Globalization and FDA Compliance Trends

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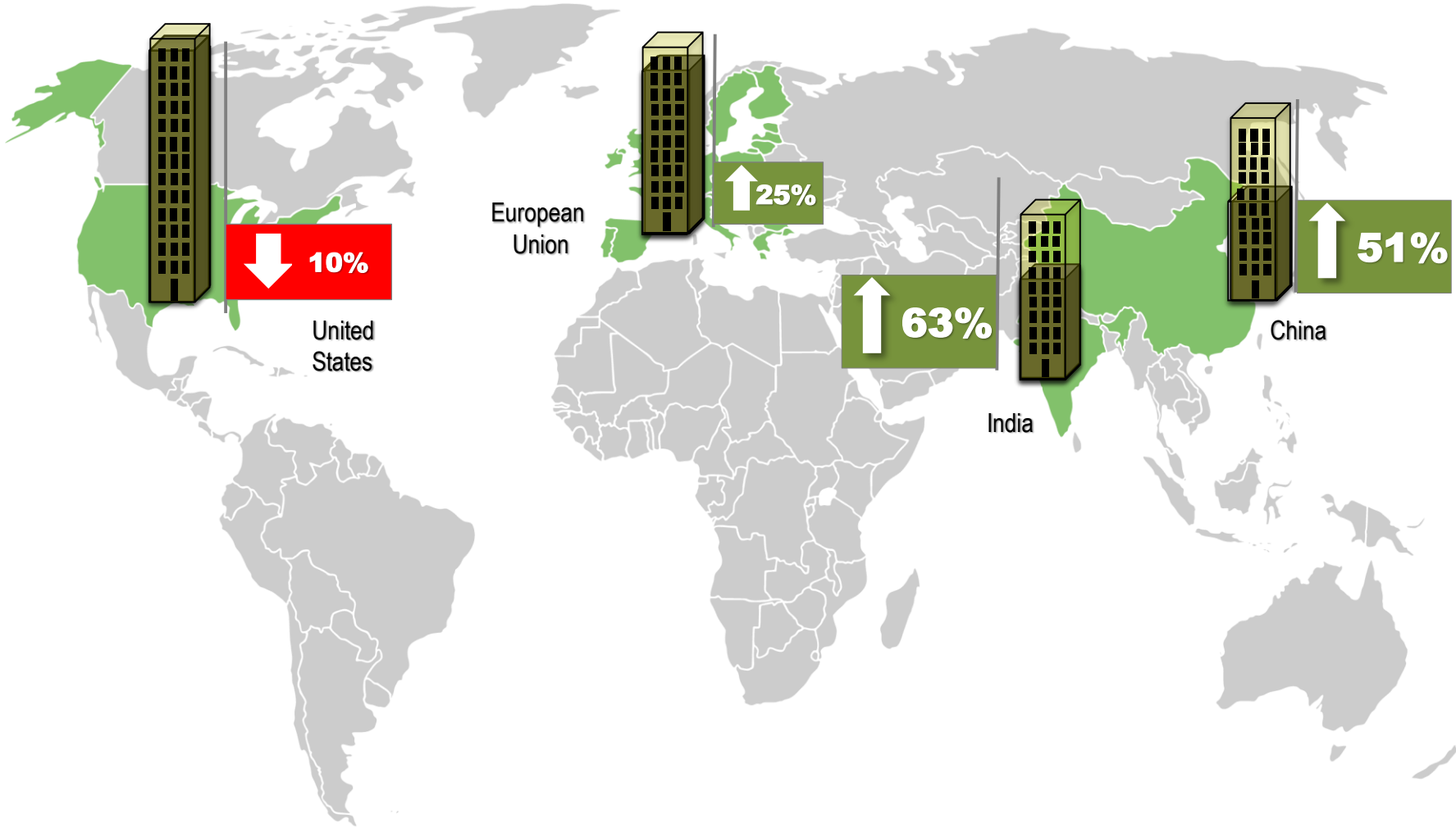
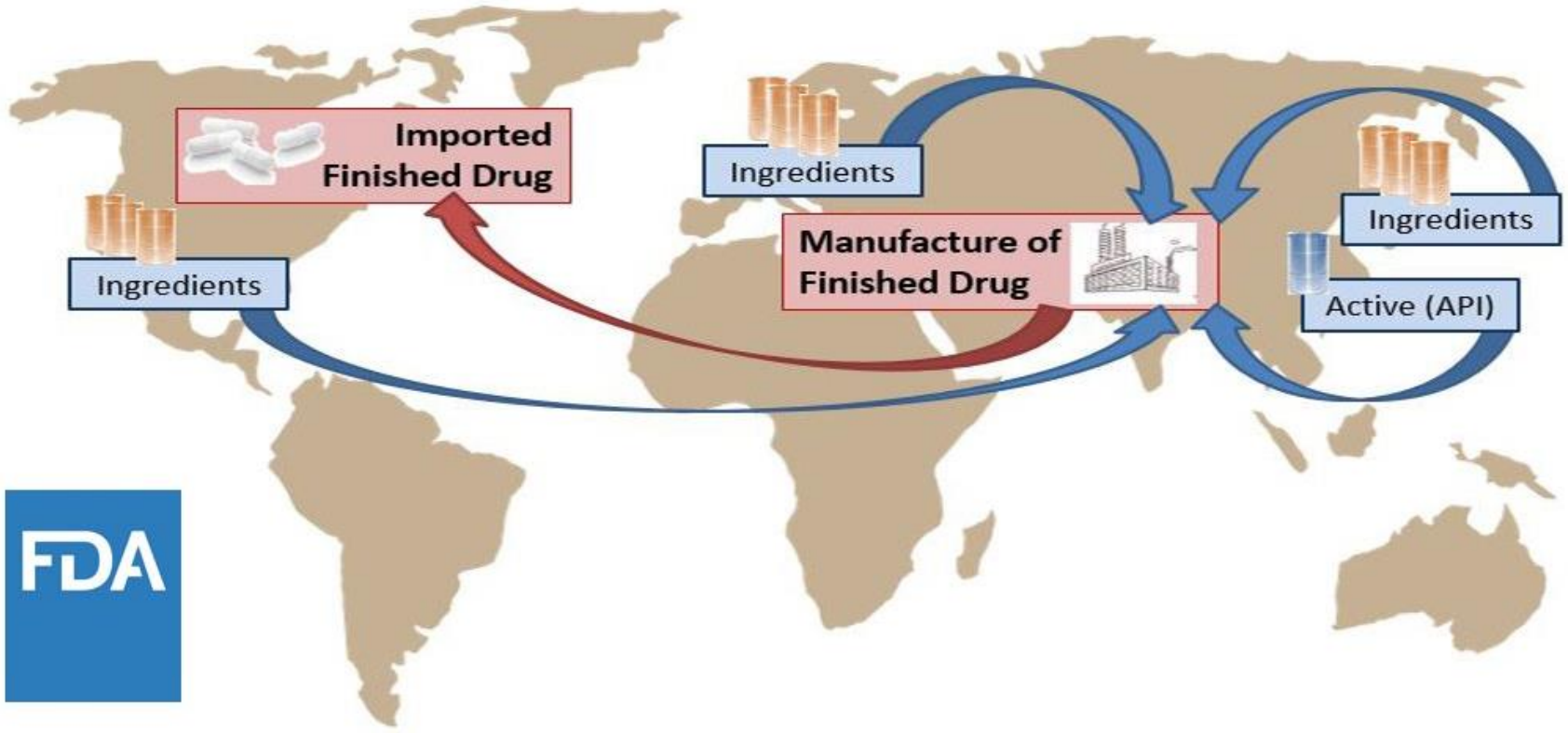
FDA Registered Drug Facilities 2011-2018



Global Drug Manufacturing Supply Chain



Source: Tweet by FDA Commissioner Scott Gottlieb (@SGottliebFDA) dated Jan 29, 2019

Risk-Based Site Selection Model

FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's global efforts to help assure product quality and transparency at foreign drug manufacturing facilities

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For Immediate Release September 5, 2018

Statement

Over the past 25 years, globalization of drug manufacturing has prompted the FDA to change its regulatory landscape. The shift to overseas production of U.S. goods, including some drugs and their components, predominantly occurred in the early 2000s. It added new complexities to our supply chain. This required the FDA to take different steps to ensure that our drug manufacturing surveillance program kept pace with the evolving landscape and make sure consumers continued to receive safe and effective drug products.

We've established a framework to help assure that drug products all meet the same high-quality standards, regardless of where they're manufactured; and whether they're brand name or generic products, or prescription or over-the-counter drugs. Today, we're announcing several steps that improve on that effort.

Helping assure the quality and safety of globally produced products requires a variety of efforts at different times throughout the lifecycle of a drug's manufacturing and finishing. Our inspections and surveillance of manufacturing facilities are an integral part of this oversight. We need to make sure that our inspections are prioritized based on potential risks to patients, and that we're using our resources efficiently.

Source : https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm619435.htm
https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM619302.pdf

Inspectional Data 2013-2017

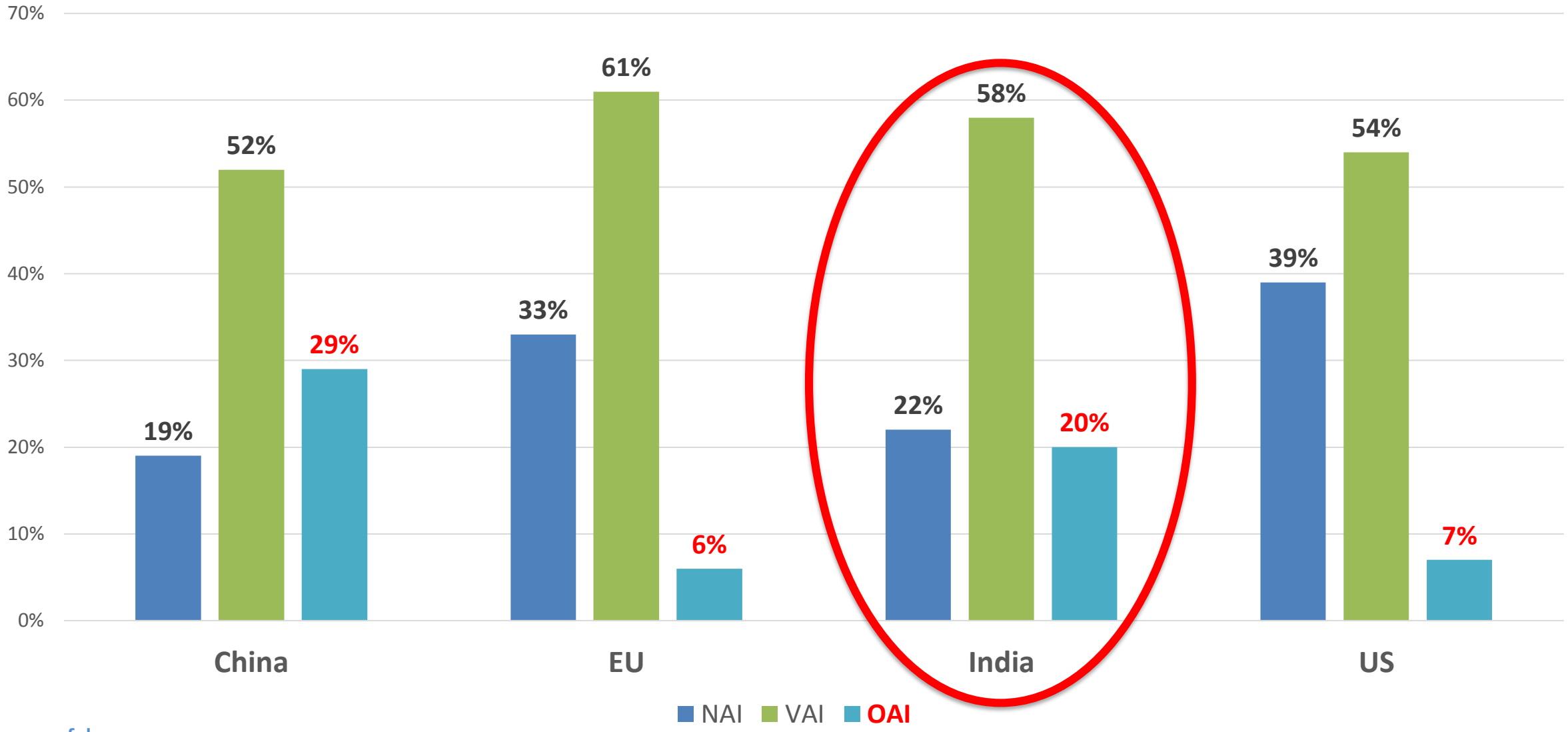
Location/Firm Type	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Domestic Inspections*					
Generics Only†	198	213	187	201	268
Generic & Non-Generic	156	137	139	136	120
Total	**354**	**350**	**326**	**337**	**388**
Foreign Inspections*					
Generics Only†	291	379	440	377	446
Generic & Non-Generic	76	114	113	104	101
Total	**367**	**493**	**553**	**481**	**547**
Total Domestic and Foreign					
Generics Only†	489	592	627	578	714
Generic & Non-Generic	232	251	252	240	221
Total	**721**	**843**	**879**	**818**	**935**

*An inspection was characterized as "Generic" and GMP if the firm inspected registered with the CDER User Fee Facility Data Management (UFFDM) Self-Identification system in the appropriate fiscal year and the appropriate Program Assignment Code (PAC) (e.g., 56002) was reported in the Field Accomplishments and Compliance Tracking System (FACTS).

†A firm was characterized as "Generics Only" if it was not identified in the CDER Self-Identification system as "Manufactures Non-Generics."

Source: Tweet by FDA Commissioner Scott Gottlieb (@SGottliebFDA) dated Jan 29, 2019

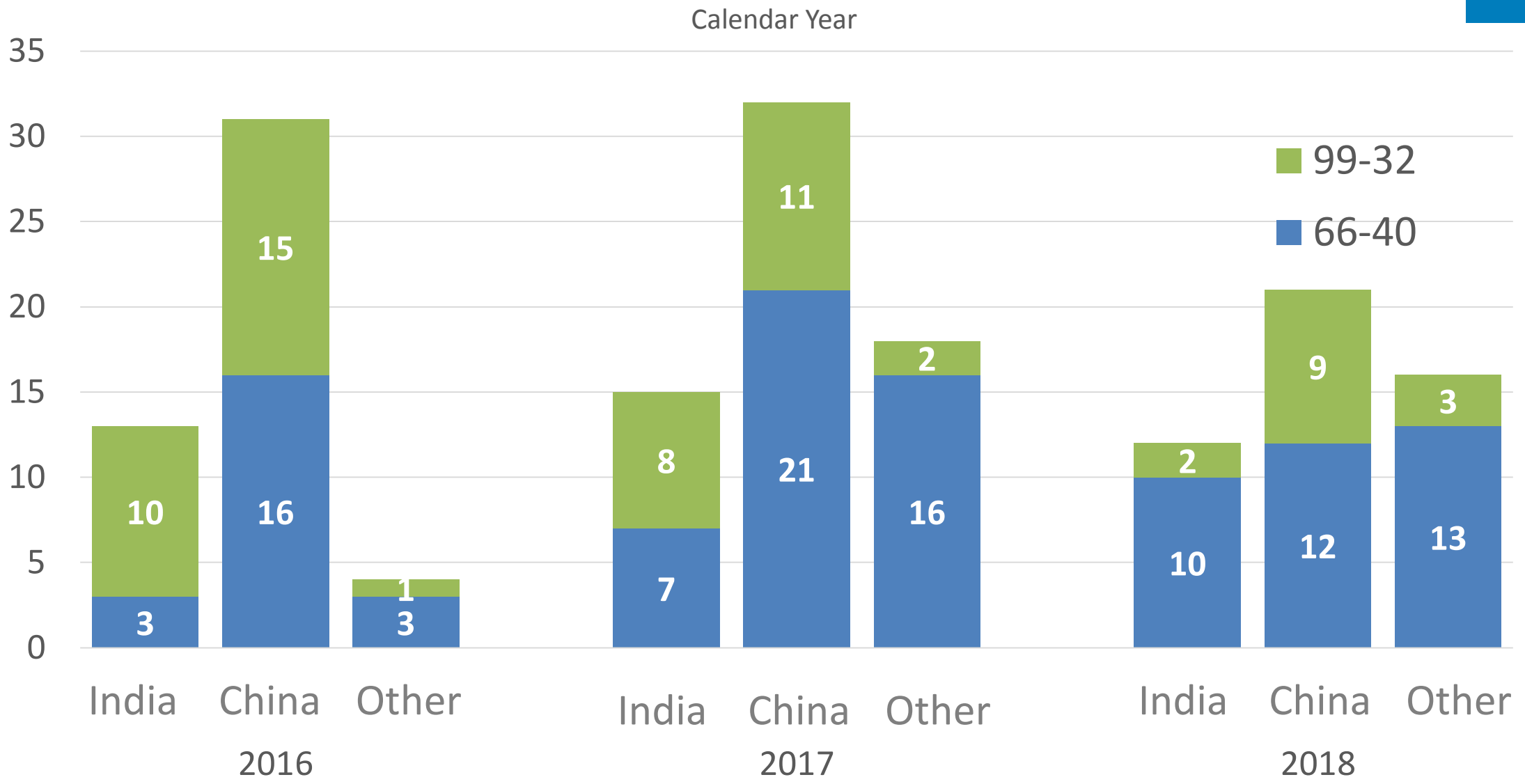
FY2017 Inspectional Outcomes



CGMP Warning Letters

Excludes warning letters related to compounding.
*As of September 30, 2018.

Import Alerts



Recent Initiatives

- Recognition of Voluntary Consensus Standards - 2019
  - https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM631269.pdf
- Enhancing the Utility of the Orange Book – 2019
  - https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM630099.pdf
- Ensuring data integrity and compliance with CGMP – 2018
  - https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM495891.pdf

Questions may be sent to

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