

A collection of red and white capsules is scattered across the slide. In the top left, a group of about seven capsules is clustered together. In the center, one capsule lies horizontally. In the bottom right, another capsule is shown in a three-quarter view, highlighting its rounded shape and the red and white segments.

Making Sure My Meds Are Safe *Manufacturers and Quality Controls*

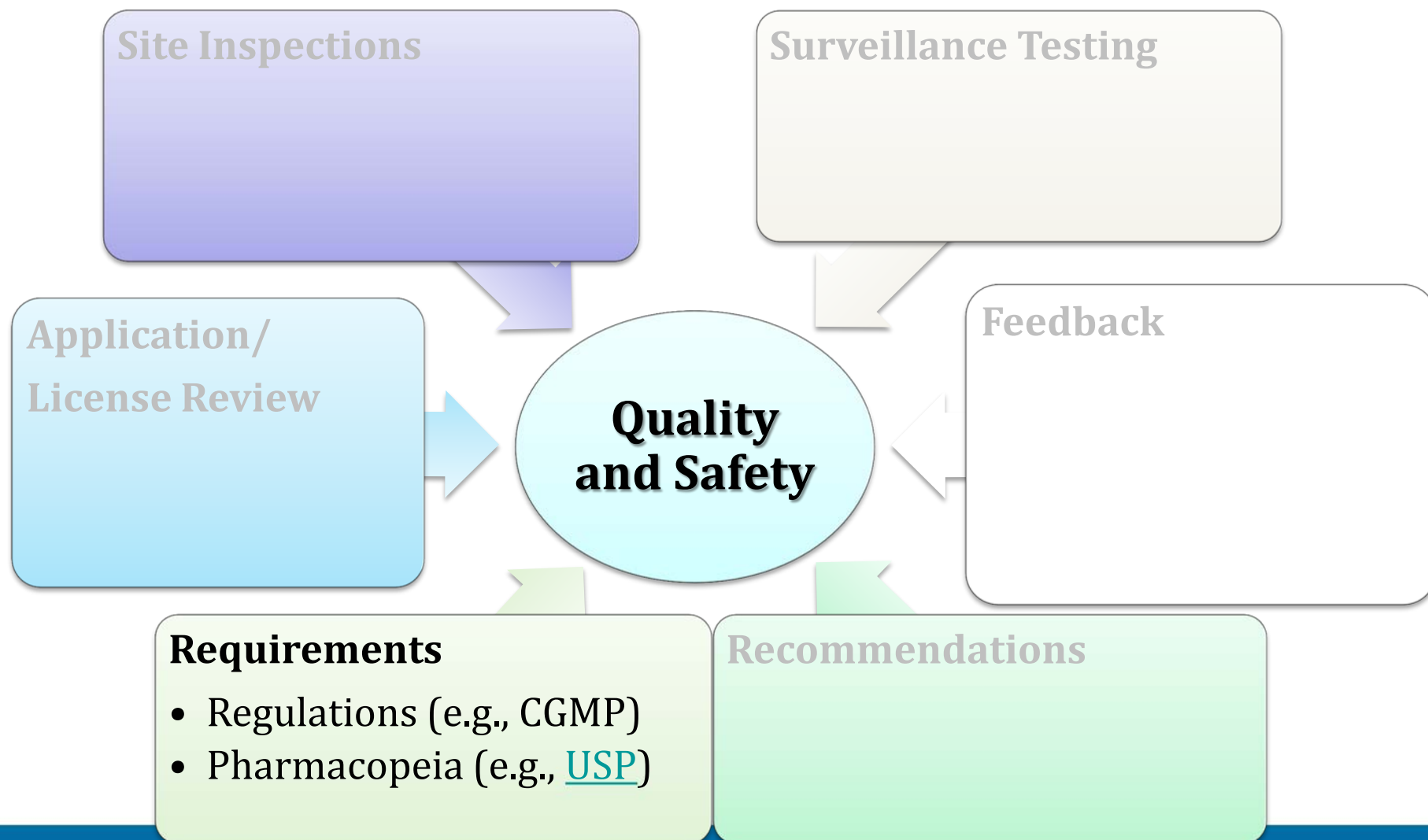
March 31, 2016

Brian Hasselbalch, Deputy Director (acting)
Office of Policy for Pharmaceutical Quality
Center for Drug Evaluation and Research
FDA

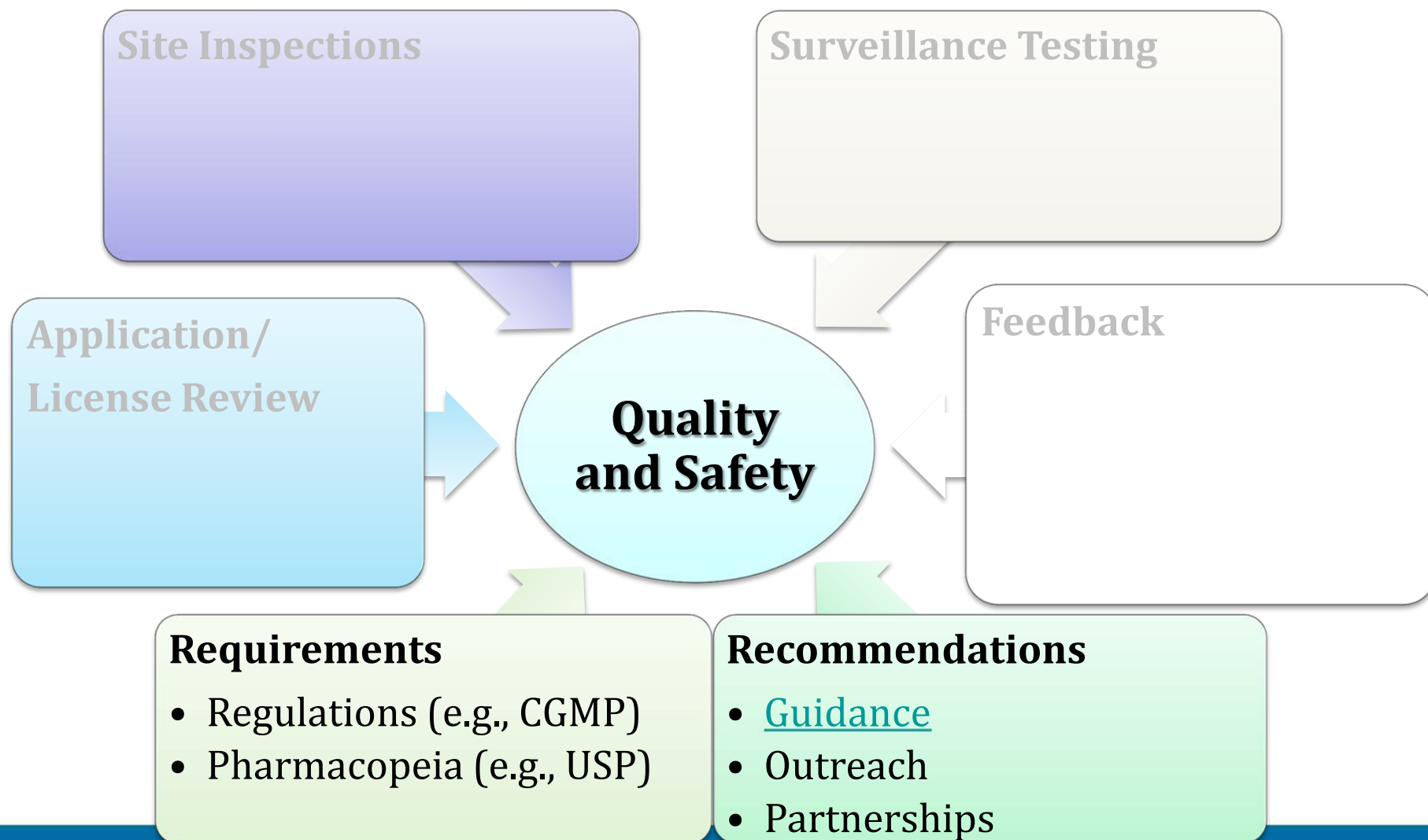
FDA Oversight of Human Drug Quality



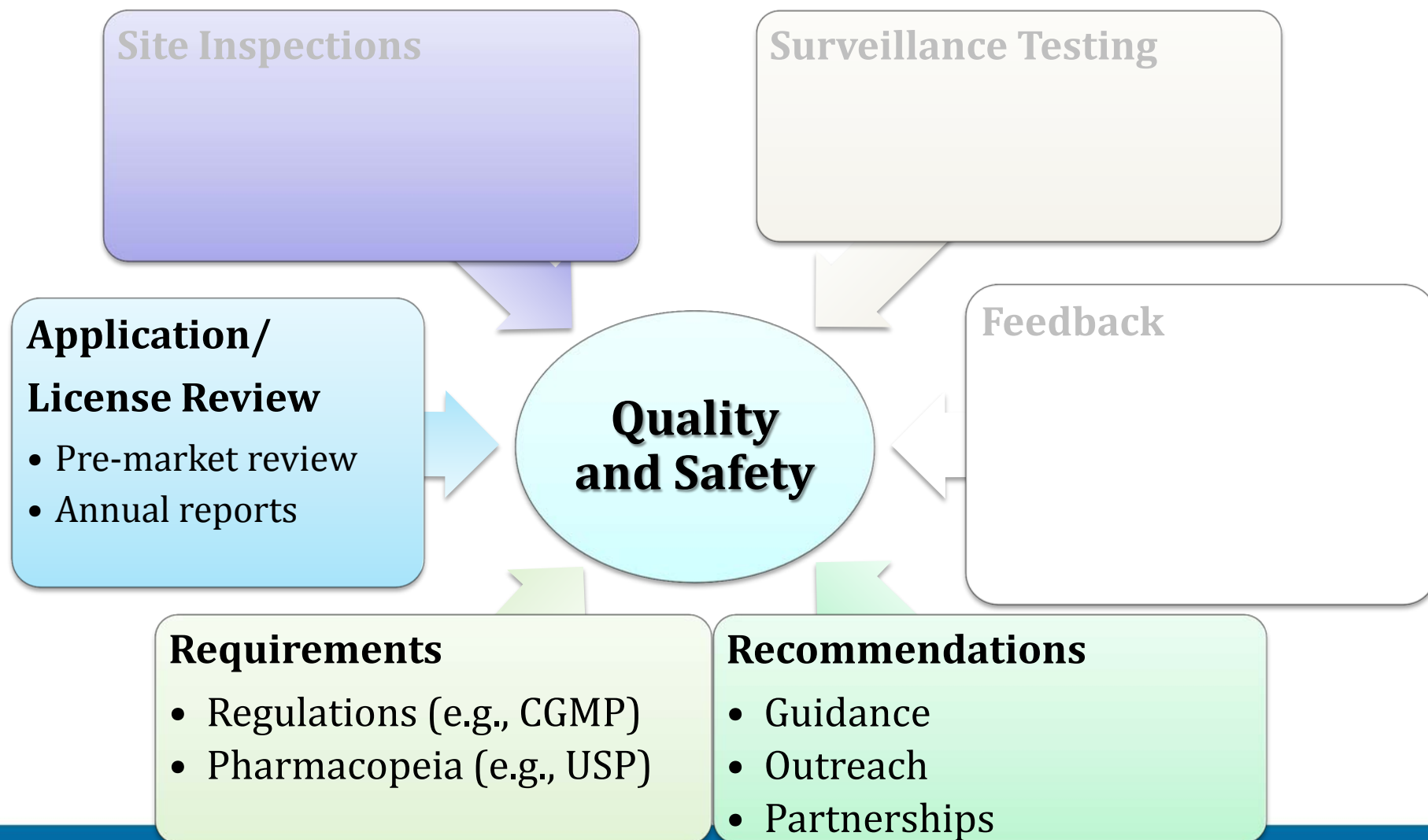
FDA Oversight of Human Drug Quality



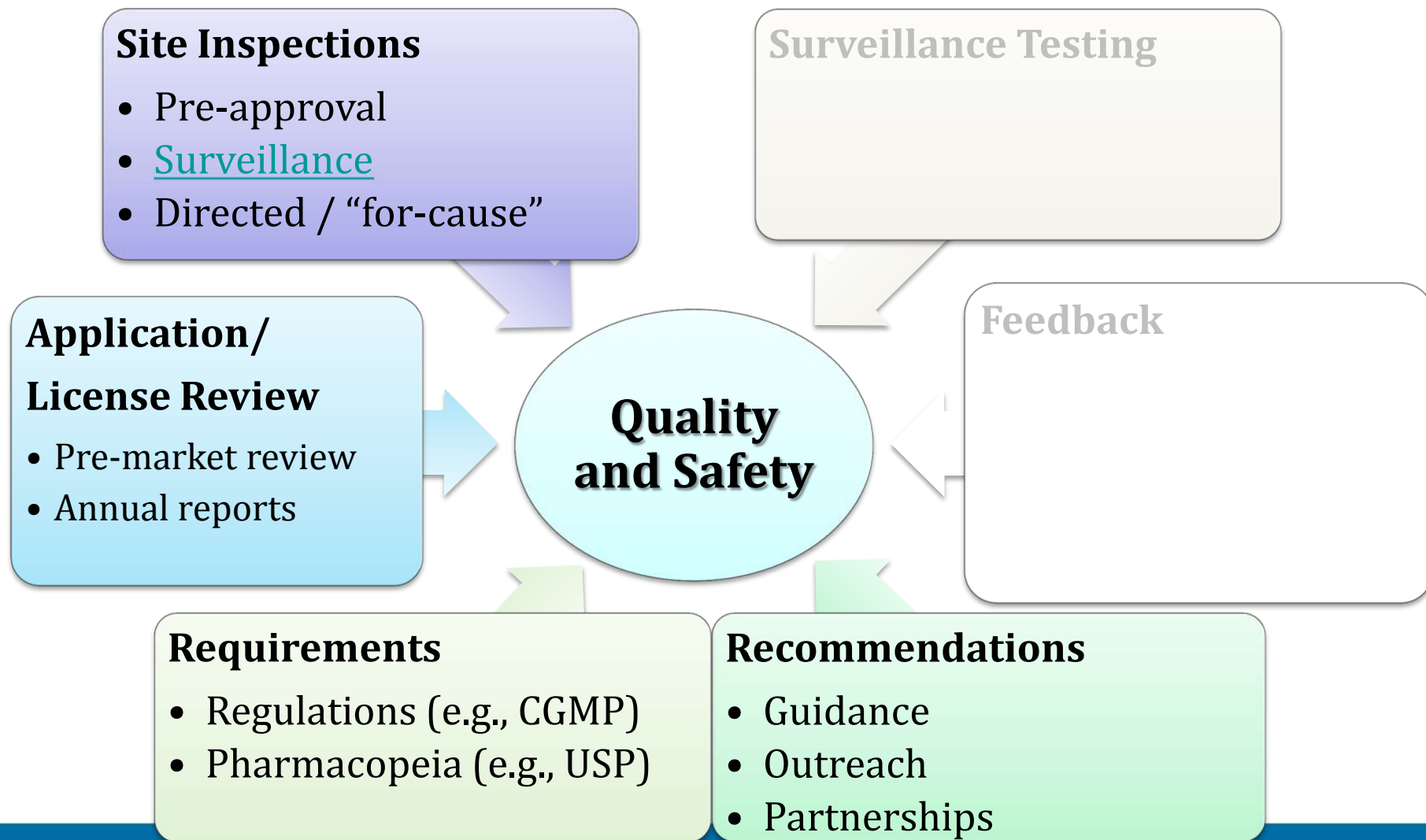
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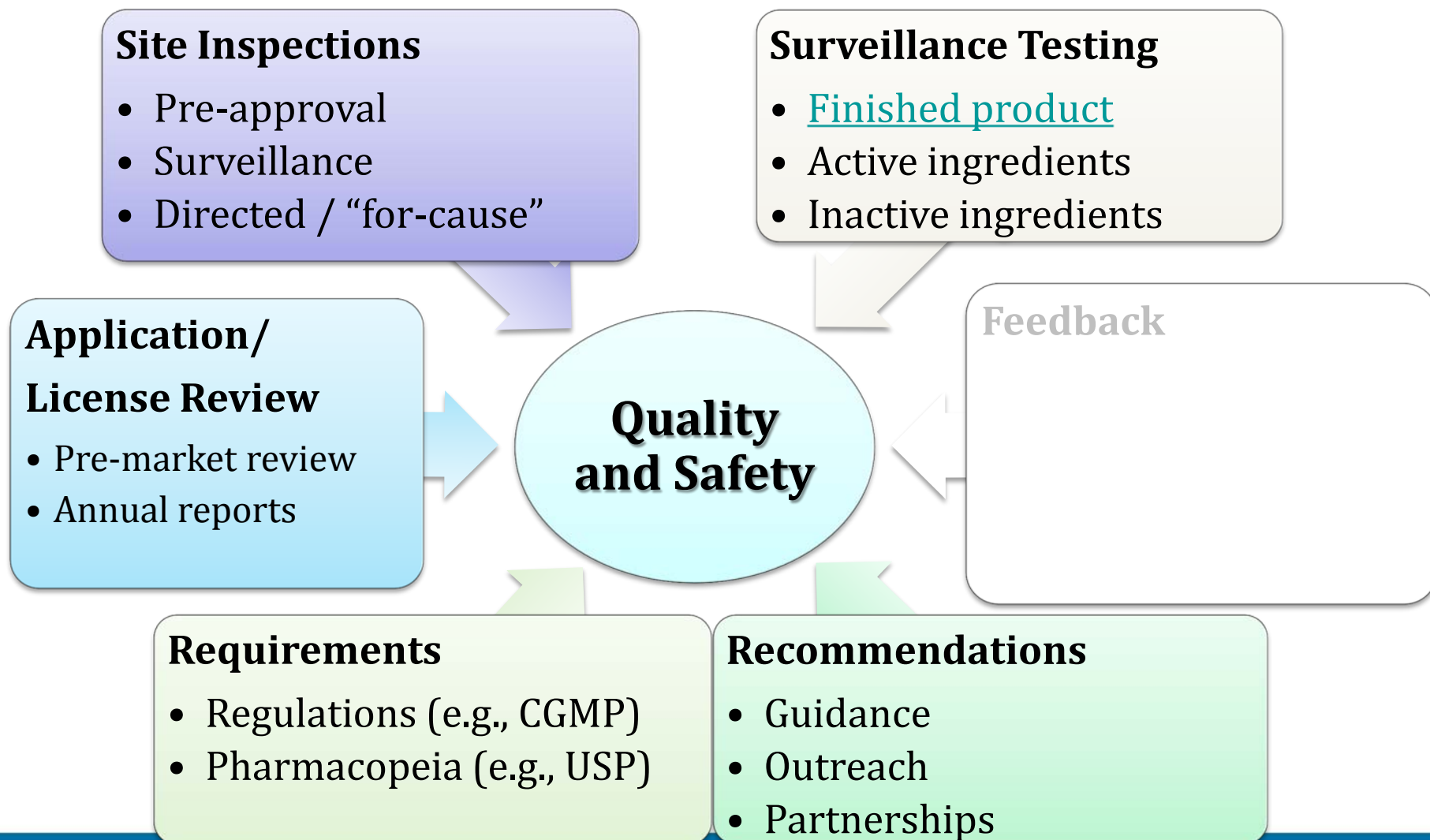
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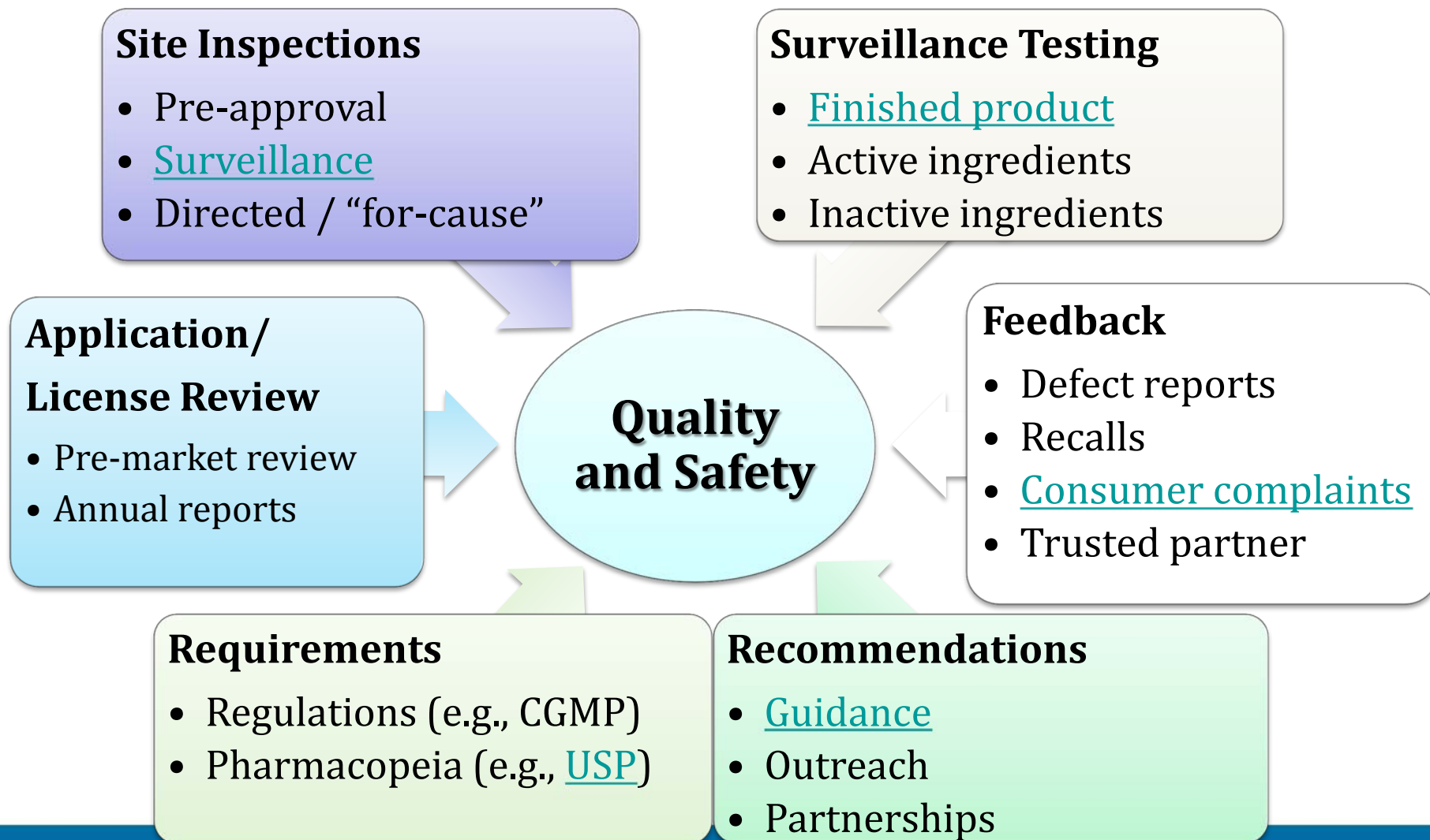
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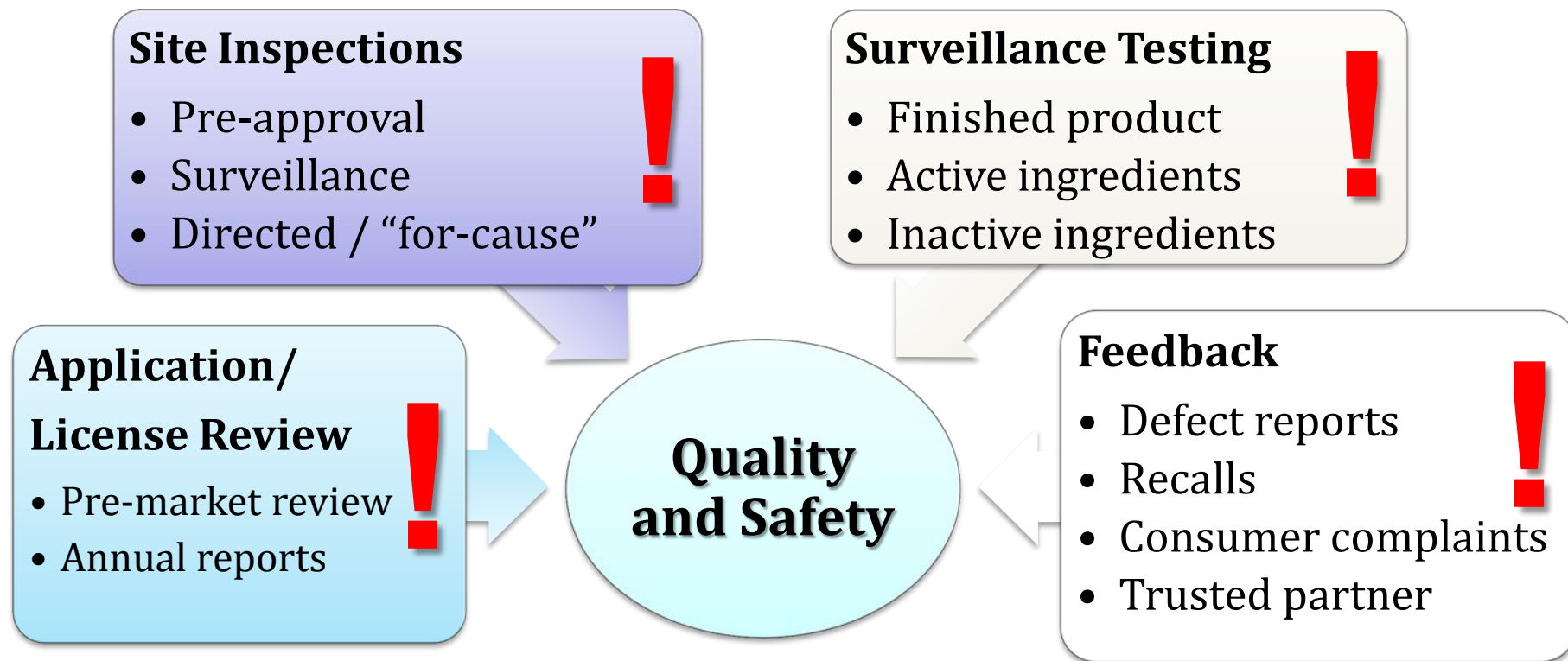
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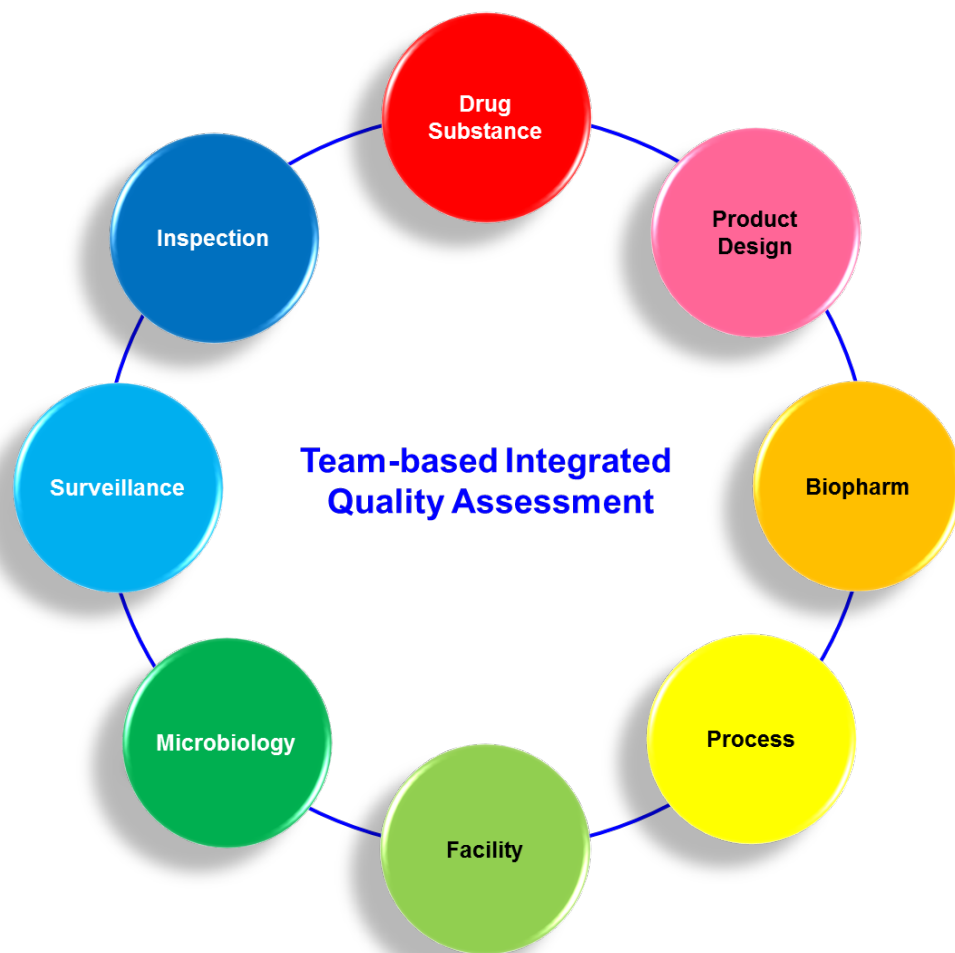


Regulatory Actions and Enforcement

Periodically Inspected Manufacturing Operations

- Dosage form (e.g., tablets, capsules, creams, liquids, gas, transdermals, metered-dose inhalers) ✓
- Active ingredient ✓
- Contract sterilizers ✓
- Contract laboratories ✓
- Contract and independent packagers/labelers ✓
- Outsourcing facilities (i.e., “503B” compounders) ✓
- Drugs made in US only for export ✓
- Inspected for-cause:
 - Inactive ingredient and primary containers !
 - Clinical trial material !

Integrated Quality Assessment Approach: IQA Team

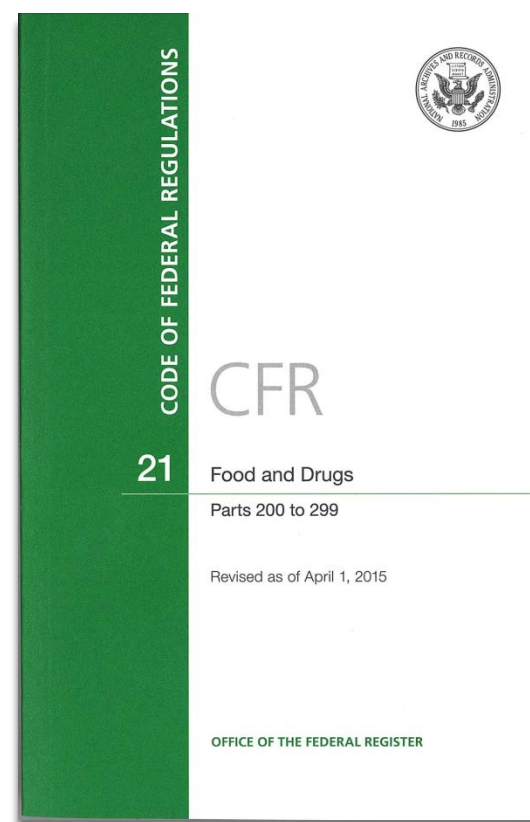


A team of experts performing a quality assessment of an application—NDA, BLA, ANDA—based on risk and knowledge management

Quality Regulations: Current Good Manufacturing Practice (CGMP) for Finished Pharmaceuticals

21 CFR Part 211 subparts:

- General Provisions
- Organization and Personnel
- Buildings and Facilities
- Equipment
- Control of Components and Drug Product Containers and Closures
- Production and Process Controls
- Packaging and Labeling Control
- Holding and Distribution
- Laboratory Controls
- Records and Reports
- Returned and Salvaged Drug Products



Office of Pharmaceutical Quality (OPQ)

Effective January 11, 2015

Mission

... ensures that **quality medicines are available** to the American public

Vision

... be a **global benchmark** for regulation of pharmaceutical quality

Slogan

“One Quality Voice”





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