

# **IPA's 7<sup>th</sup> Advanced GMP Workshop**

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U.S. Food and Drug Administration (FDA)  
Oct, 2022**



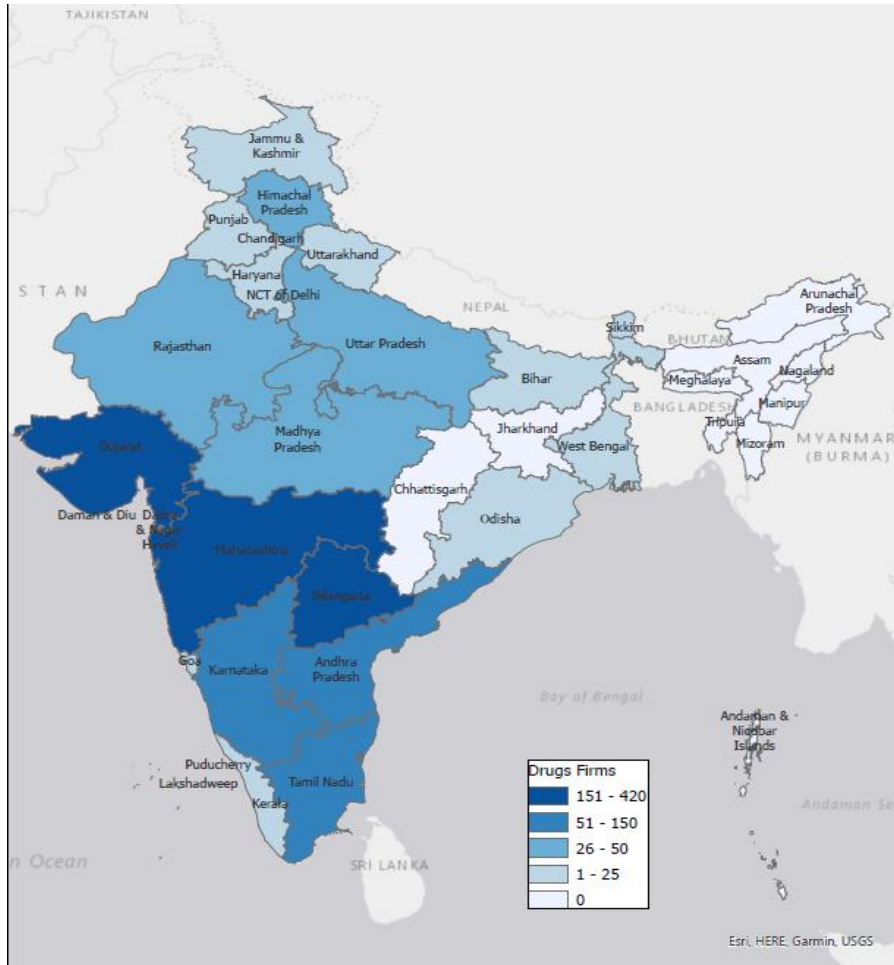
# FDA at a Glance

FDA



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.



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)



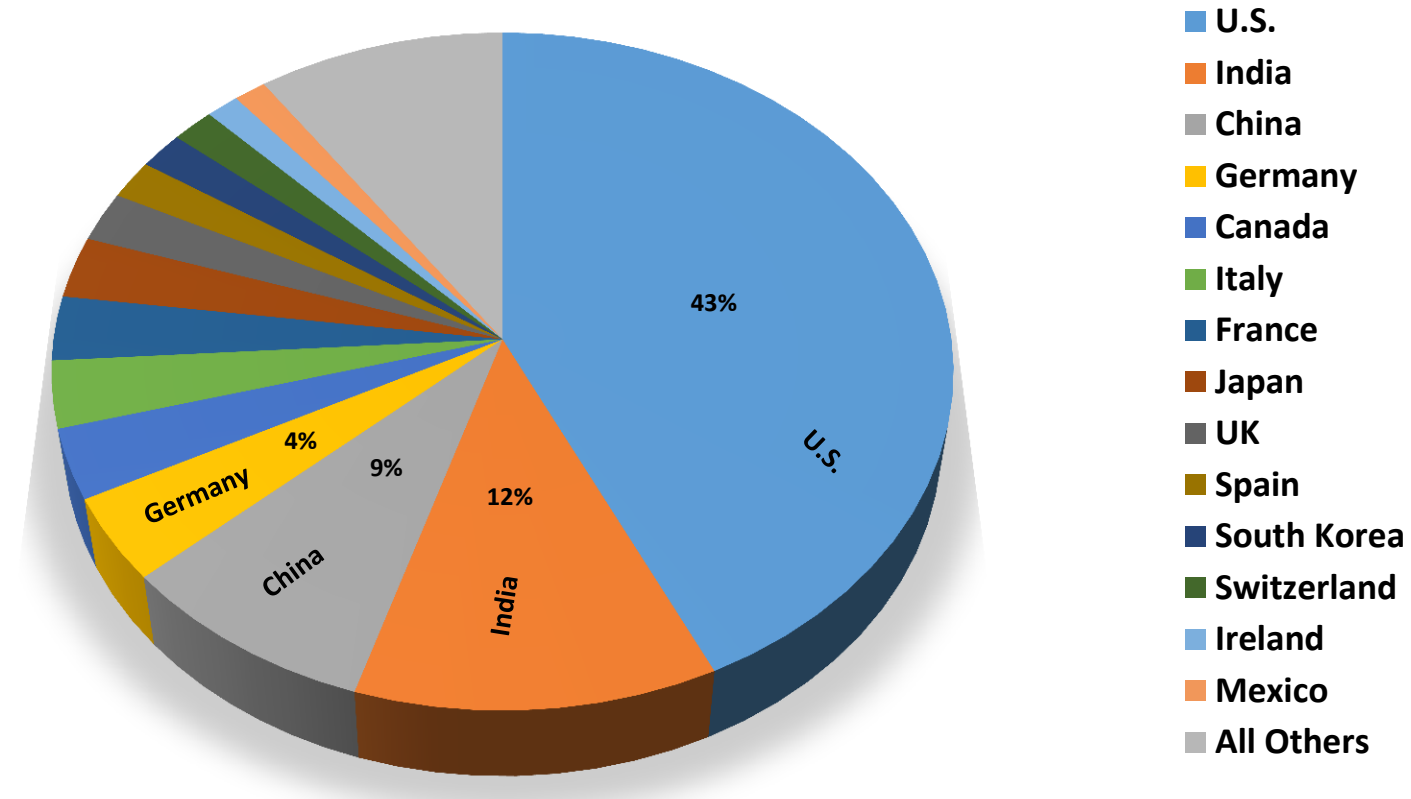
- ***Pharmaceutical Quality*** affects every patient.
- The main regulatory standard for ensuring pharmaceutical quality is the ***Current Good Manufacturing Practice (CGMPs)*** regulation for human pharmaceuticals.

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





# FY 21 Manufacturing Site Demographics

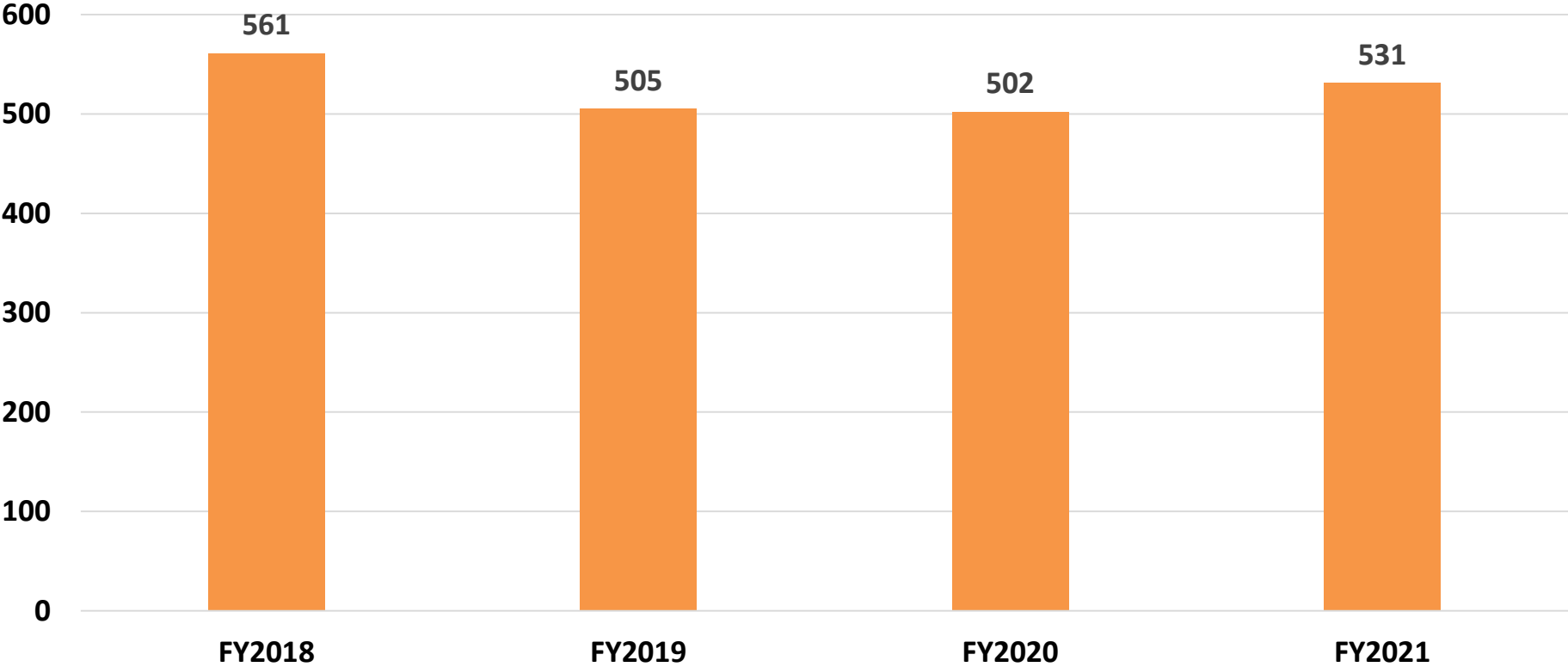


Fiscal year (FY) begins on 1<sup>st</sup> October of previous calendar year and ends 30<sup>th</sup> September of that calendar year.

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



# Number of FDA Registered Pharmaceutical Firms in India



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

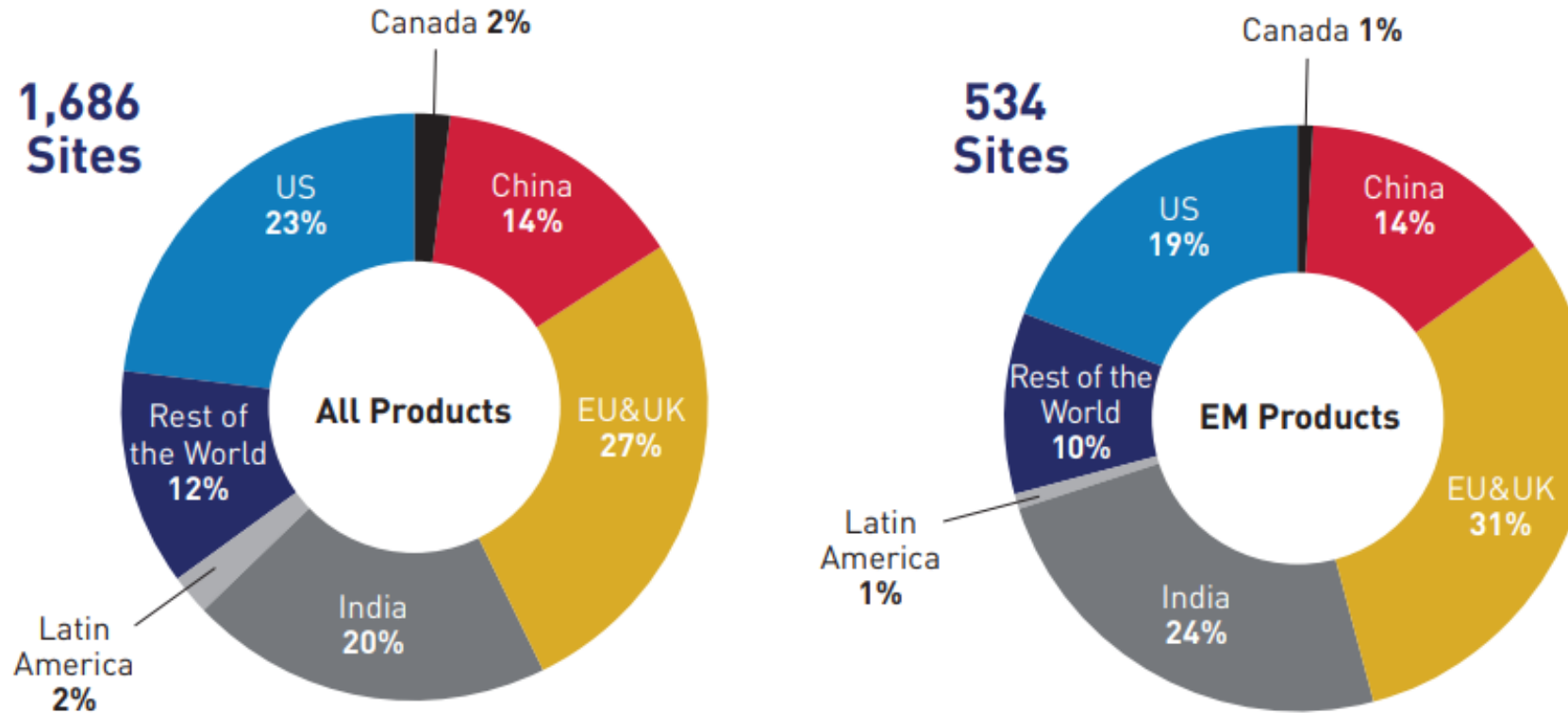
Reference: <https://www.fda.gov/media/161172/download>



# FY 21 API Manufacturing Site Demographics



## API MANUFACTURE



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



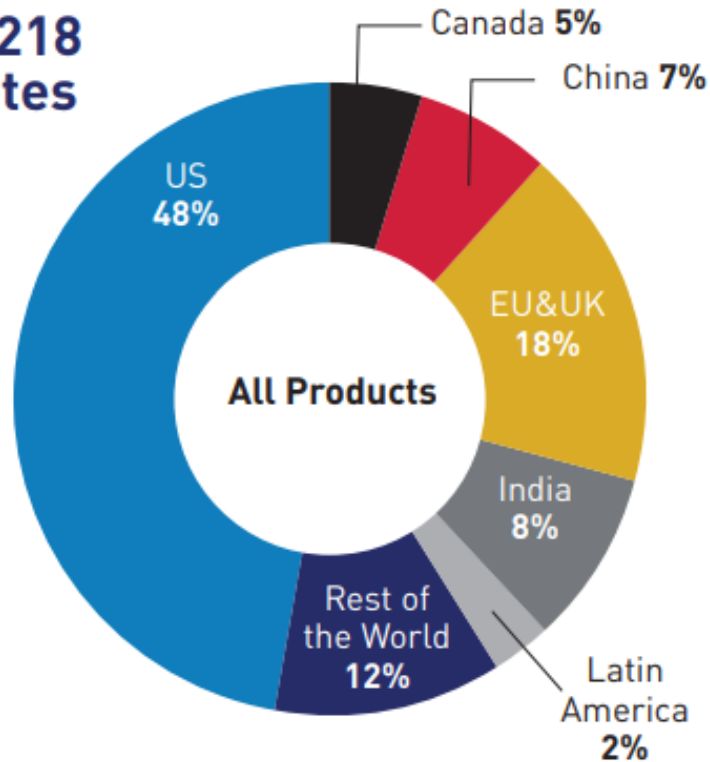


# FY 21 FDF Manufacturing Site Demographics

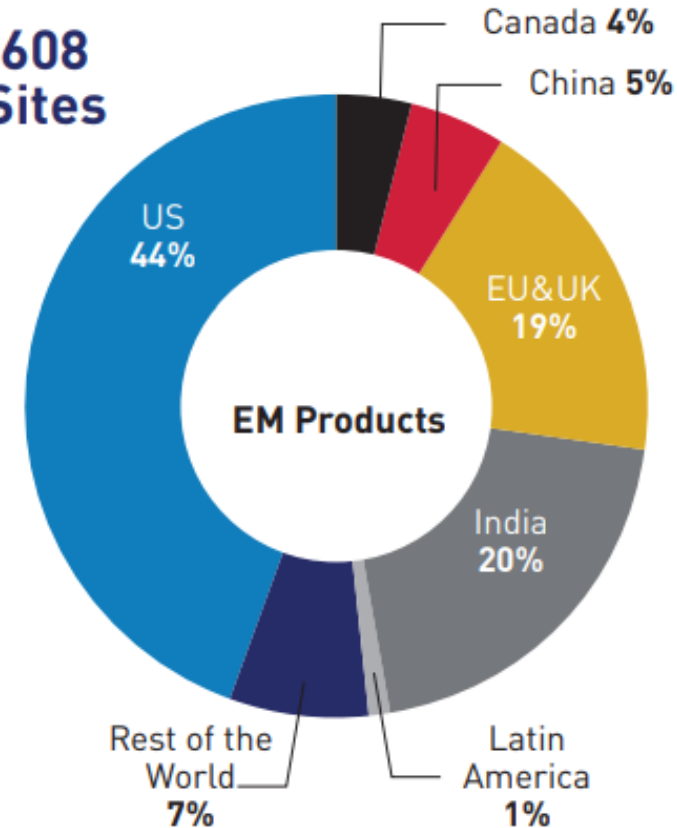


## FDF MANUFACTURE

**2,218  
Sites**



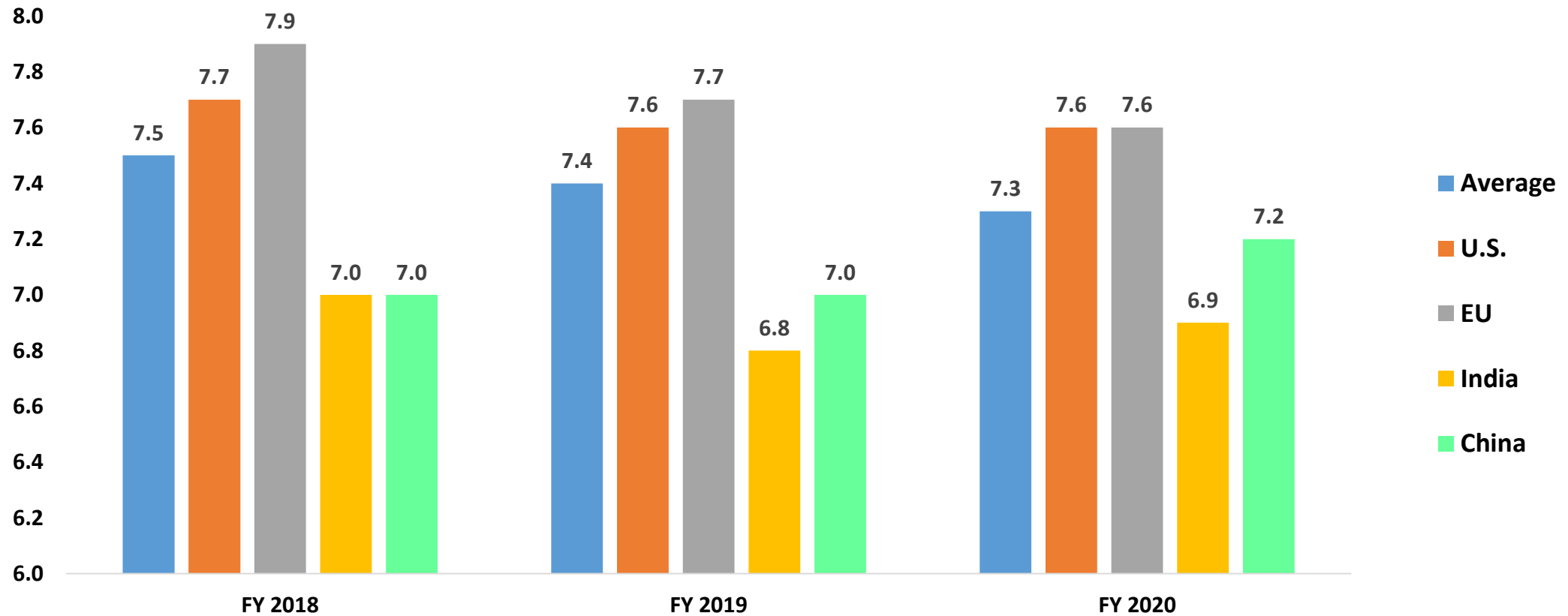
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Reference: <https://www.fda.gov/media/161172/download>

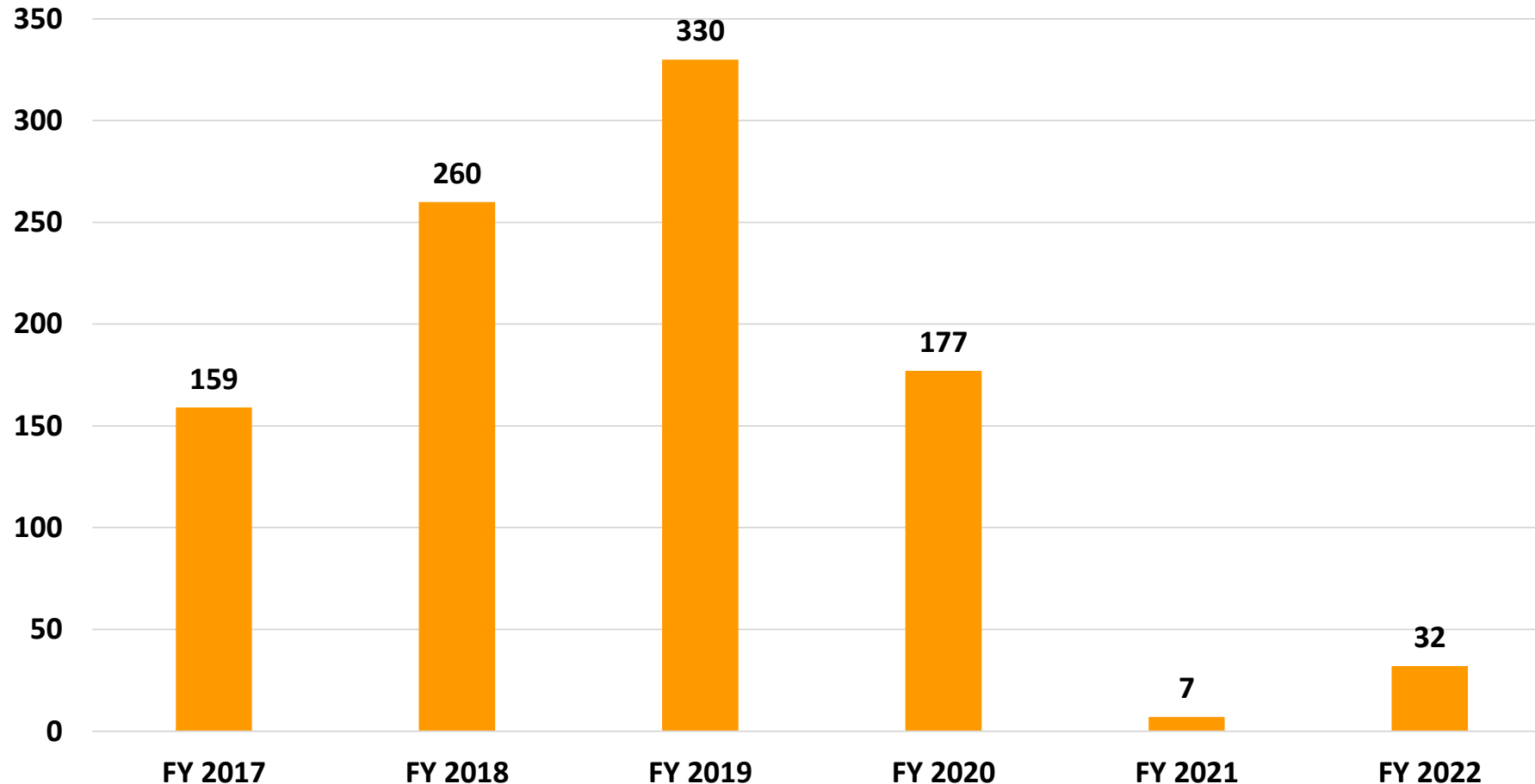


# Site Inspection Score for FY 2018-2020



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

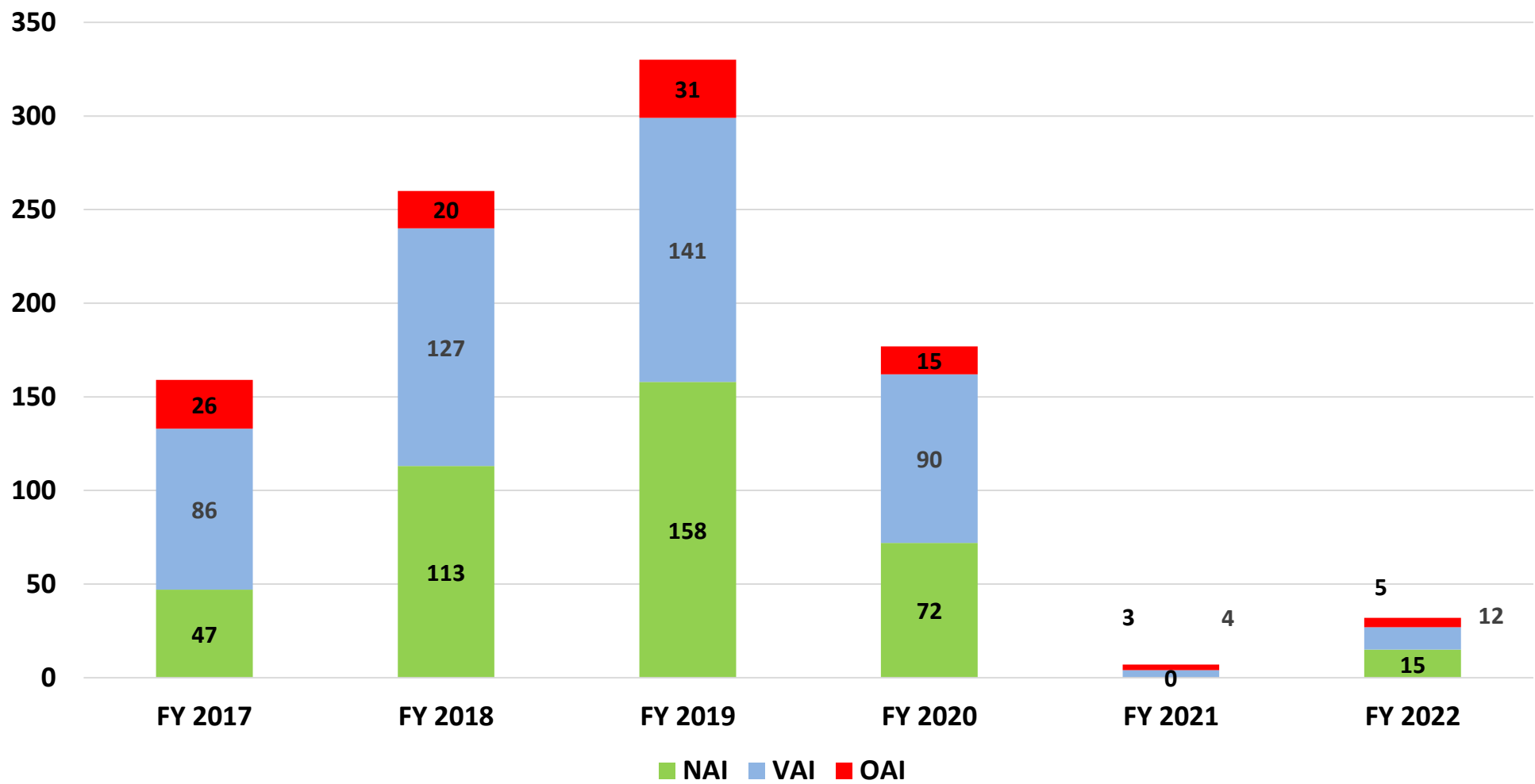
# Number of Pharmaceutical Inspections in India



Reference: <https://datadashboard.fda.gov/ora/cd/inspections.htm>

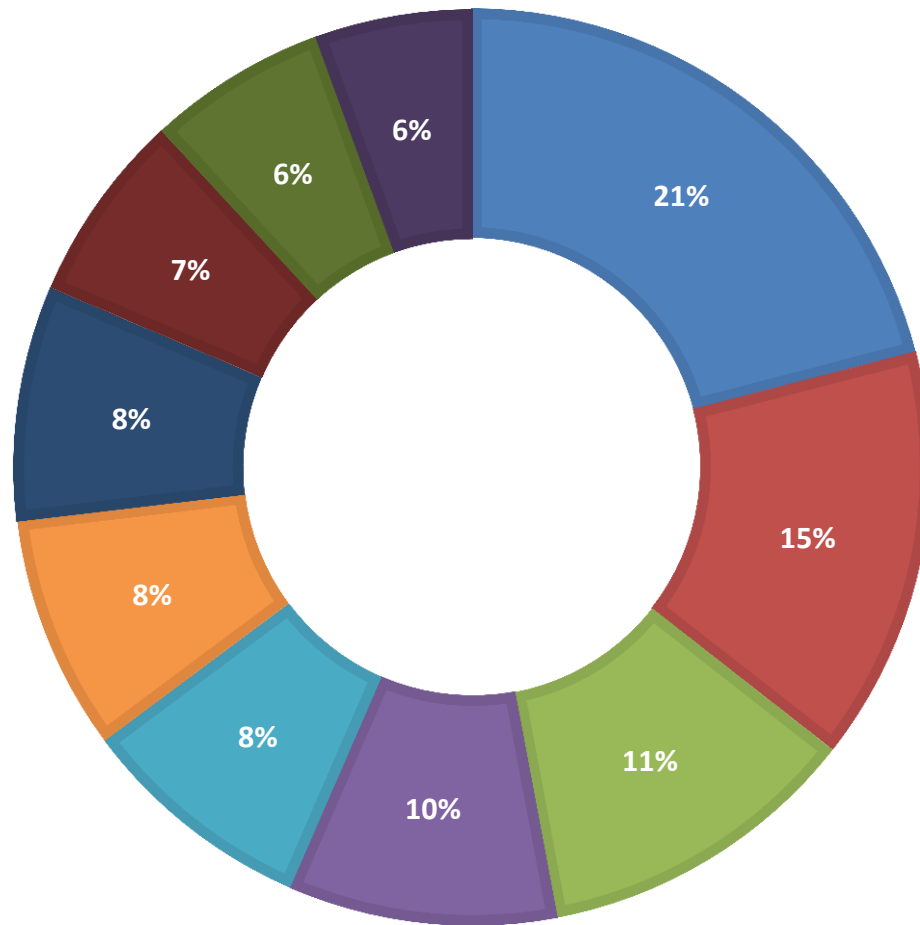


# Classification of Pharmaceutical Inspections in India



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

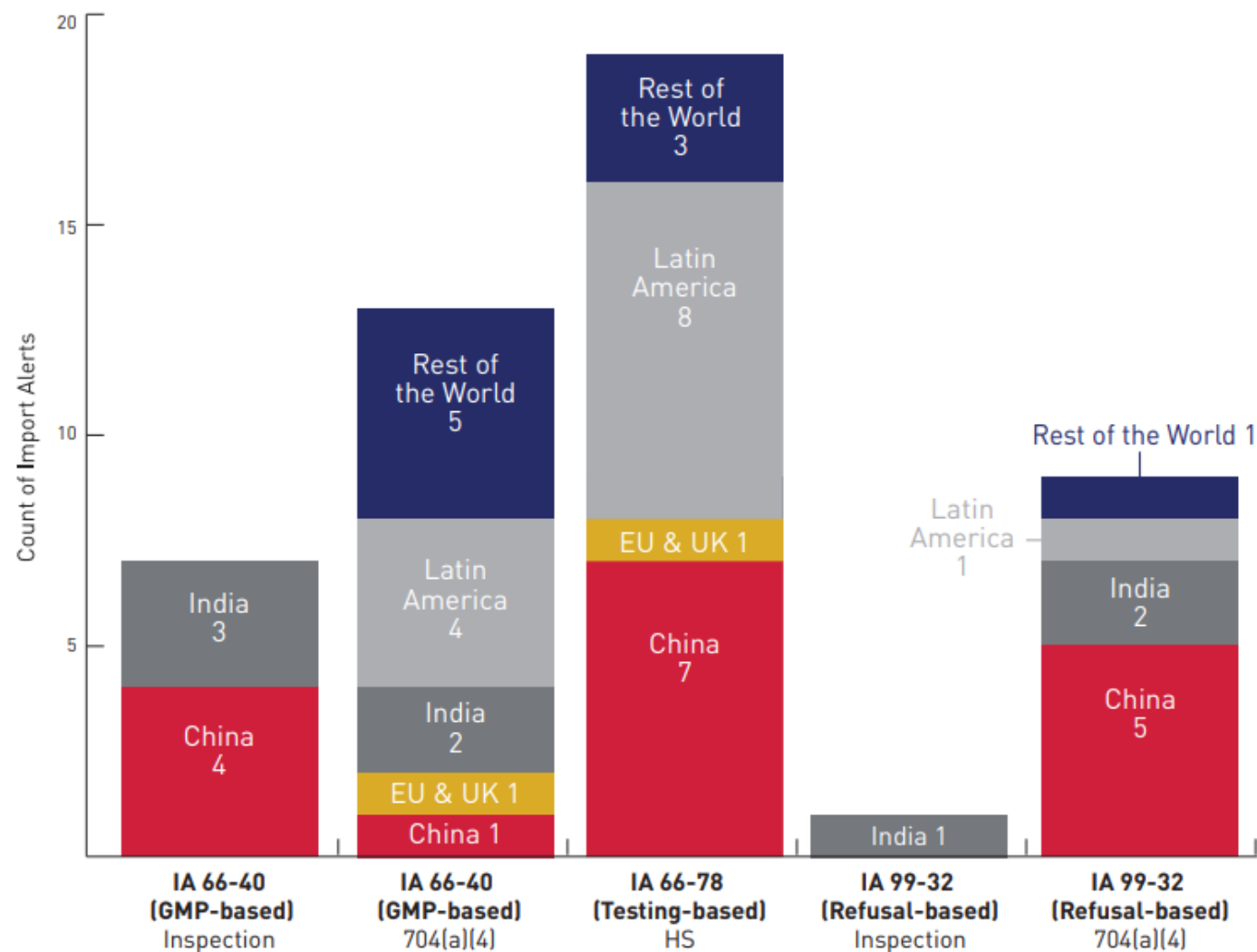
# Inspectional Findings in India for FY 2017-2022



- 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/inspections.htm>

# FY 21 Import Alerts



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

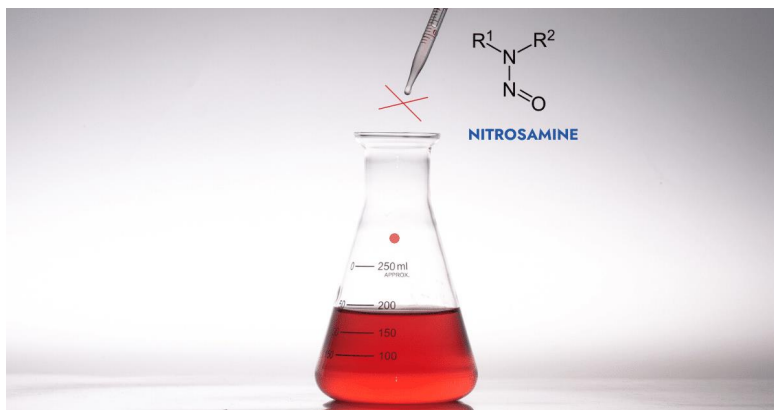
# INO Focus Areas



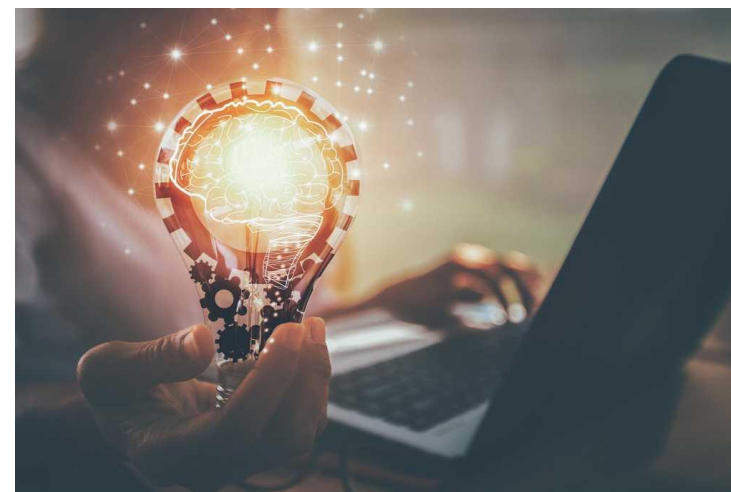
**Advanced Manufacturing Technologies**



**Biopharmaceuticals**



**Nitrosamine Impurity**



**Innovations**



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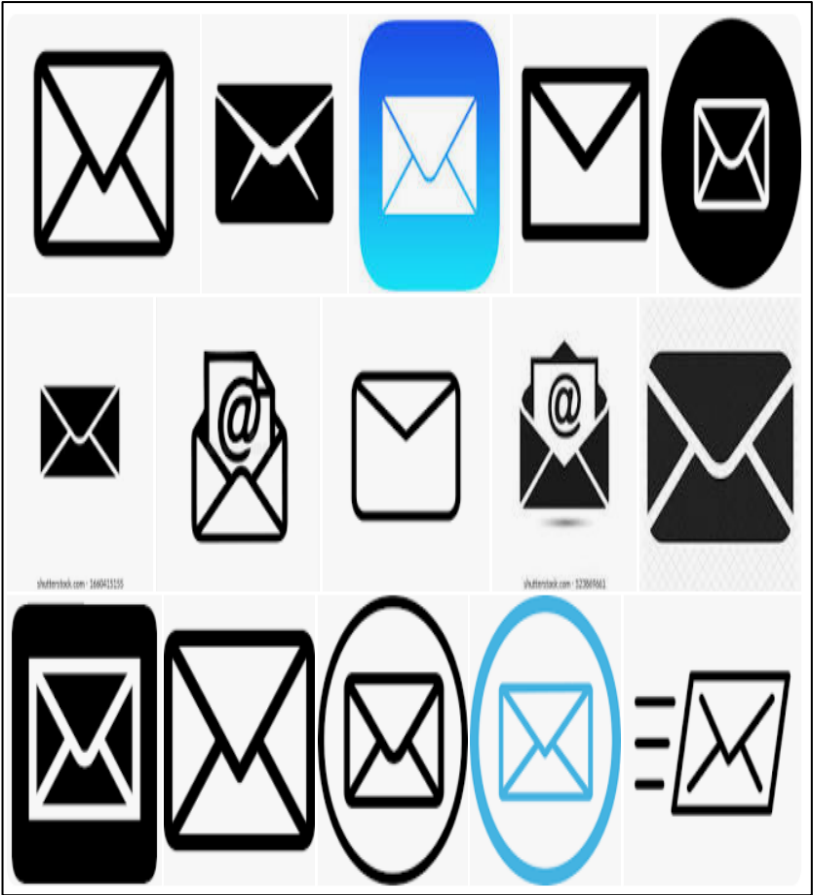
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