Pre-Approval Inspections during the COVID-19 Pandemic

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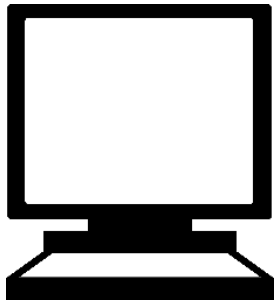
Pharmaceutical Quality

A quality product of any kind consistently meets the expectations of the user.



Pharmaceutical Quality

A quality product of any kind consistently meets the expectations of the user.

Drugs are no different.

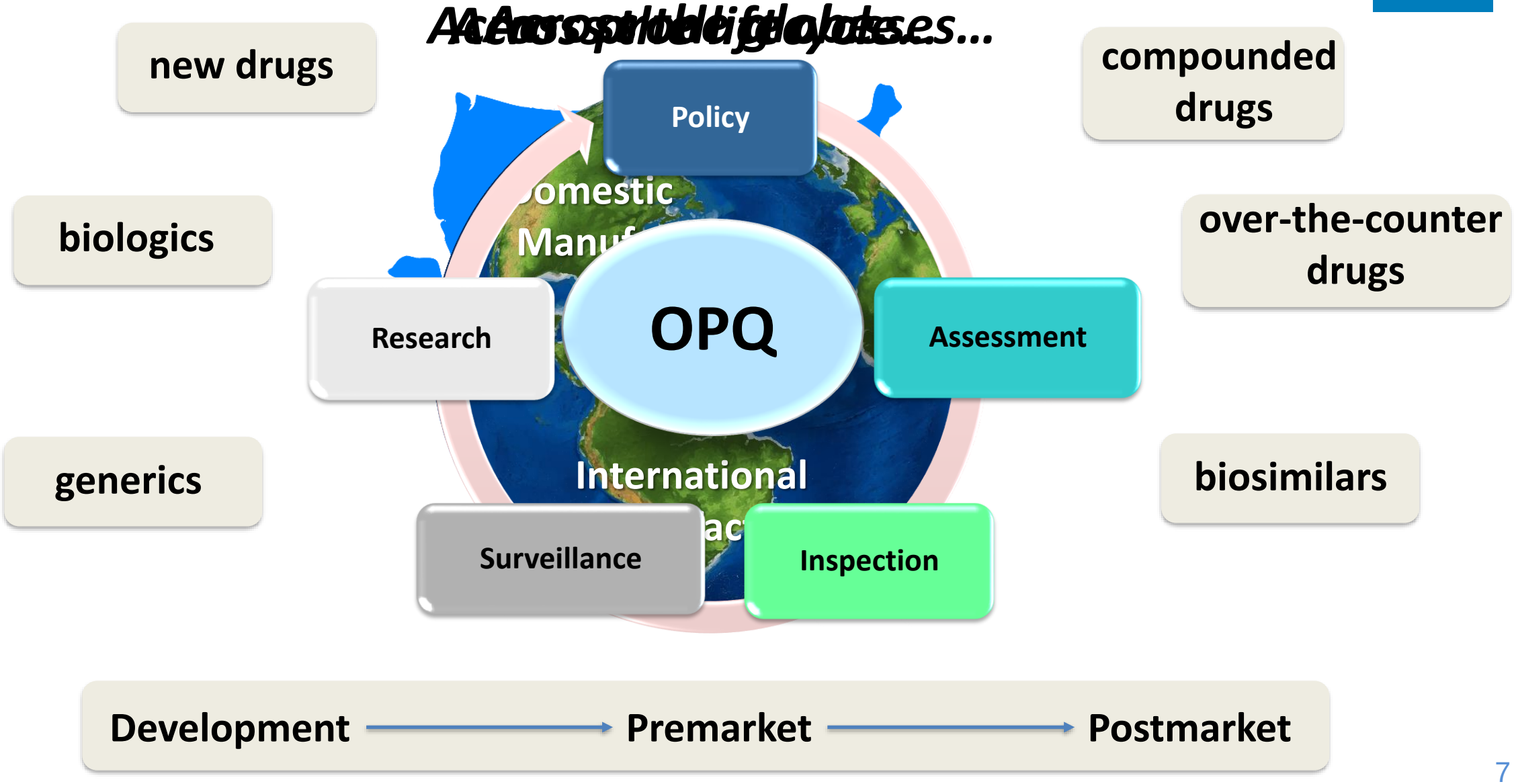

Patients expect safe and effective medicine with every dose they take.

Pharmaceutical quality is

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


It is what gives patients confidence in their *next* dose of medicine.

Office of Pharmaceutical Quality



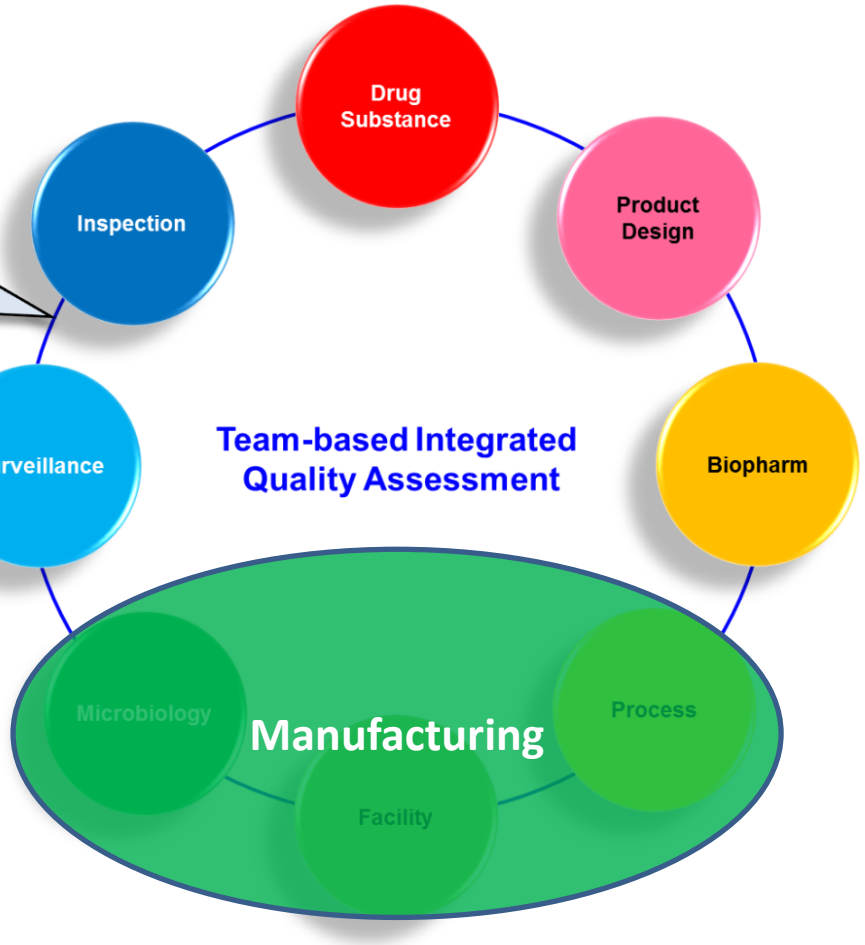
Office of Pharmaceutical Assessment - OPMA

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

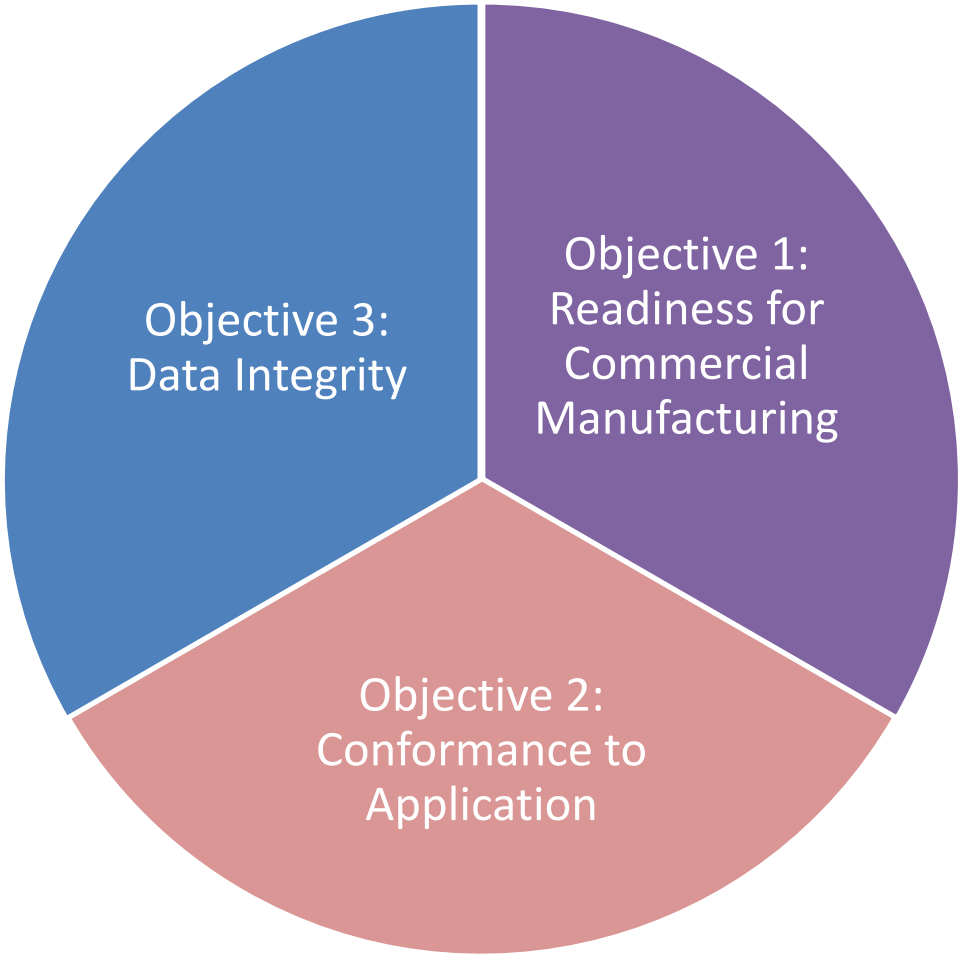


OPMA →

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 Maturity System

Don’t Forget We are Patients too!