Making Sure My Meds Are Safe
Manufacturers and Quality Controls

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FDA
FDA Oversight of Human Drug Quality

- Site Inspections
- Surveillance Testing
- Quality and Safety
- Feedback
- Application/License Review
- Requirements
- Recommendations
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  - Regulations (e.g., CGMP)
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**Surveillance Testing**

**Application/License Review**
- Pre-market review
- Annual reports

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- Pre-approval
- Surveillance
- Directed / “for-cause”

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- Finished product
- Active ingredients
- Inactive ingredients

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Feedback
- Defect reports
- Recalls
- Consumer complaints
- Trusted partner

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Quality and Safety

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
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”