

State of Pharmaceutical Quality for Generics

Fiscal Year 2019

Raphael Brykman

Senior Scientific Advisor

Office of Quality Surveillance, Office of Pharmaceutical Quality
CDER | US FDA

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Learning Objectives

- Awareness of OPQ's Report on the State of Pharmaceutical Quality
- General understanding of regulated (and Generic) industry demographics
- Nitrosamine impact on Generics

Data Caveats

- All data is taken at close of Fiscal Year 2019
 - FY 2019 -> Oct 1, 2018 – Sept 30, 2019
- Site and Product Catalogs are updated monthly
 - “Sites” refer to manufacturers¹ of human medicines
 - Medical Gas and Pharmacy Compounding sites not included in these analyses
- “ANDA sites” means the site is listed in at least one ANDA, regardless of whether or not the site is actively marketing/manufacturing

¹Manufacturer is defined as anyone engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug

Poll Question

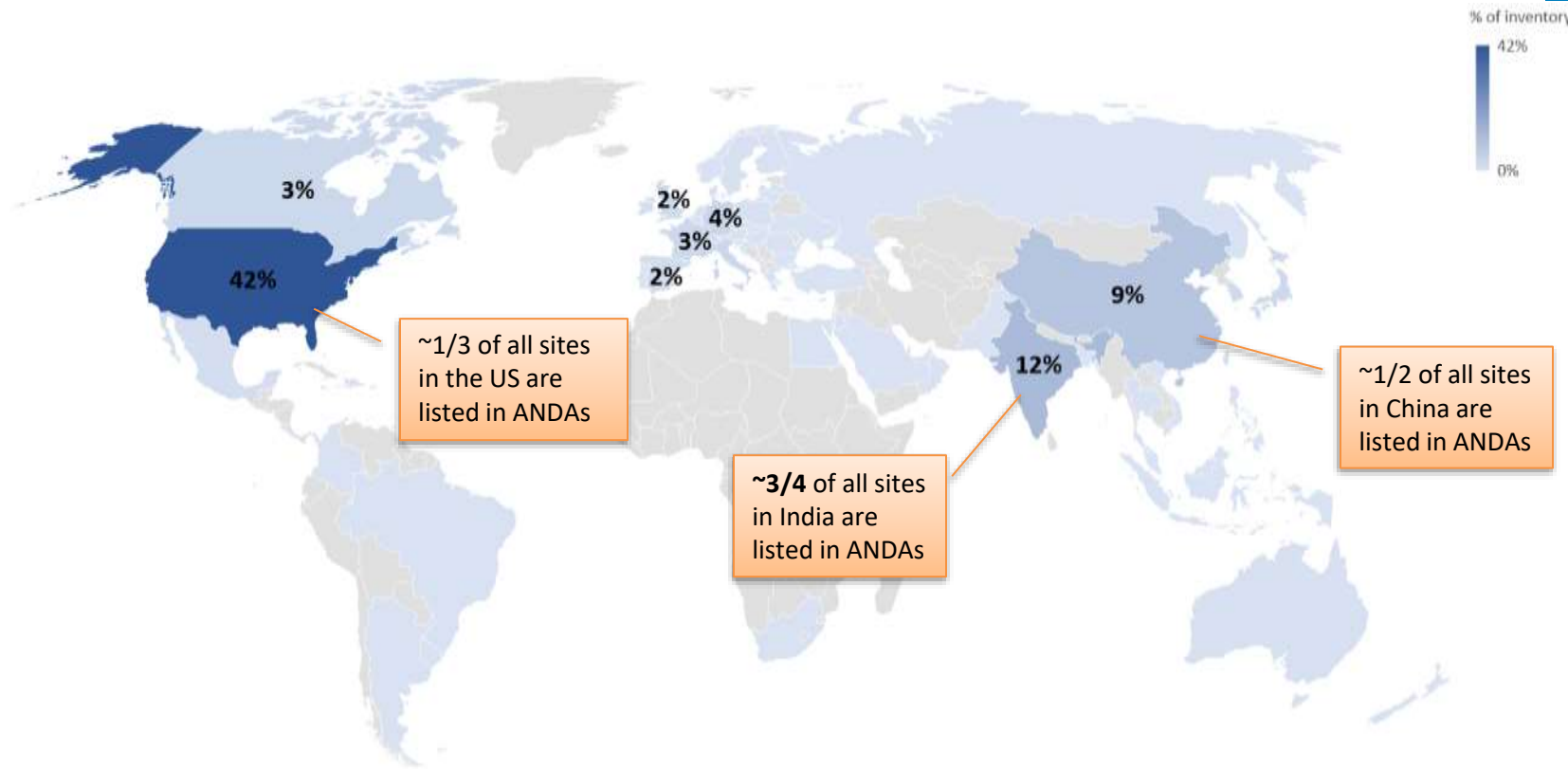
Level of familiarity with OPQ's Report on the State of Pharmaceutical Quality (RSPQ)

- A. Very familiar (I've read the report)
- B. Somewhat familiar (read a news article about it)
- C. Not at all (never heard of it)

OPQ's Report on the State of Pharmaceutical Quality



FY 2019 Site Catalog - Site Distribution

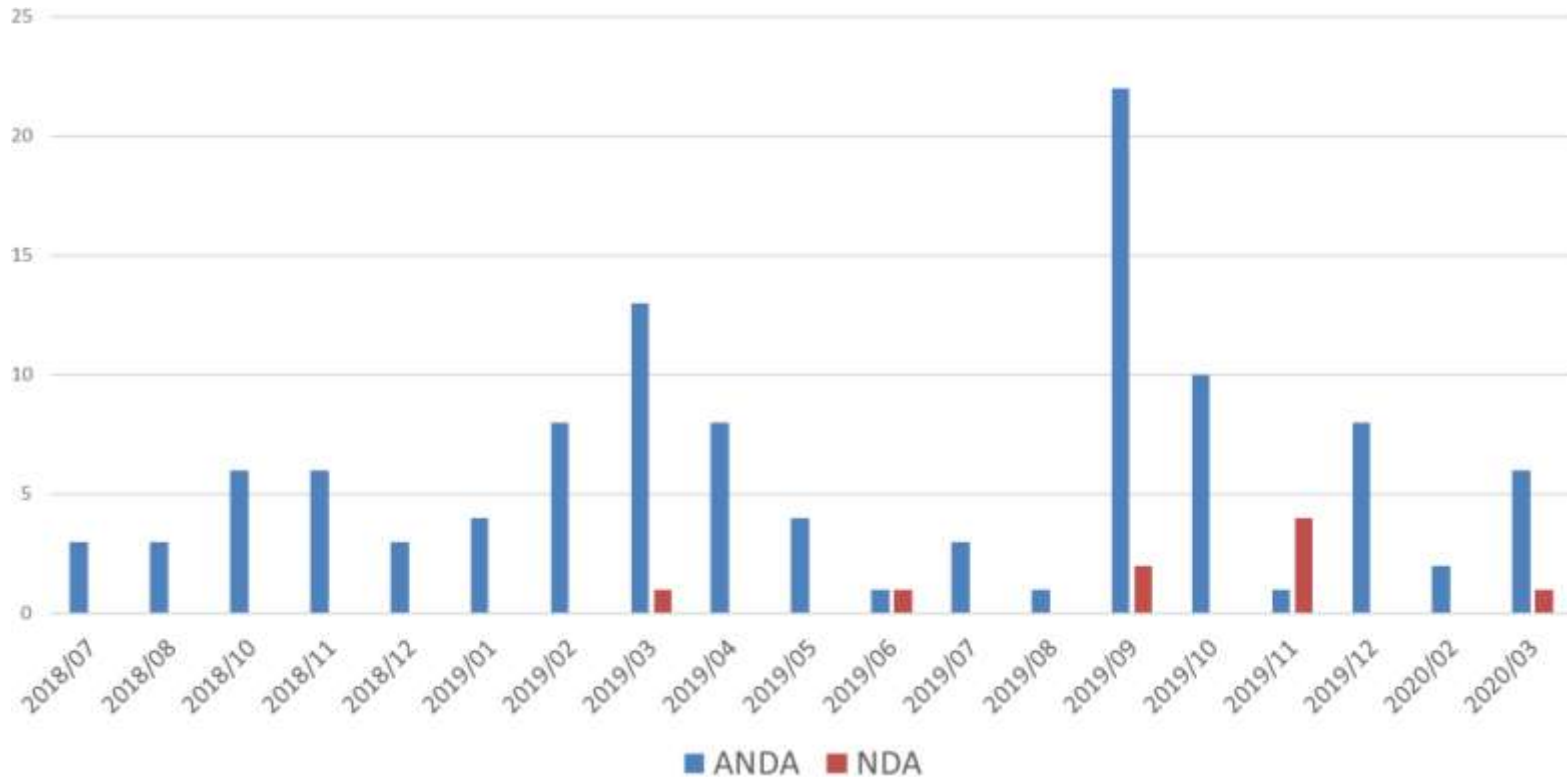


Industry Snapshot



- Overall FY2019 OAI outcomes from inspections are *statistically*¹ higher in India than US or China.
- Increase in proportion of ANDA sites within India from FY2017-FY2019
- Generic industry significantly impacted by nitrosamine contamination incident
 - ~20 nitrosamine-related FDA inspections in FY2019
 - 16 in India, 10 of which were OAI

Field Alert Reports – keyword “nitrosamine”



Nitrosamines

- Contamination detected almost 2 years ago
- Dozens of recalls for Cardiovascular drugs, leading to a temporary shortage of Valsartan
- Contamination found in other products, including Ranitidine
- Evolving issue with solvents
 - Detectable levels of nitrosamine found in recovered solvents used in the pharmaceutical industry

Looking forward

- Through investigations come better risk assessments
 - Heightened awareness of contamination pathways within a process
- More refined test methods for detecting impurities
 - Issues with recovered solvents
- **Control of Nitrosamine Impurities in Human Drugs - Guidance For Industry**

Resources



- [OPQ's Report on the State of Pharmaceutical Quality](#)
- [Field Alert Report Submission - Draft Guidance](#)
- [MedWatch Forms for FDA Safety Reporting](#)
- Nitrosamine guidance – *coming soon!*



Challenge Question #1

Starting in June 2018, in which drug class were nitrosamines first detected:

- A. Immunological Agents
- B. Cardiovascular Agents
- C. Opioids
- D. Medical Gas



Challenge Question #2

Which of the following countries has the highest percentage of ANDA sites?

- A. US
- B. India
- C. Europe
- D. China

Thank you

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