U.S. FOOD & DRUG ADMINISTRATION

Pharmaceutical Quality: A Global Priority

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Pharmaceutical Quality for Global Stakeholders
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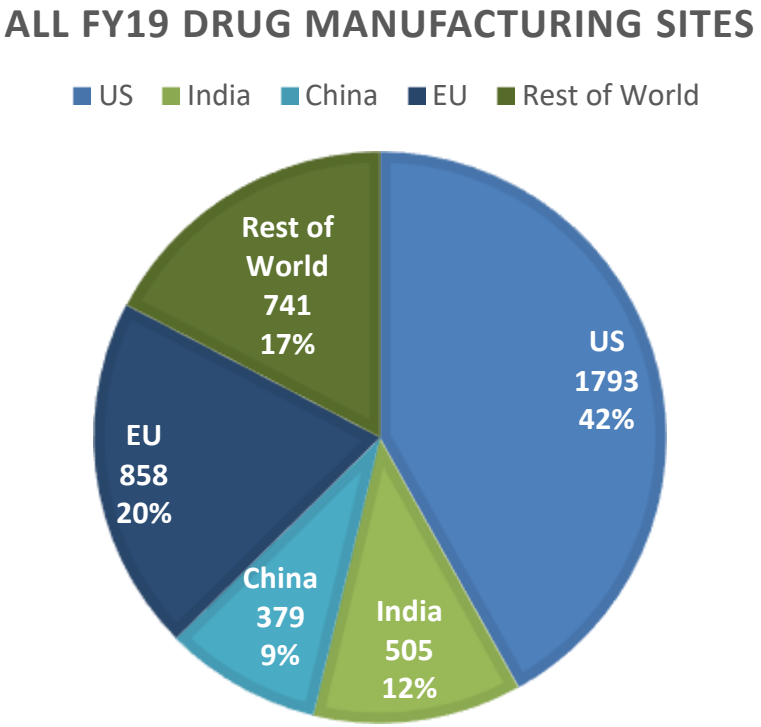
Global Manufacturing

- **Most** drug manufacturing sites for the U.S. market are abroad
- **Nearly a third** of all API manufacturing sites are in India and China



Pharmaceutical quality is

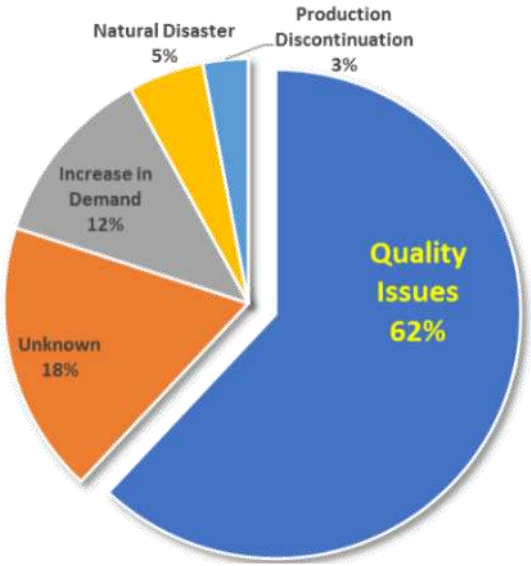
assuring *every* dose is safe and effective, free of contamination and defects.

The Importance of Pharmaceutical Quality

- Pharmaceutical quality is what assures drugs **on the market** are safe and effective
- A **global commitment** to quality benefits everyone and expands patient access without sacrificing quality
- When quality goes wrong, **everything** can go wrong

Consequences of Quality Issues

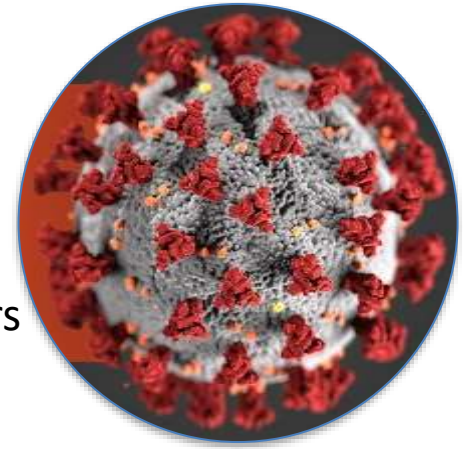
- **Drug shortages**
  - Anagrelide HCl Capsules (CGMP)
  - Erwinaze (foreign particles)
- **Recalls**
  - Impurities such as nitrosamines
- **Erosion in confidence**
  - Patient and health care provider



All Drugs Newly in Shortage

Global Quality Challenges from COVID-19

- **Business uncertainty**
  - Rapidly changing demand & supply
- **Complex global supply chains with many interdependencies**
  - Challenges with scale-up, distribution, etc.
  - Disruption in transport, decreased air cargo capacity
  - Absenteeism in plants due to contagion, stay at home orders or social distancing requirements
  - Insufficient international regulatory convergence when manufacturers need maximum agility to carry out post-approval changes
- **Regulating an industry without inspections**
  - All but mission-critical FDA inspections postponed



CDER's Tools for Regulating Quality

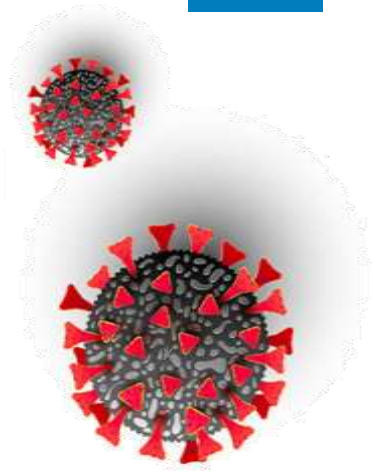
CDER's Drive to Global Quality

- Global quality is a **partnership** with many stakeholders, including regulators and industry
  - **ICH Q12** - harmonized management of post-approval changes across regulators
  - **ICH Q13** - harmonized scientific and regulatory framework to encourage adoption of advanced technologies such as continuous manufacturing

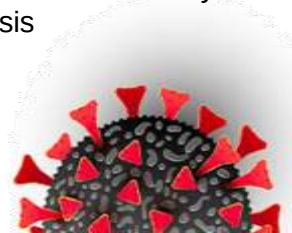
ICH
harmonisation for better health

Some Lessons Learned from COVID-19

- **Provide FDA clarity on manufacturing and supply chain changes**
  - Treatment for patients, prevent shortages, etc.
- **Ensure companies can quickly register facilities and list products**
  - +257 new registrants for prescription drug products
- **Utilize alternative tools to inspections as an interim measure while travel or access to facilities are constrained**
  - Conducting remote assessments of facilities
    - Request information in lieu of an inspection - FD&C 704(a)(4)
    - Mutual Recognition Agreement (MRA)
  - We will resume inspections as soon as feasible, on a region-by-region/country-by-country basis



*Pre-approval and for-cause inspections deemed mission-critical have been considered on a case-by-case basis



How to Continue Assuring Quality

- **Supply Chain Redundancy and Resiliency**
  - Ensure manufacturing disruptions will not lead to shortages
- **Quality management**
  - Systems needed to mature quality management in industry
- **Regulatory convergence**
  - International harmonization to simplify pharmaceutical product lifecycle management
- **Global Partnerships**
  - Manufacturers and their suppliers needs to work together
  - Health authorities need to work together
  - Industry and health authorities need to work together

No one can do this alone.

Let’s work together to heighten global pharmaceutical quality to improve the lives of patients.

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