

# **Quality:** The Key Ingredient for Stable Pharmaceutical Supply Chains

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**Pharmaceutical Quality Symposium**

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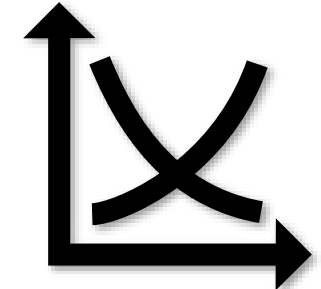
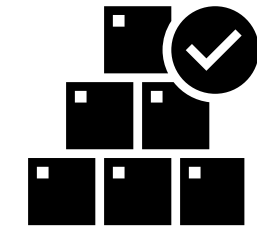
Everyone deserves confidence  
in their *next* dose of medicine.

**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

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# Pharmaceutical Quality Assessment



**Advancing  
Quality  
Assessment**

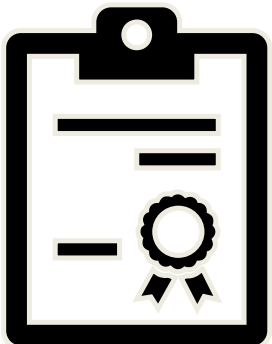
**Patient-Focused  
Specifications**

**Modernizing  
Quality  
Assessment**

**Collaboration for  
Generic Drug  
Success**

**Inspections in a  
Post-Pandemic  
World**

**Pre-license  
Inspections**





# Quality Policy

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# Pharmaceutical Quality Policy



**Policy  
Documents**

**International  
Harmonization**

**ICH Q12**

**Nitrosamines  
Guidance**

**USP & FDA**

**Product-Specific  
Guidances**



# Supply Chain Quality

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# Pharmaceutical Supply Chain Quality

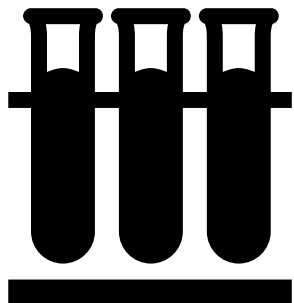
**Testing for  
Diethylene  
Glycol and  
Ethylene Glycol**

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

**Quality  
Management  
Maturity**

**Drug Quality  
Sampling  
& Testing**

**CDER Site  
Selection Model**



# Advanced Manufacturing

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# Advanced Manufacturing

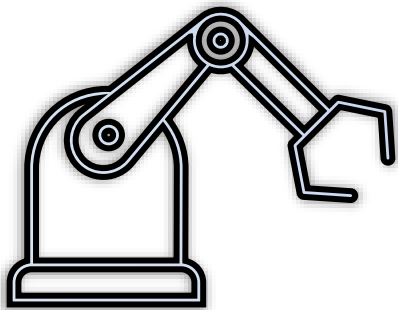
**Emerging  
Technology  
Program**

**FRAME**

**ICH Q13**

**Continuous  
Manufacturing  
Research**

**AI in  
Pharmaceutical  
Manufacturing**



The background of the lower half of the slide is a photograph of a laboratory. A person with dark hair in a ponytail is seen from behind, working at a lab bench. The bench is cluttered with various pieces of laboratory equipment, including beakers, flasks, and test tubes. The entire image is covered with a semi-transparent blue overlay, and a thin red vertical bar is positioned on the right side.

# 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