U.S. FOOD & DRUG ADMINISTRATION

Pre-Approval Inspections During the COVID-19 Pandemic

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Office of Pharmaceutical Quality, CDER
US Food and Drug Administration

CDER Small Business & Industry Assistance
Pharmaceutical Quality for Global Stakeholders; July 23rd, 2020

Office of Pharmaceutical Quality

Across the lifecycle...

new drugs

biologics

generics

compounded drugs

over-the-counter drugs

biosimilars

Development → Premarket → Postmarket

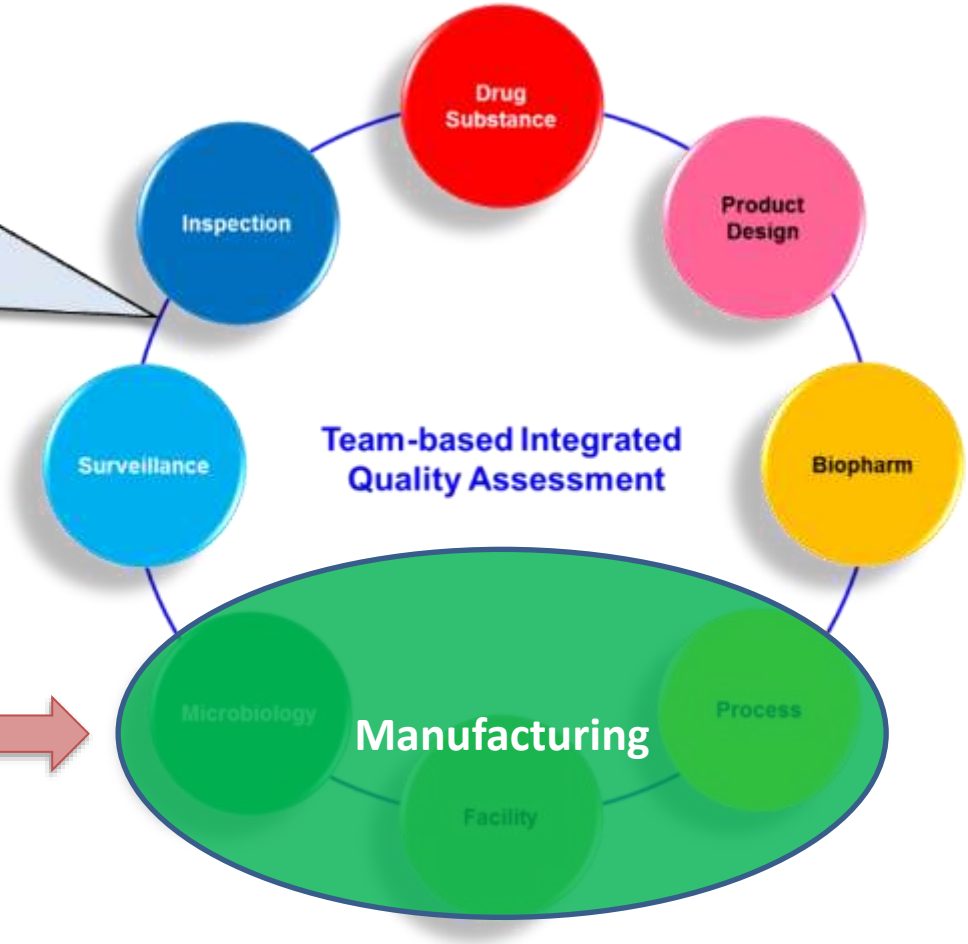
Office of Pharmaceutical Manufacturing Assessment - OPMA

Mission: Ensure that Quality is built into commercial manufacturing processes and facilities over the product lifecycle

Office of Pharmaceutical Quality (OPQ) State of Quality Report (Jun 2020):
https://www.fda.gov/media/125001/download

Team-based Integrated Quality Assessment (IQA)

Inclusive of drug substance, drug product, manufacturing, and facilities, and maximizes each team member's expertise

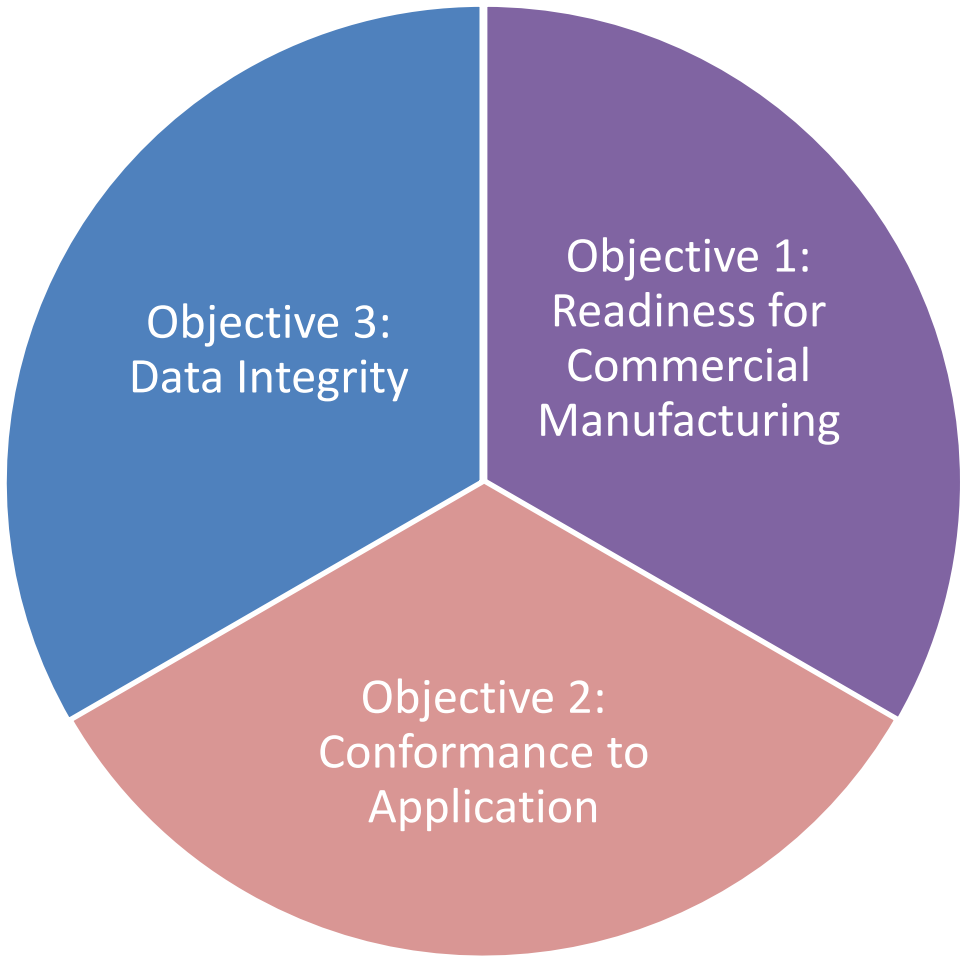


OPMA

Science- and Risk-Based approach that is patient-focused

Pre-Approval Inspection Goals

- Focus Areas
  - Readiness to Commercial Manufacturing
    - Incoming Materials
    - Process, CPPs
    - Equipment / facilities / Cleaning
    - Personnel Training & Competence
  - Conformance to Application
  - Data Integrity



Gathering Information to Support Facility Assessment

- Records Request under § 704(a)(4) of the FD&C Act
- Using information shared by other regulatory agencies (e.g. mutual recognition, confidentiality agreements)
- Additional information from applicants

704 (a) (4) Record Request

- FDA may request records from a facility upon completion of the application risk assessment
- For PAIs, applicability will depend upon the risk factors (process, facility, micro, etc.) driving need for inspection
- Records requested will be used to assess capability of the facility and its quality systems to perform the manufacturing operations
- If risks not mitigated, an on-site inspection may still be required

Information from Other Regulators

- Mutual Recognition Agreement (MRA) between FDA and EU:
  - Rely upon information from inspections conducted within each other's borders
  - Applicable to surveillance inspections

- Though MRA has not been established for PAIs, information from MRA partner inspections may be used

- Confidentiality agreements allow FDA and other Regulatory Authorities to share information

Mission Critical PAIs during COVID-19

- Mission Critical
  - Breakthrough Therapy Designated (BTD) products
  - Drug Shortages
  - Products used to diagnose, treat, or prevent a serious disease or medical condition for which there is no other appropriate substitute
- Factors in Determining Mission Critical
  - Safety of all those involved in inspections and public health benefits
  - Clinical benefit and medical necessity

What the Industry Can Do

- Be in close communication with staff at your manufacturing and testing facilities
- Ensure timely responses to Agency's Requests
- Treat the records request as you would an inspection
  - Provide complete, specific and accurate documents
- Be ready to provide information about other regulatory inspections at your facilities
- Consider alternate facilities where possible for increased flexibility

FDA Resources

- **Manufacturing, Supply Chain, and Drug Inspections | COVID-19 Website**
  - Inspections Q&A
  - Manufacturing and Supply Chain Change Requests Q&A
  - Regulatory Operations and Policy Q&A

https://www.fda.gov/drugs/coronavirus-covid-19-drugs/manufacturing-supply-chain-and-drug-inspections-covid-19

Best Defense is a Strong Quality System

Don’t Forget We are Patients Too!