U.S. FOOD & DRUG ADMINISTRATION

3rd Advanced GMP Workshop

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Goa, India

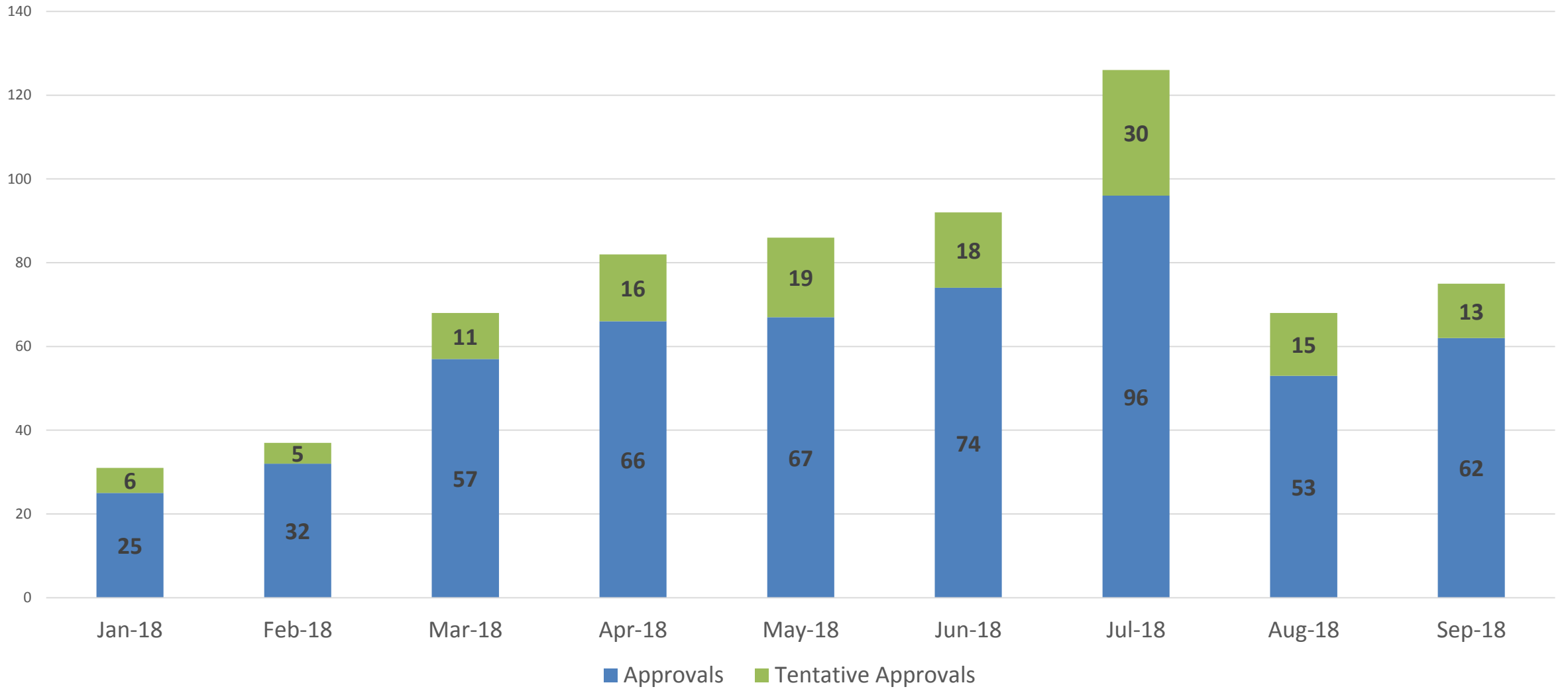
Globalization…By the Numbers

- Production of FDA-regulated goods and materials outside of the U.S. has exploded over the last decade.
- FDA-regulated products originate from more than:
  - 150 countries
  - 130,000 importers
  - 300,000 facilities outside of the U.S.
- Number of FDA-regulated shipments at 300 U.S. ports has more than quadrupled over the last 10 years.
  - 6 million shipments of imported food and medical products crossed our borders in 2004 compared to 32 million in 2015

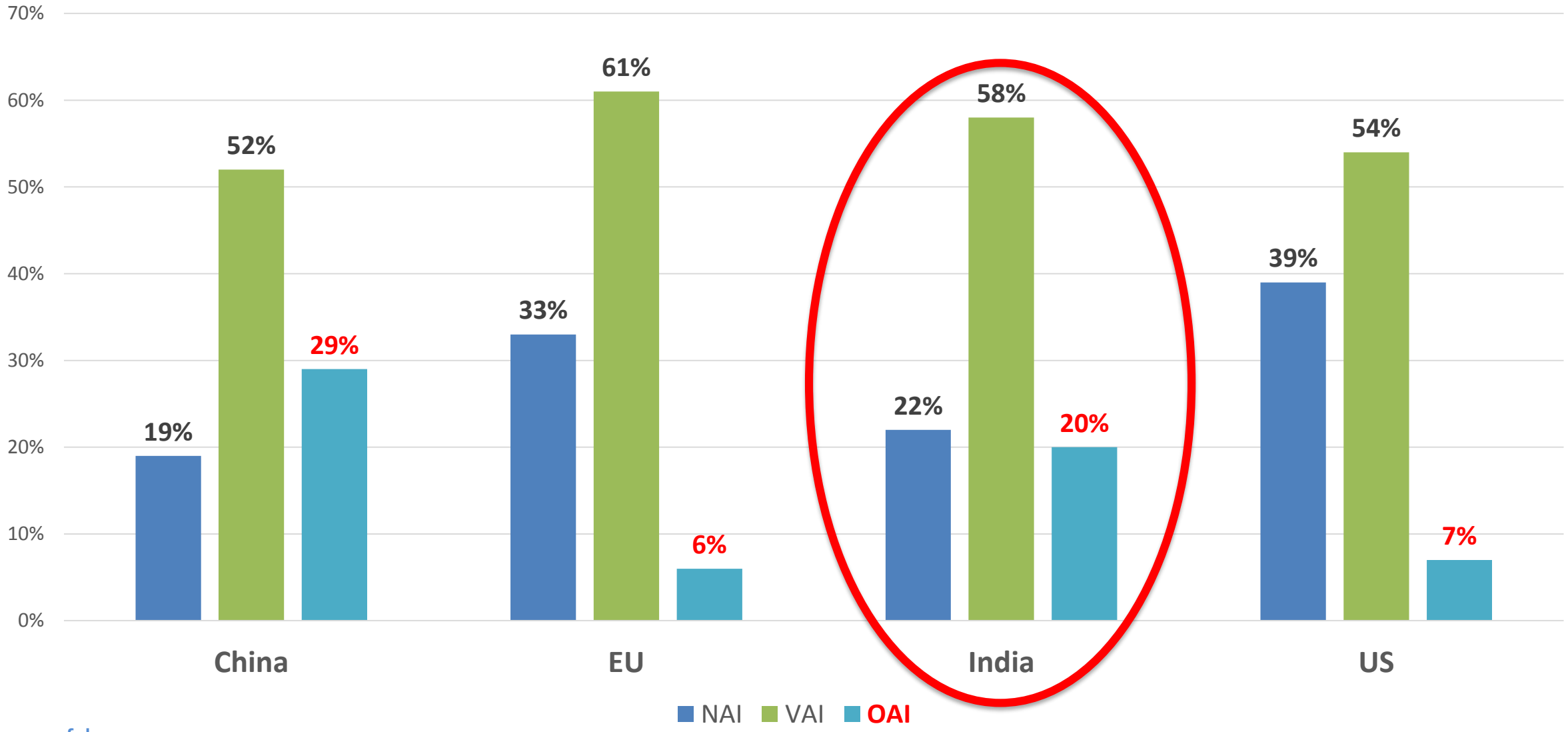
FDA's International Activities

- Advancing diplomacy
  - Facilitating collaborations with regulators from other countries, multi-lateral organizations, etc.
- Collecting and sharing intelligence and information
  - Increased knowledge of global landscape, data on FDA-regulated products
  - Conducting inspections in countries with facilities that export to the U.S. market
  - Strengthening global regulatory systems
- Utilizing global data networks and analytics
  - Potential threats identified through real-time information sharing

Generic Drug Approvals



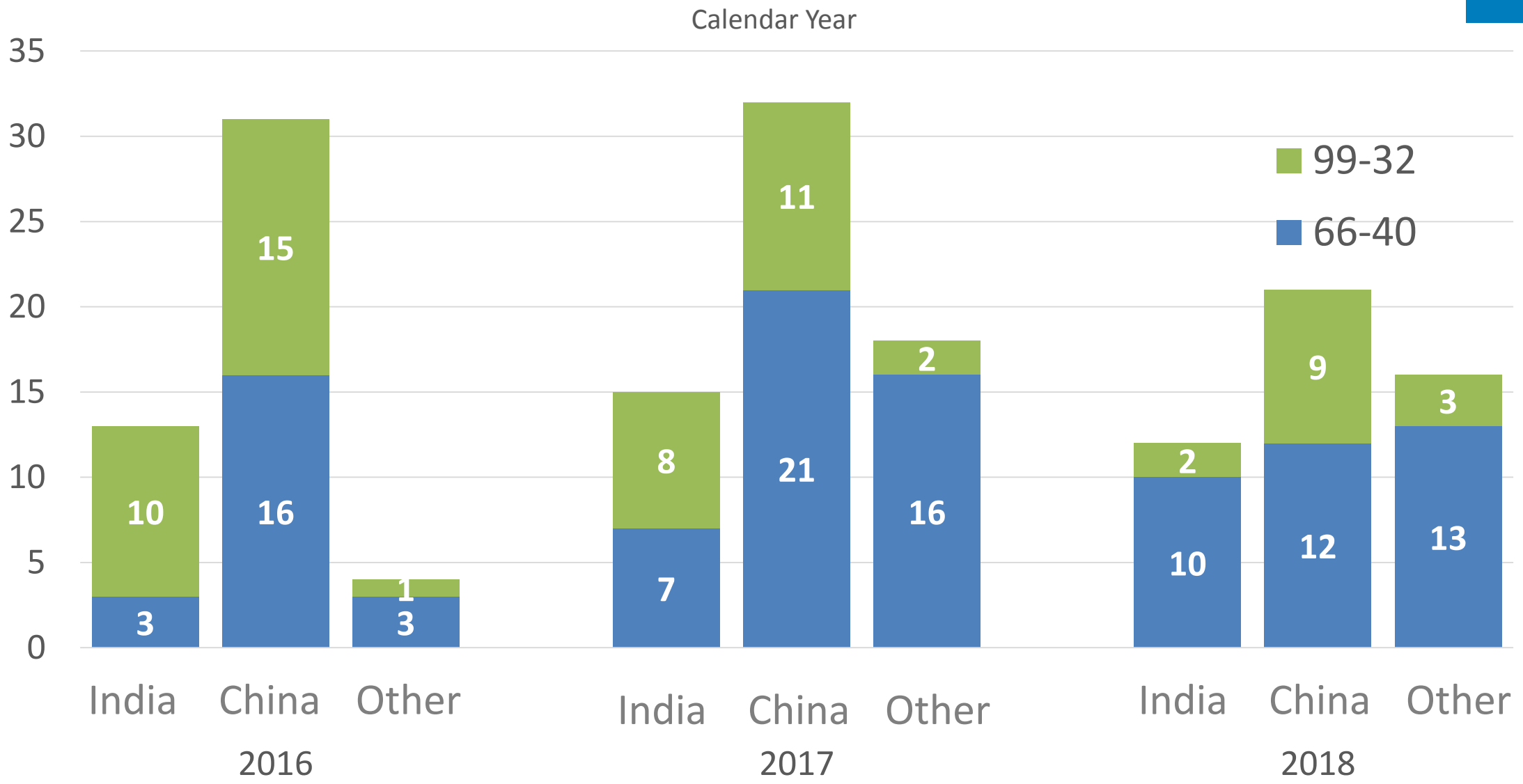
FY2017 Inspectional Outcomes



CGMP Warning Letters

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

Import Alerts



Recent Non-Compliance Trends
(and related lapses of management oversight)

Recommended Reading

- Contract Manufacturing Arrangements for Drugs: Quality Agreements – 2016
  - https://www.fda.gov/downloads/drugs/guidances/ucm353925.pdf
- Data Integrity and Compliance with CGMP (Draft) - 2016
  - https://www.fda.gov/downloads/drugs/guidances/ucm495891.pdf
- Quality systems approach to Pharmaceutical CGMP Regulations - 2006
  - https://www.fda.gov/downloads/Drugs/Guidances/UCM070337.pdf
- Investigating Out-of-Specification Results for Pharmaceutical Production - 2006
  - https://www.fda.gov/downloads/drugs/guidances/ucm070287.pdf
- Guidance on Sterile Drug Products Produced by Aseptic Processing – 2004
  - https://www.fda.gov/downloads/Drugs/Guidances/ucm070342.pdf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