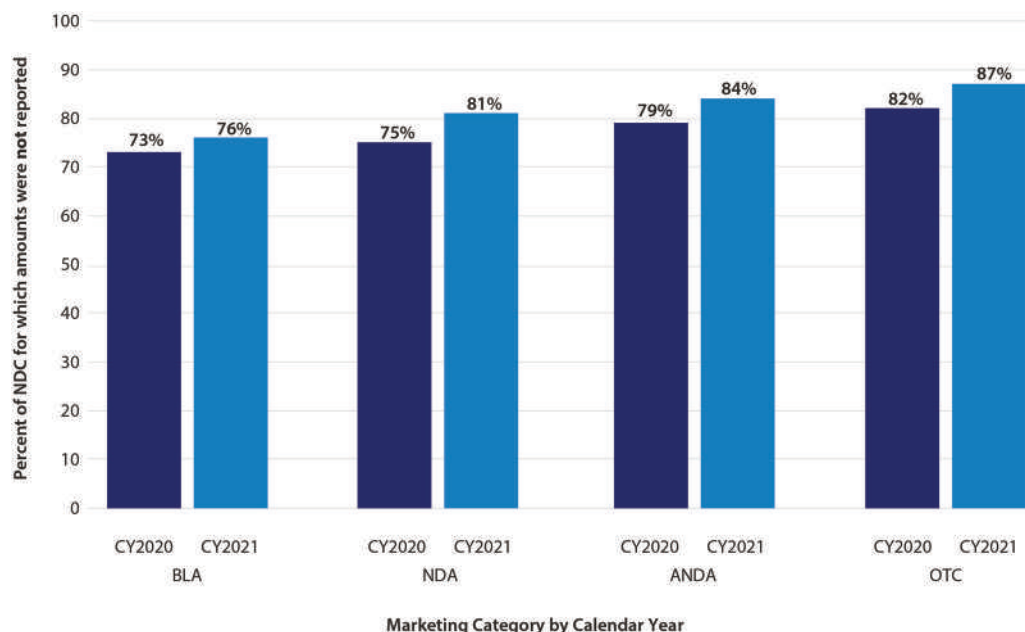
In October 2021 FDA published its draft guidance on [Reporting Amount of Listed Drugs and Biological Products Under Section 510\(j\)\(3\) of the Federal Food, Drug, and Cosmetic Act](#). It recommends ways industry can report amounts of listed drugs. Concurrently, FDA opened a [NextGen Portal](#) to receive reports from registrants or their authorized agents. Experiences with reporting and public docket comments ([FDA-2021-D-1031](#)) will inform FDA's final guidance. FDA also seeks to improve the NextGen Portal user experience; one improvement increased the number of records that a user can upload at once by 20-fold.



Video of Advisory Committee: <https://www.youtube.com/watch?v=78XsEBZuVBc>

For active products listed in FDA’s Electronic Drug Registration and Listing System ([eDRLS](#)), **Figure 8** shows the percent of NDC¹⁵ for which amount reports were submitted¹⁶. From CY2020 to CY2021,¹⁷ there was a drop in reporting across all marketing categories. While establishments are awaiting final guidance, annual reporting continues to be required; however, the reporting timeframes in the draft guidance are recommendations. The figure also shows that OTCs have been reported at lower rates than application products.

Figure 8. Percent of NDC in eDRLS for which amount reports were not submitted by marketing category



15. The NDC is a 10- or 11-digit identifier for drugs listed with FDA that consists of three segments: “labeler code” (manufacturer or distributor), “product code” (drug product: formulation, dosage form, and specific strength), and “package code” (commercial package size and type).

16. CARES amount data current as of November 2022.

17. CARES amount reporting is based on the calendar year (CY).

FDA intends to use CARES drug amount data to support drug quality surveillance to:

1. Approximate market share
2. Gain insights on vulnerabilities and dependencies in the drug supply chain. Amount data will be more informative than approximating manufacturing with site counts. This could identify gaps in domestic EM production and track progress toward domestic manufacturing.
3. Support responses to natural disasters, supply chain interruptions, and potential shortages by identifying alternative manufacturing sites.
4. Strengthen the [Site Selection Model](#) and better prioritize surveillance inspections by providing an improved proxy for exposure to drug products.
5. Normalize PQDs by the amount of each product manufactured for distribution. With these data, PQDs rates can be evaluated for impact and potential signals.

Looking Forward: The State of Quality

FDA will continue to monitor sites and products using adverse events, inspection outcomes, and testing results to inform quality surveillance. The NIPP, QMM, and CARES amount reporting initiatives demonstrate FDA's commitment to innovate pharmaceutical quality oversight. With these advances, FDA will improve inspections and quality assessments to enhance supply chain resilience, reduce drug shortages, bolster emergency response, and strengthen stakeholder engagement. Using these enhanced risk management tools, FDA can better prioritize quality surveillance resources to protect the public from noncompliant products and increase confidence in the supply and quality of marketed drugs.



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