

Quality: The Key Ingredient for Stable Pharmaceutical Supply Chains

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Pharmaceutical Quality Symposium

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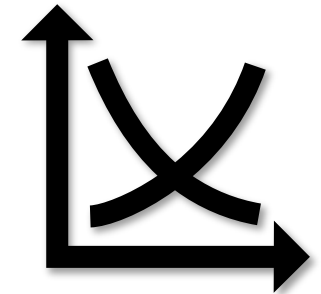
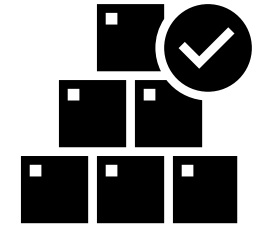
Everyone deserves confidence
in their *next* dose of medicine.

Pharmaceutical quality
assures the
availability,
safety,
and efficacy
of *every* dose.

The Key Ingredients for Pharmaceutical Quality



- **Quality Assessment**
- **Quality Policy**
- **Supply Chain Quality**
- **Advanced Manufacturing**



Quality Assessment

US FDA Center for Drug Evaluation and Research

Pharmaceutical Quality Assessment



**Advancing
Quality
Assessment**

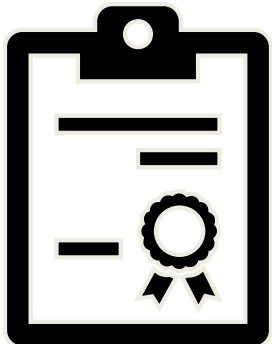
**Patient-Focused
Specifications**

**Modernizing
Quality
Assessment**

**Collaboration for
Generic Drug
Success**

**Inspections in a
Post-Pandemic
World**

**Pre-license
Inspections**



The background of the slide is a blurred photograph of a laboratory. In the foreground, a person with dark hair in a ponytail is seen from behind, looking at a piece of equipment. The background shows various laboratory glassware, including bottles and beakers, on a counter. The entire image has a light blue tint.

Quality Policy

US FDA Center for Drug Evaluation and Research

Pharmaceutical Quality Policy



Policy Documents

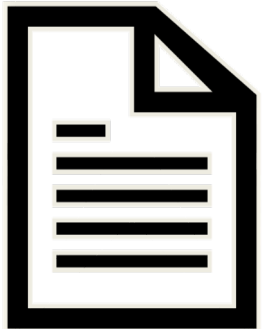
International Harmonization

ICH Q12

Nitrosamines Guidance

USP & FDA

Product-Specific Guidances





Supply Chain Quality

US FDA Center for Drug Evaluation and Research



Pharmaceutical Supply Chain Quality

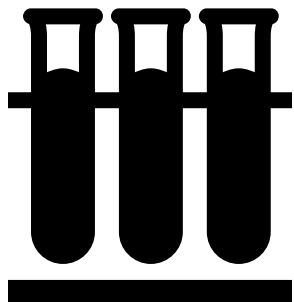
**Testing for
Diethylene
Glycol and
Ethylene Glycol**

**Microbiological
Quality
Considerations
for Non-Sterile
Manufacturing**

**Quality
Management
Maturity**

**Drug Quality
Sampling
& Testing**

**CDER Site
Selection Model**



The background of the slide is a blurred photograph of a laboratory. In the foreground, a person with dark hair in a ponytail is seen from behind, looking at equipment. The background shows various glass bottles, beakers, and laboratory stands on a bench.

Advanced Manufacturing

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Advanced Manufacturing



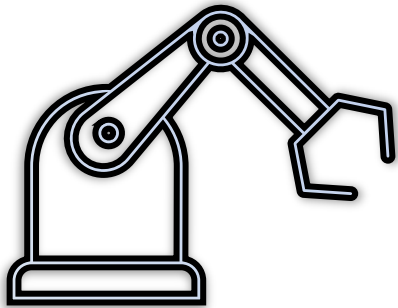
**Emerging
Technology
Program**

FRAME

ICH Q13

**Continuous
Manufacturing
Research**

**AI in
Pharmaceutical
Manufacturing**





In Closing

US FDA Center for Drug Evaluation and Research





Regulators or industry cannot assure quality by working separately.

Pharmaceutical quality requires our data-driven, science-based collaboration.



U.S. FOOD & DRUG
ADMINISTRATION