IPA's 7th Advanced GMP Workshop

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U.S. Food and Drug Administration (FDA)
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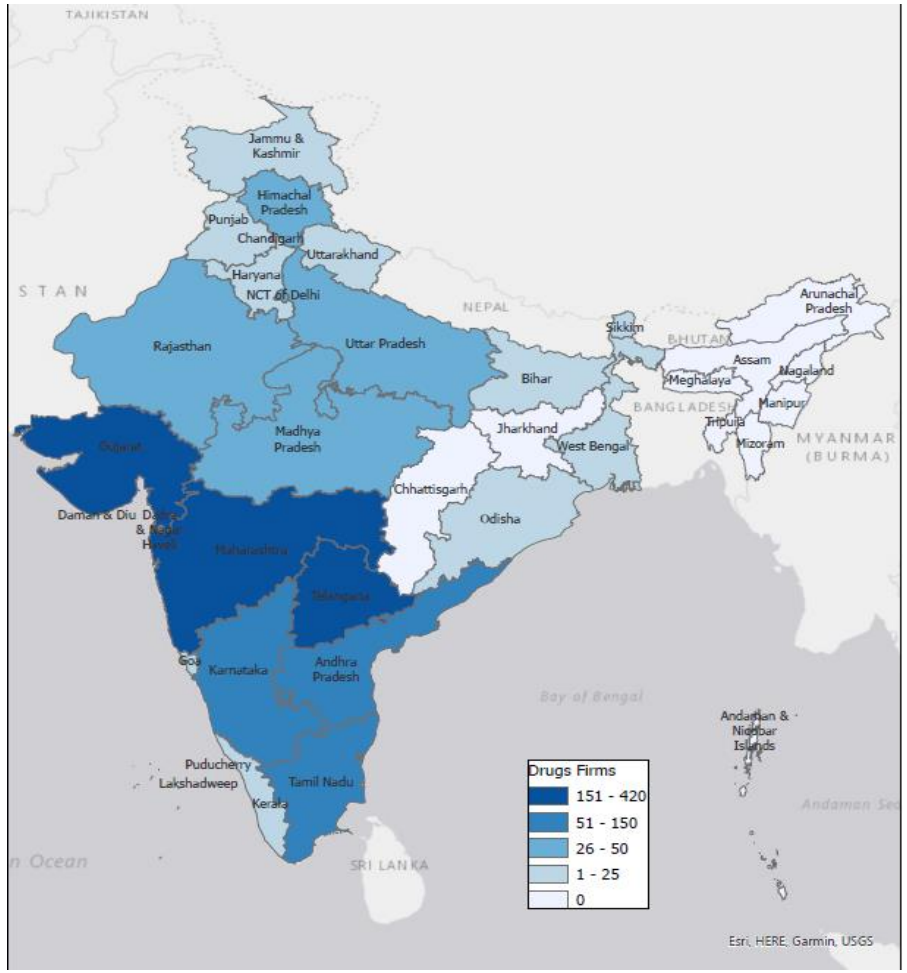
FDA at a Glance

Reference: https://www.fda.gov/media/154548/download

https://www.fda.gov/media/149613/download

- FDA is responsible for assuring the safety, effectiveness, quality and security of food, medical products, cosmetics, tobacco, vaccines and other biological products, and veterinary drugs in the U.S.
- FDA-regulated products account for about 20 cents of every dollar of annual spending by U.S. consumers, or approximately $2.8 trillion.
- FDA has about 18,062 full-time employees.
- FY 2023 budget request is $8.4 billion.

India



As of July 2021

Disclaimer: Heat maps are intended to convey concentration of registered facilities only. Other resources should be consulted to verify current political map boundaries

- India has the largest number of FDA-registered drug manufacturing facilities outside of the U.S.
- India is one of the largest exporters of drug products to the U.S.

FDA Goals in India

- Develop a deeper knowledge about India's regulatory environment.
- Better understand the capacity of India's national and state regulators.
- Learn about the intersections between India's regulators and the regulated industry.
- Identify and analyze emerging issues that may impact FDA's regulatory decisions about India products entering the U.S. market.
- Assess the general safety of India's Medical Products and Food Exports to the United States.
- Increase Indian regulators and industry's knowledge of FDA legal requirements.
- Conduct inspections of FDA regulated products intended for the U.S.

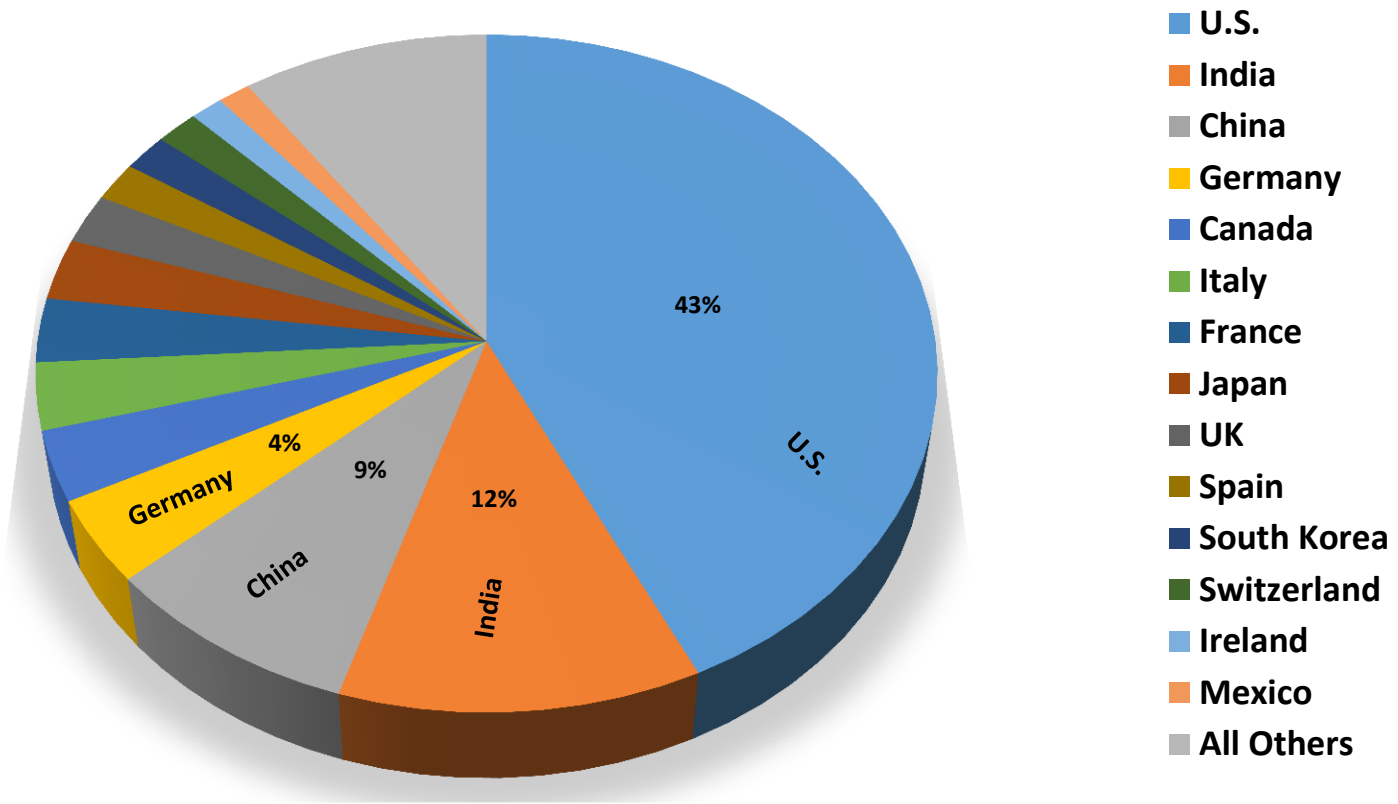
Current Good Manufacturing Practices (CGMPs)

- ***Pharmaceutical Quality*** affects every patient.

- The main regulatory standard for ensuring pharmaceutical quality is the ***Current Good Manufacturing Practice (CGMPs)*** regulation for human pharmaceuticals.

Reference: https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations

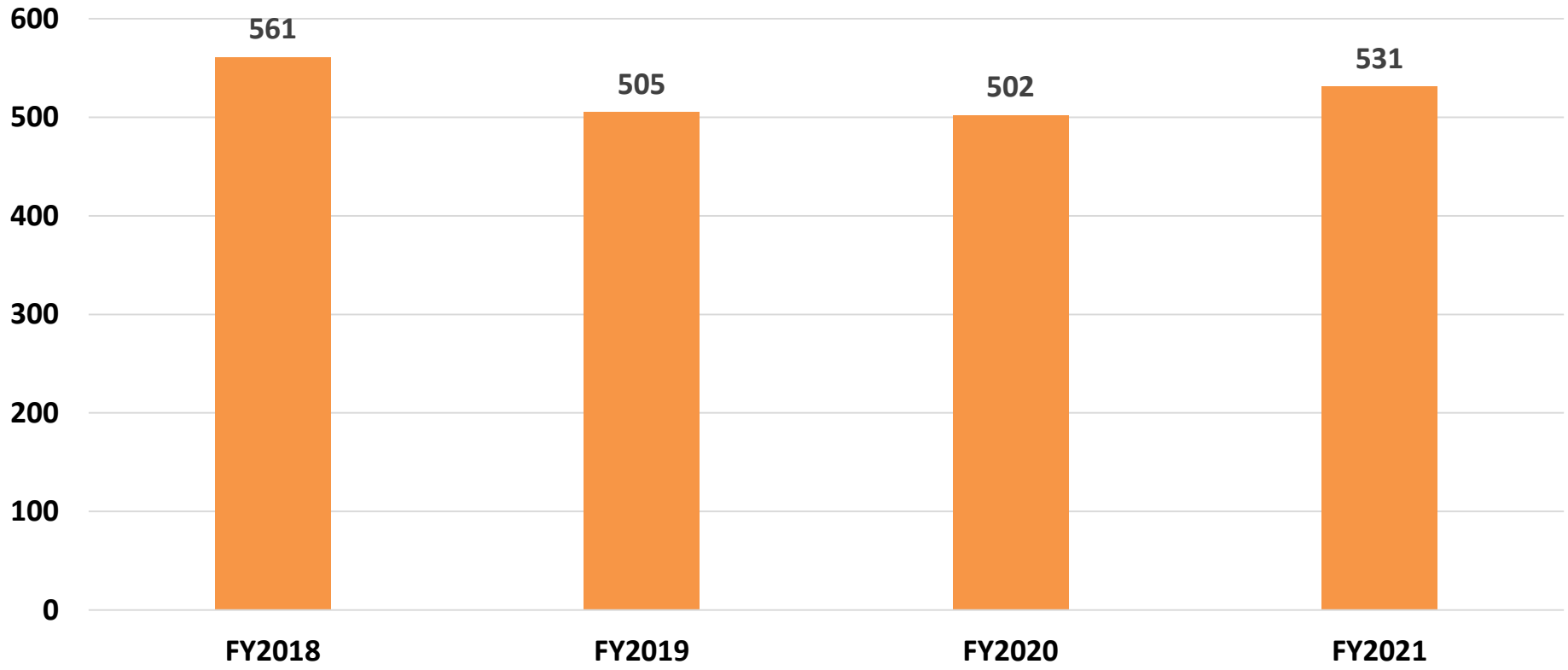
FY 21 Manufacturing Site Demographics



Fiscal year (FY) begins on 1st October of previous calendar year and ends 30th September of that calendar year.

Reference: https://www.fda.gov/media/161172/download

Number of FDA Registered Pharmaceutical Firms in India



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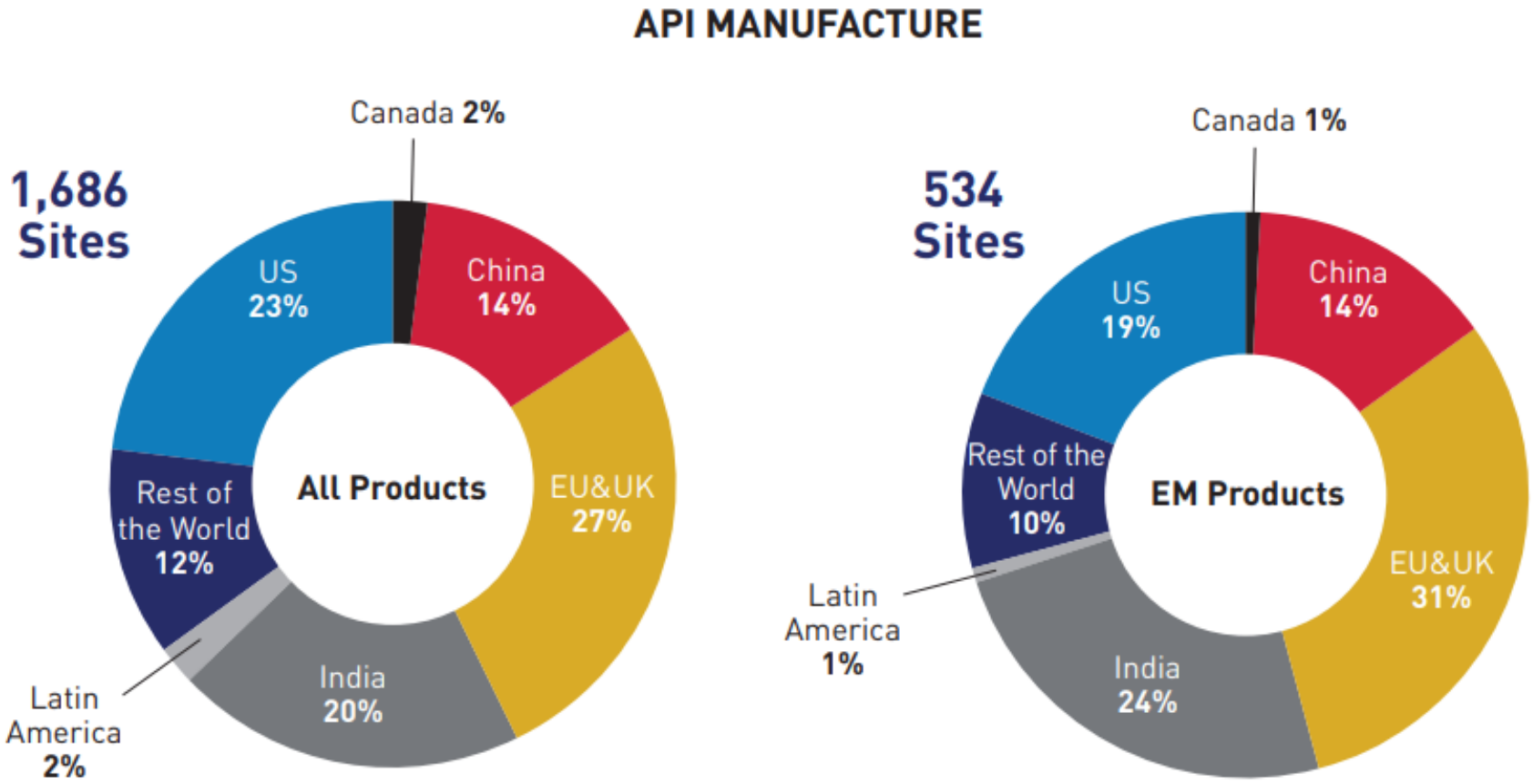
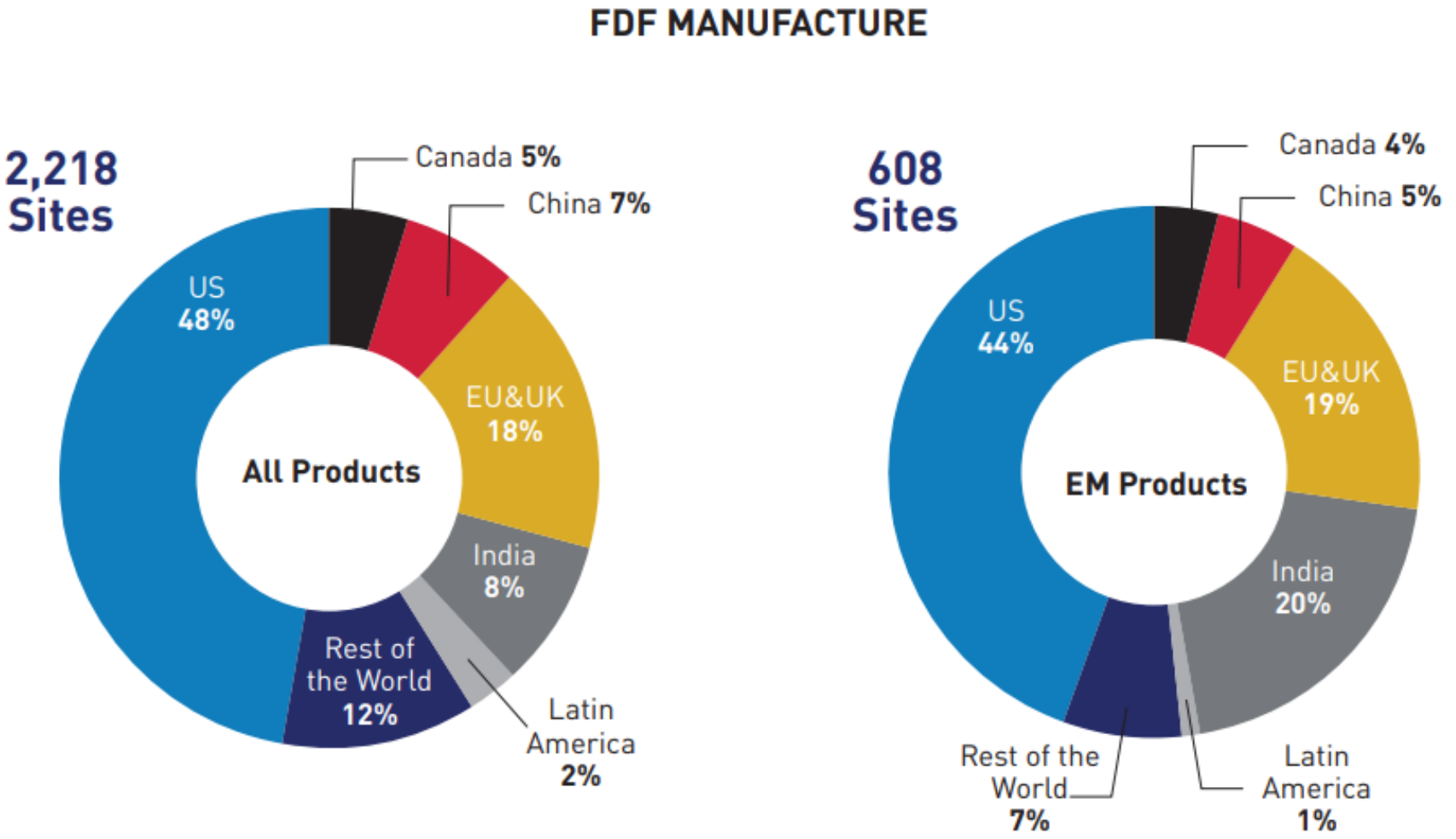
FY 21 API Manufacturing Site Demographics



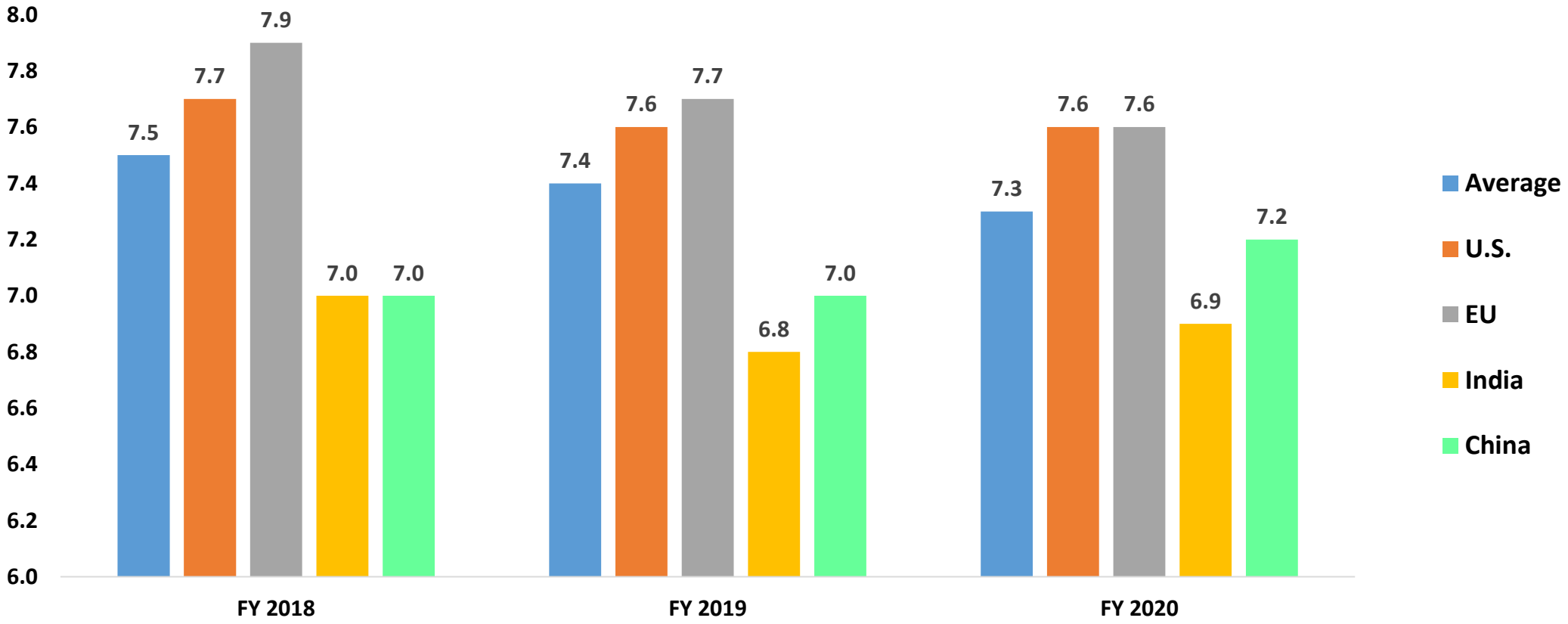
Reference: https://www.fda.gov/media/161172/download

FY 21 FDF Manufacturing Site Demographics



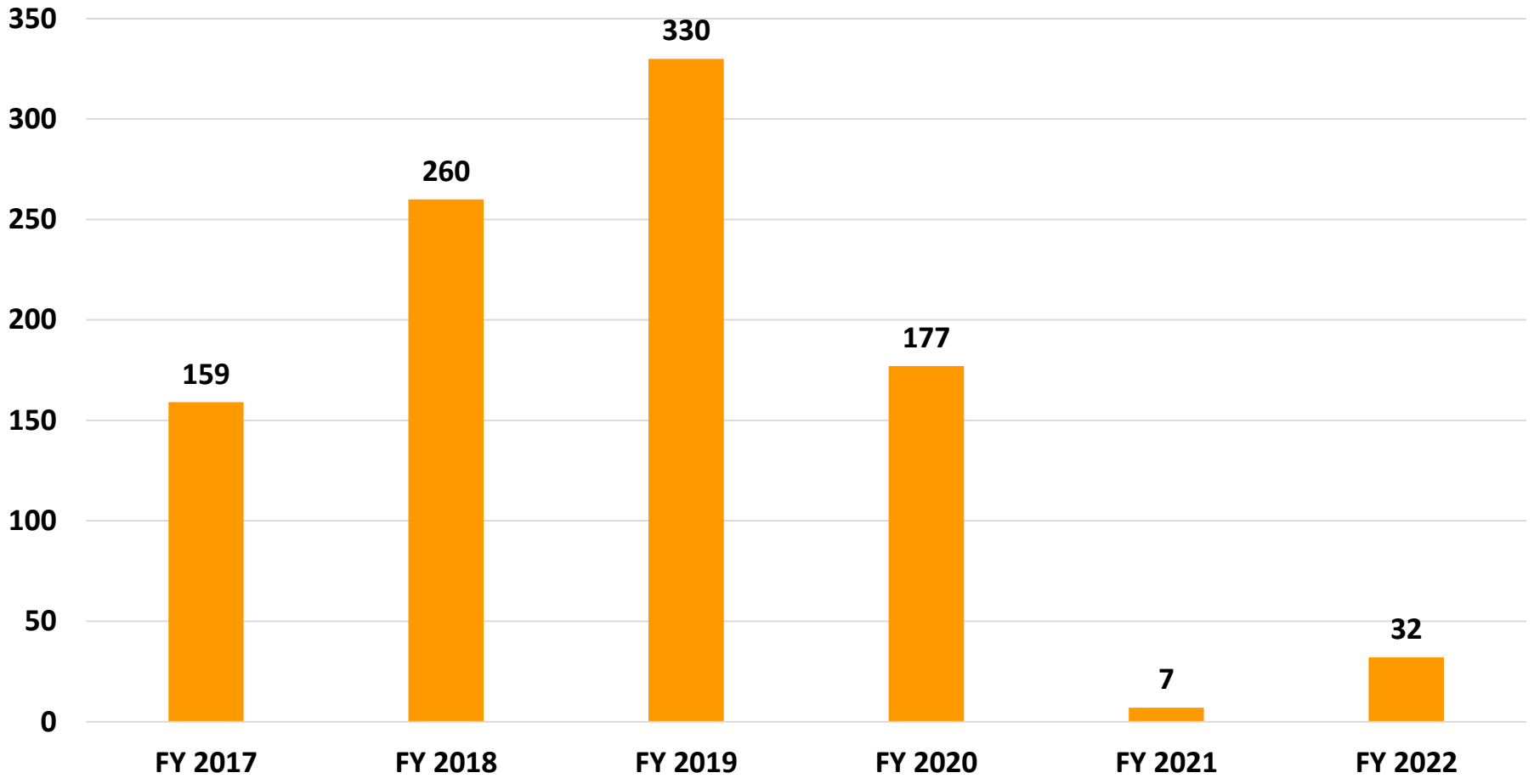
Reference: https://www.fda.gov/media/161172/download

Site Inspection Score for FY 2018-2020



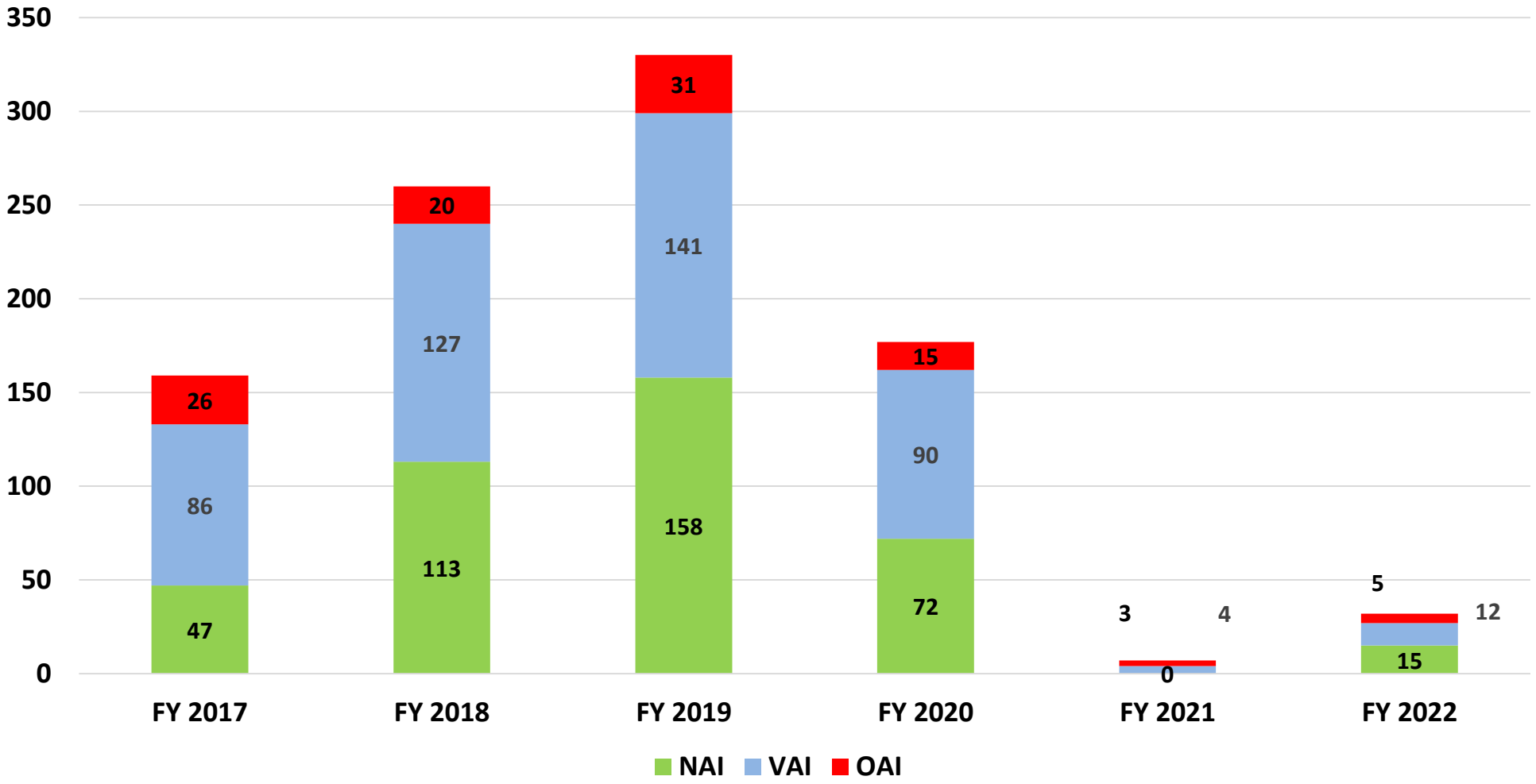
Reference: https://www.fda.gov/media/125001/download

Number of Pharmaceutical Inspections in India



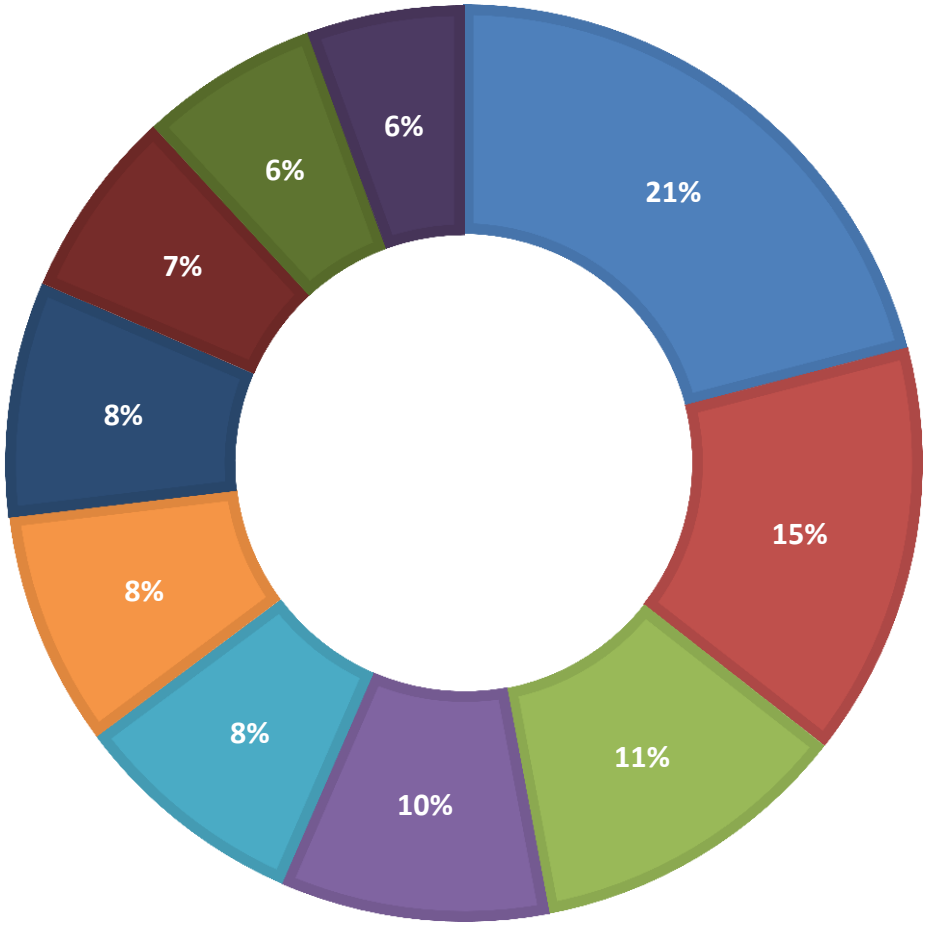
Reference: https://datadashboard.fda.gov/ora/cd/inspcetions.htm

Classification of Pharmaceutical Inspections in India



Reference: https://datadashboard.fda.gov/ora/cd/inspcetions.htm

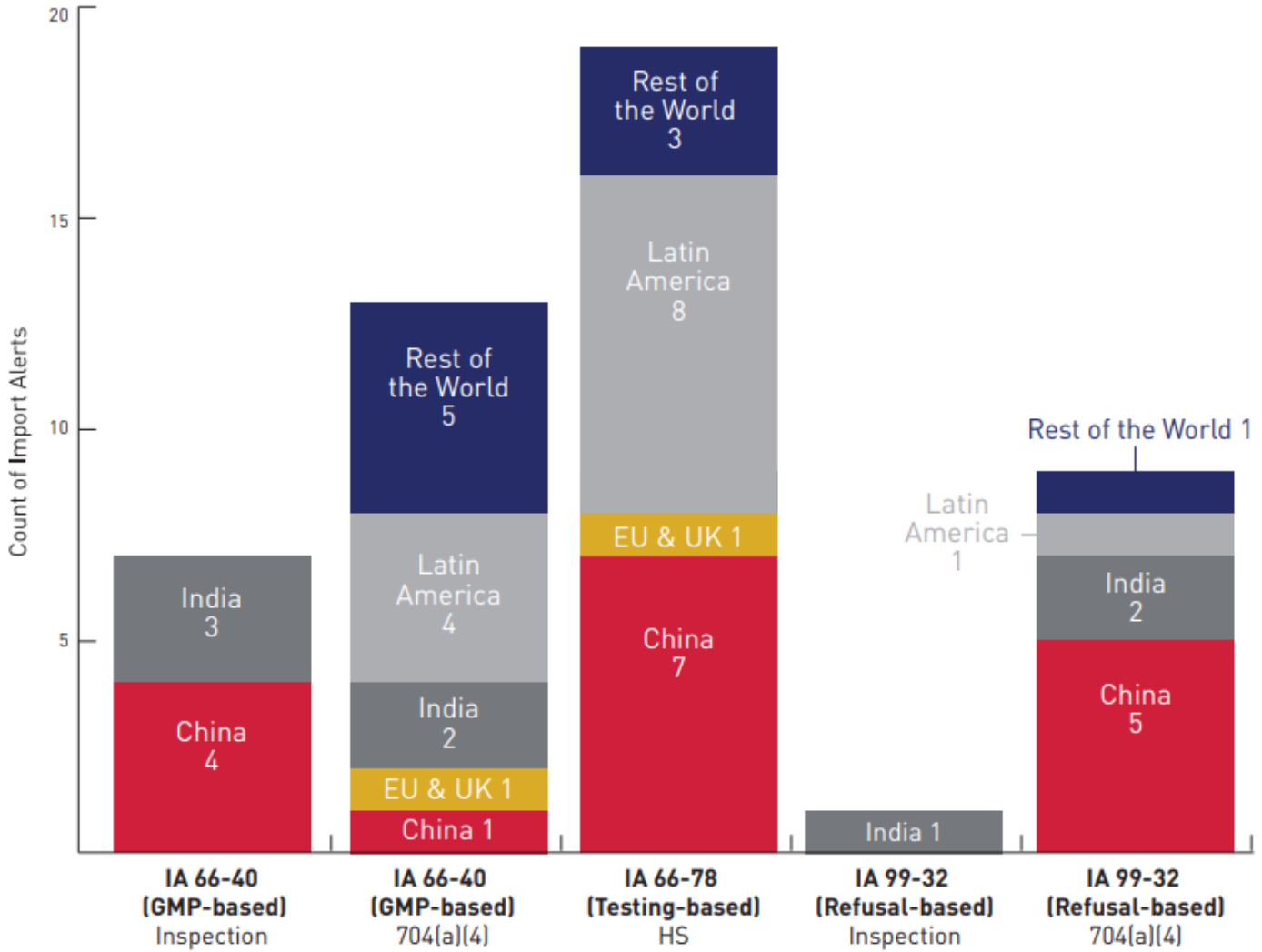
Inspectional Findings in India for FY 2017-2022



- Procedures not in writing, fully followed
- Scientifically sound laboratory controls
- Investigations of discrepancies, failures
- Absence of Written Procedures
- Training , Education , Experience overall
- Procedures for sterile drug products
- Computer control of master formula records
- Control procedures to monitor and validate performance
- Written record of investigation incomplete
- Complete test data included in records

Reference: https://datadashboard.fda.gov/ora/cd/inspcetions.htm

FY 21 Import Alerts



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INO Focus Areas

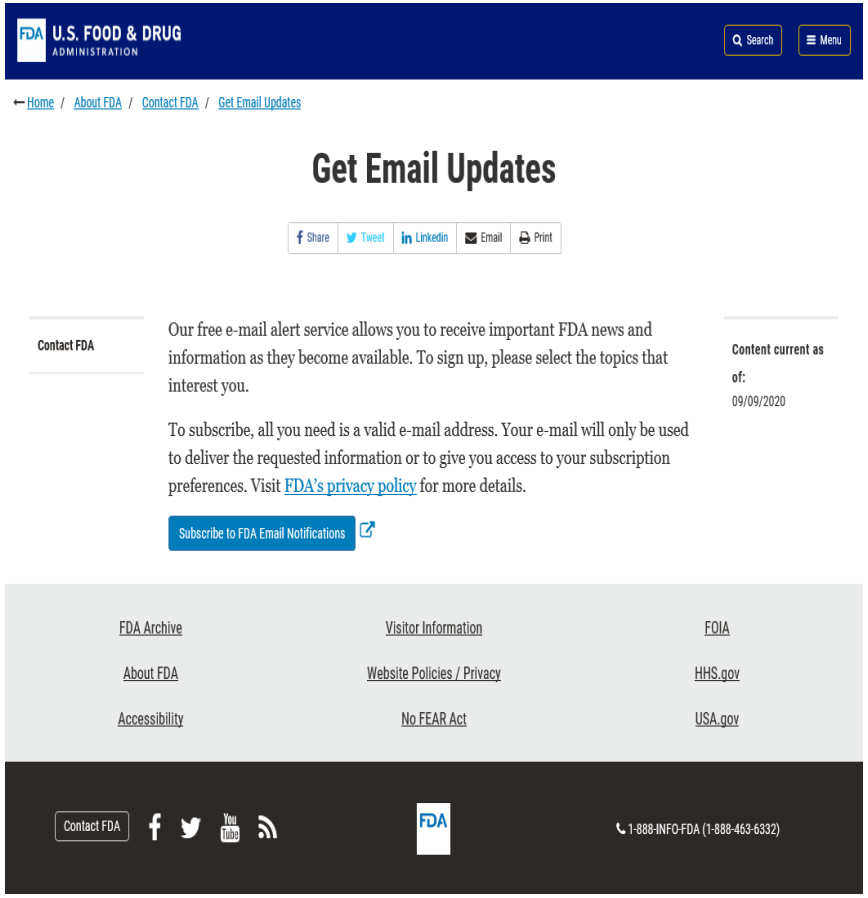
Advanced Manufacturing Technologies

Biopharmaceuticals

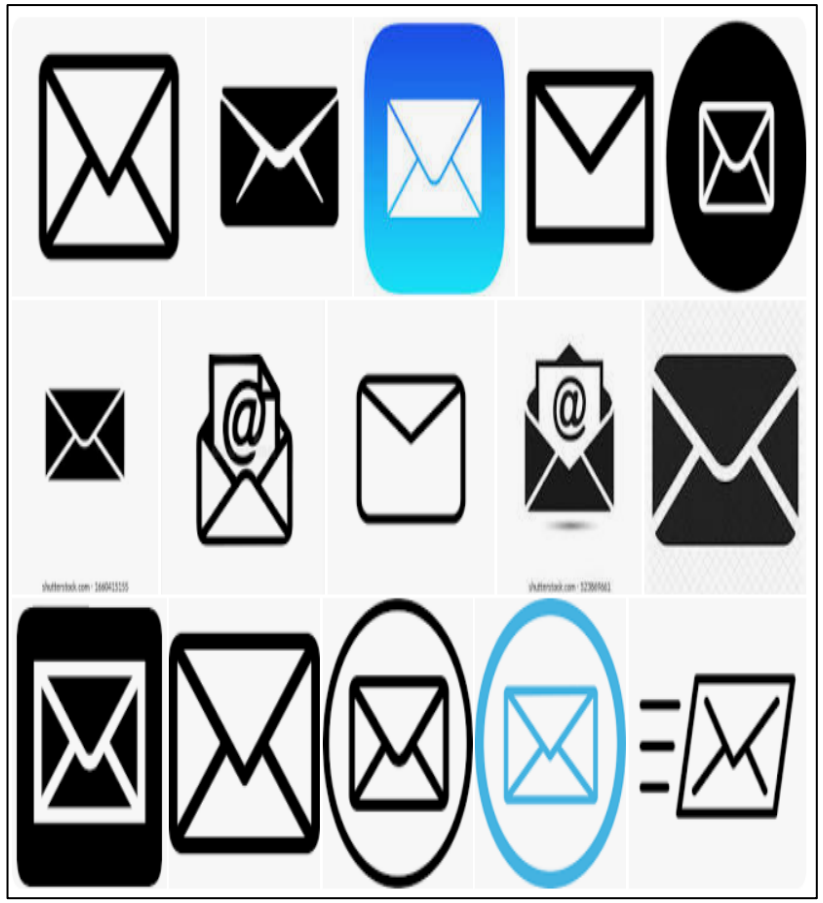
Nitrosamine Impurity

Innovations

Stay Informed!



https://www.fda.gov/about-fda/contact-fda/get-email-updates



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