U.S. FOOD & DRUG ADMINISTRATION

State of Pharmaceutical Quality Surveillance Findings Fiscal Year 2019

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SBIA Midnight Madness– July 23, 2020

Agenda

- Pharmaceutical Quality
- Manufacturing Site Surveillance
- Product Quality Surveillance
- Comprehensive Quality Surveillance

Pharmaceutical Quality

A quality product of any kind consistently meets the expectations of the user or consumer.

Drugs are no different.

Patients expect safe and effective medicine with every dose they take.

Pharmaceutical quality is

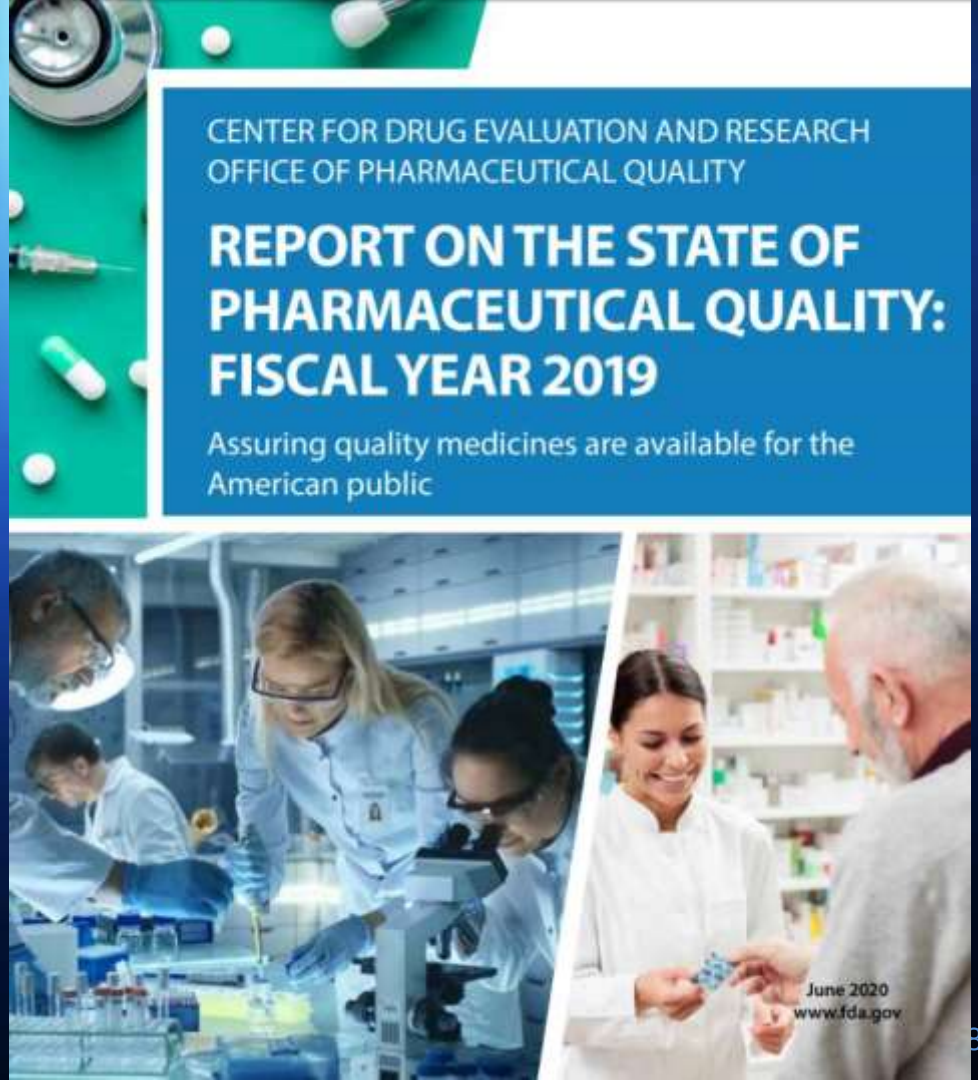
assuring *every* dose is safe and effective, free of contamination and defects.

It is what gives patients confidence in their *next* dose of medicine.

Pharmaceutical Quality

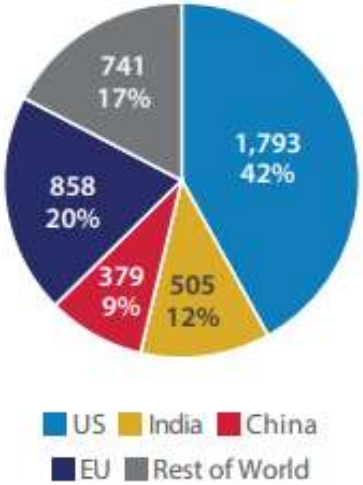
- The Report on the State of Pharmaceutical Quality summarizes **various measures** of the pharmaceutical manufacturing **industry's ability** to deliver **quality drug products** to U.S. patients and consumers.
- Select quality indicators and trends are assessed to provide insight into the quality of the U.S. drug supply chain.

OPQ's Report on the State of Pharmaceutical Quality 2019

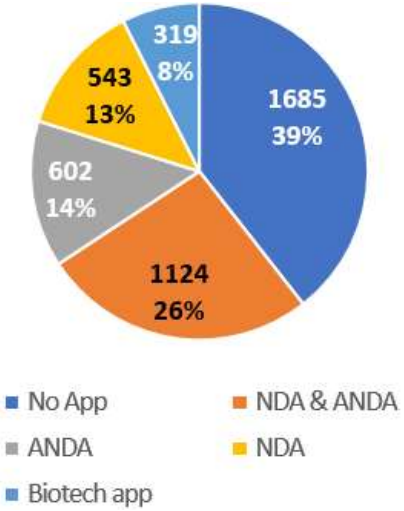


Pharmaceutical Industry Snapshot (FY19)

Manufacturing site[1] demographics reflect the distribution and diversity of site characteristics across the pharmaceutical industry.



4 out of 10 drug manufacturing sites are not listed in any applications (No App sector).



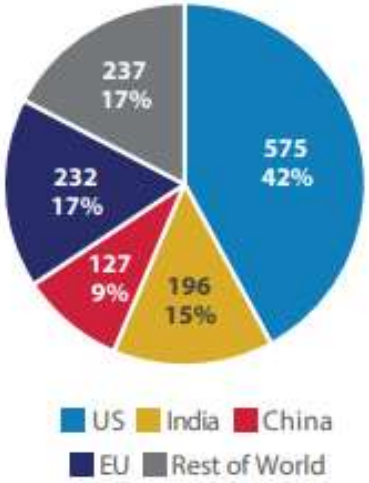
[1]Manufacturer is defined as anyone engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug

Inspections and Quality

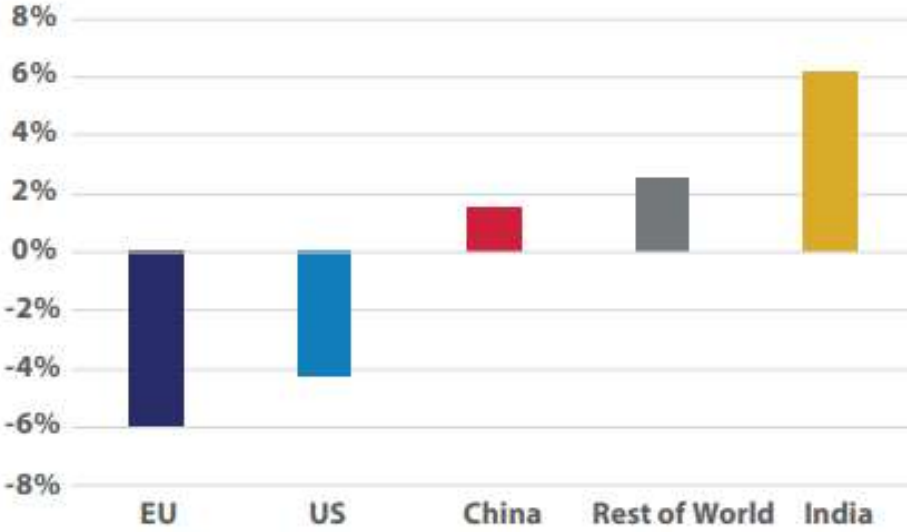
- Quality is cost effective
  - Reduces deviations, adverse events, drug shortages, and product recalls
  - Positive attribute for purchasing decisions
- Inspections are part of an overall regulatory system that encourages quality drug manufacture

Manufacturing Site Inspections (FY19)

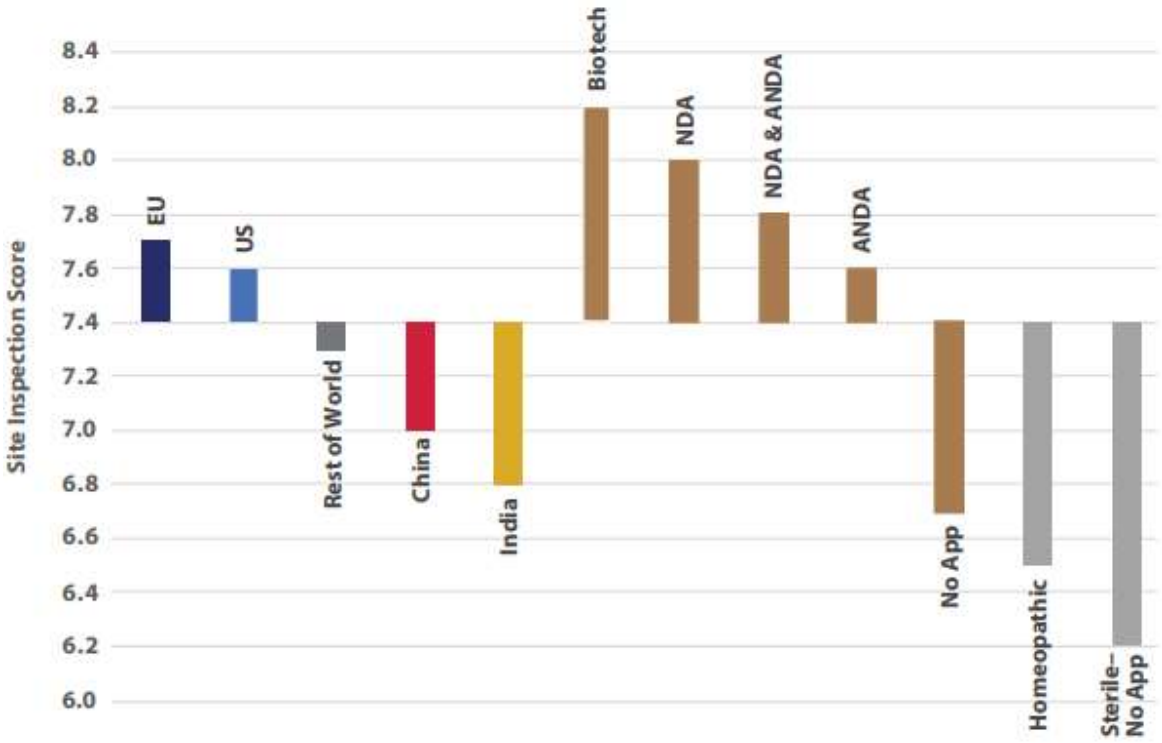
Drug Manufacturing Site Inspections Including Those Reviewed and Classified Under the MRA in FY19



Change in Percentage of Annual Drug Manufacturing Site Inspections Performed by FDA Over Two-Year Period (FY17-19)



Manufacturing Site Compliance (FY19)



Drug Product Quality

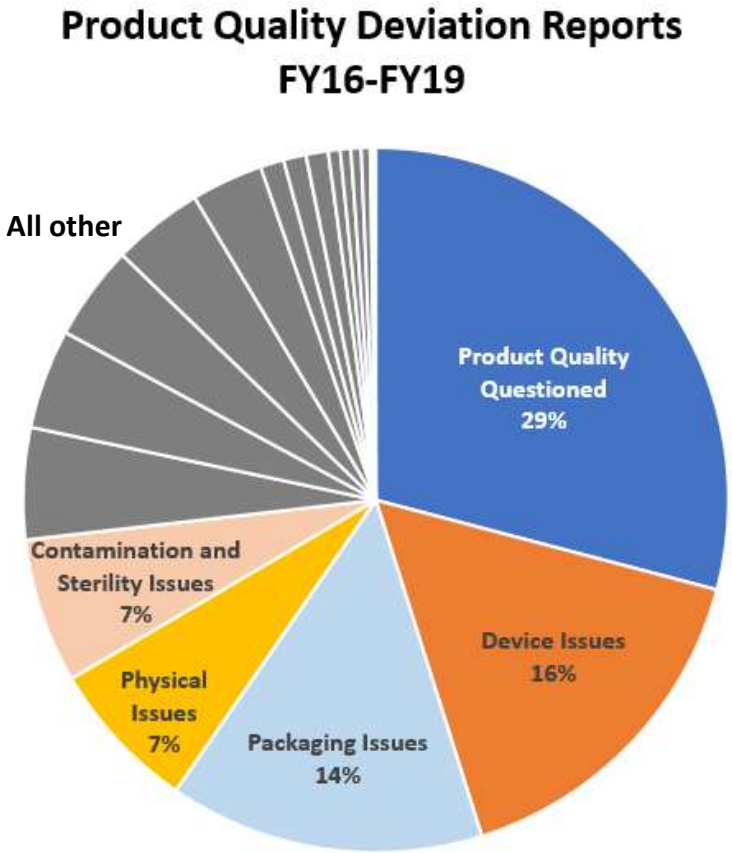
The FDA receives industry, healthcare provider, and consumer feedback on product quality via product quality defect reports.

These include:

- Field Alert Reports (FARs)
- MedWatch Reports (MWs)
- Biological Product Deviation Reports (BPDRs)
- Consumer Complaints (CC)

Drug Product Quality (FY16-FY19)

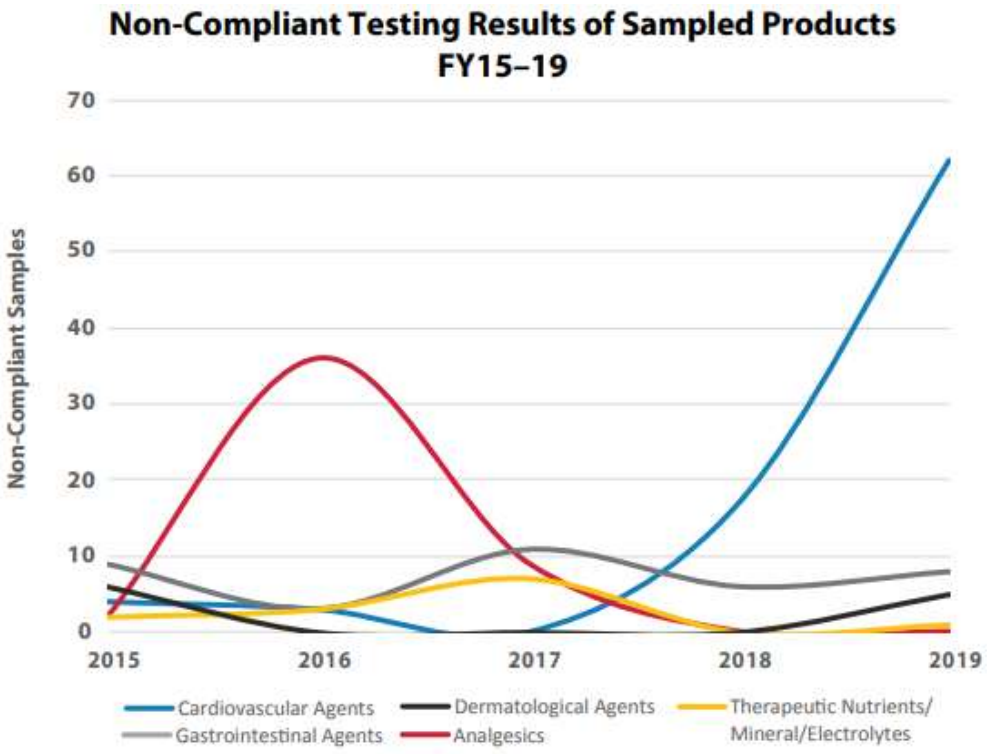
The FDA collects product quality defect reports, assesses defects and severity, and looks for trends and ways to mitigate issues.



Drug Product Sampling & Testing

Most surveillance sampling shows products on the market comply with specifications.

Non-compliance is usually associated with For-Cause targeted sampling and can confirm problems.

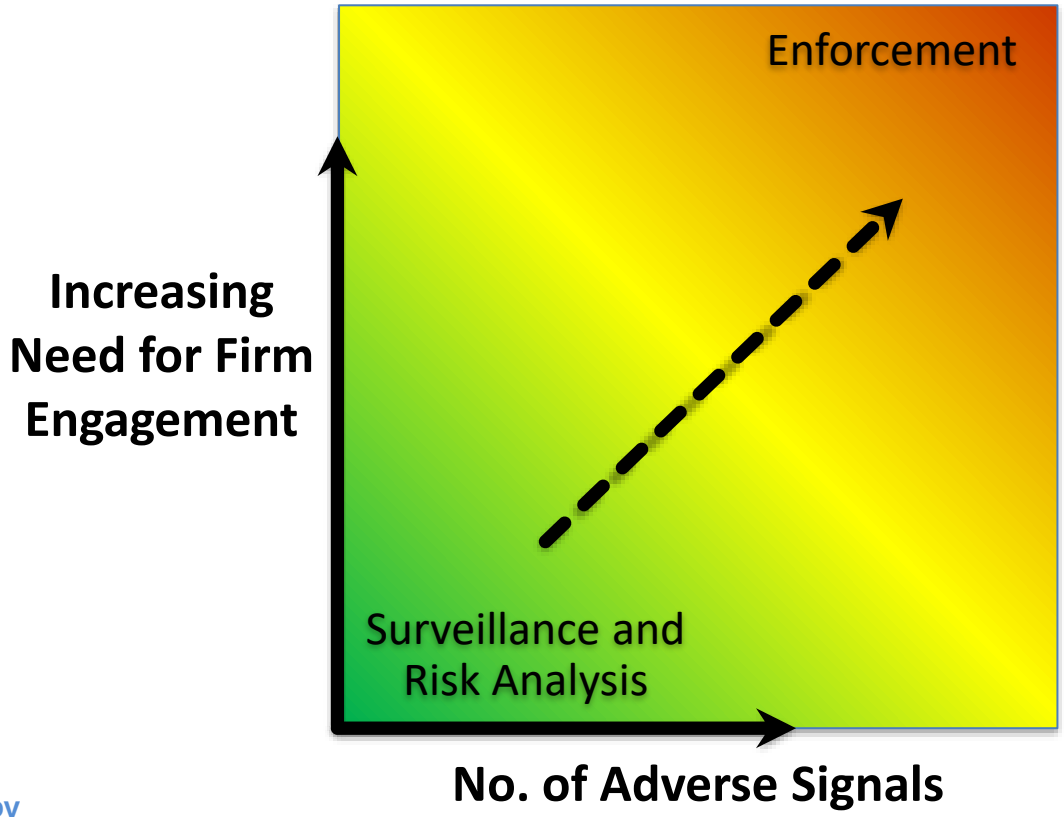


Comprehensive Quality Surveillance

- A comprehensive Quality Surveillance Program includes
  - proactive surveillance of products, sites, and
  - strategic outreach and communication to industry, patients, and consumers.

- The FDA uses the findings detailed in the Report on the State of Pharmaceutical Quality, in part, to identify better ways to **engage stakeholders** and **drive improvements** in the overall quality of pharmaceuticals and in manufacturing facilities.

Surveillance vs Enforcement



Comprehensive Quality Surveillance

- *Site Engagement Program* (SEP)
  The goal of the SEP is to have a common understanding and expectation regarding controls and approaches that will ensure availability of quality drugs and prevent shortages by creating opportunities for collaborative discussions.

- *Report on Drug Shortages: Root Causes and Potential Solutions*
  This report identifies root causes for drug shortages, including that the market does not recognize and reward manufacturers for “mature quality systems” that focus on continual improvement and early detection of supply chain issues.

Comprehensive Quality Surveillance

Quality Management Maturity (QMM)

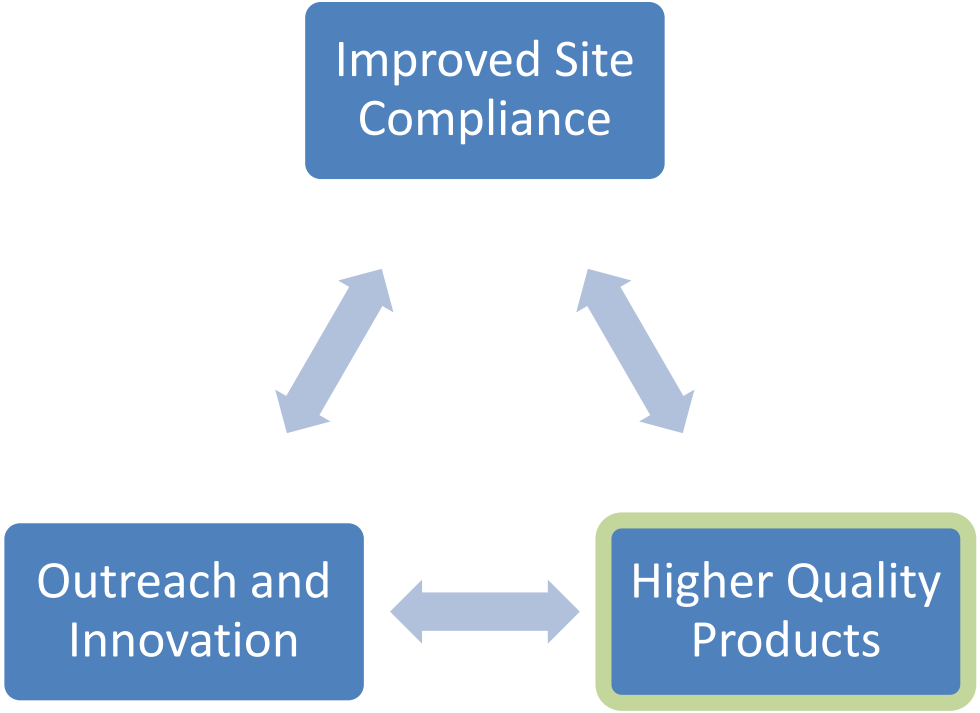
- Basic quality management systems are generally more reactive and focused on Current Good Manufacturing Practice (CGMP) compliance
- Stronger, more mature quality management systems proactively focus on performance, especially outcomes that affect the patient, including reducing quality issues that lead to complaints, shortages, and quality-related adverse events
- FDA has proposed a system to measure and rate a drug manufacturing facility's **quality management maturity**, and a firm's ability to deliver high-quality drug products reliably and without disruption

Comprehensive Quality Surveillance

<u>Pharmaceutical Innovation</u>

- *The FDA's Emerging Technology Program* (ETP) promotes the adoption of innovative approaches to pharmaceutical product design and manufacturing.
- FDA worked with international regulators to compare validated testing methods for **nitrosamine impurities** and share inspection information and advanced analytical methods for all to use. Among other positive outcomes, FDA established science-based acceptable daily intake levels for nitrosamine impurities.

Comprehensive Quality Surveillance



- **Fewer Shortages**
- **Fewer Inspections**
- **Lower Costs**

References

- OPQ's 2019 Report on the State of Pharmaceutical Quality
- Field Alert Report Submission - Draft Guidance
- MedWatch Forms for FDA Safety Reporting
- BPDR Submission – Resources
- 2019 Drug Shortage Report
- Site Engagement Program
- Emerging Technology Program

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Thank You

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