The Office of Pharmaceutical Quality's FY2023 report provides a comprehensive analysis of various facets crucial to maintaining pharmaceutical standards and safety:

1. **Manufacturing and Inspection Trends:** Throughout FY2023, the FDA conducted 776 drug quality assurance inspections, marking a significant 40% increase compared to the previous year. This heightened scrutiny encompassed a diverse array of drug manufacturing sites, with particular attention paid to facilities in the U.S., India, and China. Despite the increased inspection volume, a majority of inspected sites received satisfactory ratings, indicating compliance with FDA standards.
2. **Product Overview:** The CDER Product Catalog expanded substantially, listing 17,519 application products and 131,367 non-application products by the fiscal year's end. Notably, a considerable portion of essential medicines relied solely on foreign manufacturing for their active pharmaceutical ingredients (APIs), highlighting the globalized nature of pharmaceutical production.
3. **Import Alerts, Recalls, and Warnings:** FY2023 witnessed a notable uptick in import alerts related to drug quality issues. These alerts primarily targeted deficiencies in Current Good Manufacturing Practices (CGMP) and non-compliance in the production of hand sanitizers. Despite a slight decrease in overall recalls compared to the previous year, concerns persisted regarding contamination and other quality-related issues.
4. **Pharmaceutical Quality Analysis:** The report emphasized the critical role of record requests and inspections in identifying and addressing quality issues within the pharmaceutical industry. These proactive measures not only facilitated FDA enforcement actions but also played a pivotal role in managing drug shortages. Quality problems and increased demand were identified as the primary drivers of these shortages, underscoring ongoing challenges in maintaining consistent supply.
5. **Sampling and Testing:** Against the backdrop of the COVID-19 pandemic, FDA testing of domestic hand sanitizers revealed alarming levels of non-compliance among manufacturers. This prompted urgent educational initiatives aimed at informing consumers about safe product usage and mitigating potential health risks associated with substandard products.
6. **Commitment to Quality:** The FDA's commitment to enhancing pharmaceutical oversight was evident in initiatives aimed at improving compliance with the CARES Act reporting requirements and advancing the functionality of the CDER NextGen portal. Furthermore, stakeholder engagement efforts surrounding the development of the Quality Management Maturity (QMM) program highlighted collaborative approaches to fostering industry-wide quality improvements.
7. **Assurance of Quality:** Throughout FY2023, the FDA maintained a rigorous regimen of monitoring adverse events, evaluating inspection outcomes, and conducting product testing to ensure the continued availability and safety of pharmaceutical products. These efforts underscored the agency's dedication to safeguarding public health by upholding stringent quality standards across the pharmaceutical sector.

In summary, the FY2023 report from the Office of Pharmaceutical Quality provides a detailed assessment of ongoing efforts to uphold pharmaceutical quality, mitigate risks, and enhance regulatory oversight, thereby ensuring the safety and availability of medicines for consumers in the United States and beyond.

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**Introduction:**

* Provides comprehensive data on pharmaceutical quality, including manufacturers, surveillance programs, supply chain vulnerability, shortages, recalls, and global quality trends.
* Highlights the CARES Act Drug Amount Reporting Program and Quality Management Maturity initiatives.
* Introduces new strategies like natural hazard risk quantification to enhance quality and supply chain resilience.

**Manufacturing Site Demographics:**

* FY2023 report notes 776 drug quality inspections, a 40% increase with a focus on U.S., Indian, and Chinese sites.
* CDER Site Catalog lists over 4,800 sites globally, 42% in the U.S., with 187 inspections classified under MRAs.
* Majority of U.S. sites are "No Application," 60% produce biological, innovator, or generic drugs.
* Key countries in site catalog include U.S., India, China, Germany, and Italy, with significant growth.
* Foreign inspections make up 59%, most sites receive favorable NAI or VAI ratings.

**Drug Product Demographics:**

* CDER Product Catalog includes 17,519 application products, 131,367 non-application NDCs by FY2023.
* 80 of 168 essential medicines rely solely on foreign API sources; all have domestic finished dosage form manufacturers.
* Emphasizes risk management plans for natural hazards, cataloged products up 6%.
* FEMA NRI identifies 34% EM sites in high-risk counties; significant reports and alerts in FY2023.

**Import Alerts, Recalls, and Warning Letters:**

* FY2023 saw 93 import alerts, more than FY21-22 combined, driven by CGMP and non-responsiveness issues.
* Recalls decreased 26% from FY22; Ophthalmics were 17% of recalls.
* Common issues include CGMP, contamination; U.S., India top recalls.
* 94 warning letters, mainly for OTC monographs, issued; quarter due to non-response or CGMP issues.

**Analyses on Pharmaceutical Quality:**

* Record requests (§704(a)(4)) pivotal in identifying issues, leading to warnings and alerts.
* Quality problems and increased demand each caused 40% of recent shortages; inspections impacted by COVID-19.

**Sampling and Testing:**

* High non-compliance (71.6%) found in FDA's hand sanitizer testing during COVID-19, prompting consumer safety campaigns.

**Commitment to Quality:**

* CARES Act reporting compliance and CDER NextGen portal enhancements expected to improve drug reporting.
* Stakeholder engagement in QMM program development ongoing, aiming for voluntary quality improvement.

**Assurance of Quality:**

* FDA focuses on adverse event monitoring, inspection outcomes, and product testing to ensure drug safety and availability.