3rd Advanced GMP Workshop

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November 12, 2018
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

- **Approvals**
  - Jan-18: 6
  - Feb-18: 5
  - Mar-18: 57
  - Apr-18: 66
  - May-18: 67
  - Jun-18: 74
  - Jul-18: 96
  - Aug-18: 53
  - Sep-18: 62

- **Tentative Approvals**
  - Jan-18: 25
  - Feb-18: 32
  - Mar-18: 11
  - Apr-18: 16
  - May-18: 19
  - Jun-18: 18
  - Jul-18: 30
  - Aug-18: 15
  - Sep-18: 13
FY2017 Inspectional Outcomes

China: 19% NAI, 52% VAI, 29% OAI
EU: 6% NAI, 33% VAI, 61% OAI
India: 22% NAI, 20% VAI, 58% OAI
US: 39% NAI, 54% VAI, 7% OAI
CGMP Warning Letters

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

Calendar Year

- **India**
  - 2016: 10
  - 2017: 8
  - 2018: 2

- **China**
  - 2016: 15
  - 2017: 21
  - 2018: 9

- **Other**
  - 2016: 3
  - 2017: 7
  - 2018: 10

**99-32**

- 2016: 3
- 2017: 11
- 2018: 2

**66-40**

- 2016: 16
- 2017: 16
- 2018: 13

www.fda.gov
Recent Non-Compliance Trends (and related lapses of management oversight)
Recommended Reading

• Contract Manufacturing Arrangements for Drugs: Quality Agreements – 2016

• Data Integrity and Compliance with CGMP (Draft) - 2016

• Quality systems approach to Pharmaceutical CGMP Regulations - 2006

• Investigating Out-of-Specification Results for Pharmaceutical Production - 2006

• Guidance on Sterile Drug Products Produced by Aseptic Processing – 2004