



Clinical Trials

On Q – The Source for Quality Training

Objectives

- Define the purpose of research and the regulatory requirements
- Discuss FDA's Bioresearch Monitoring (BIMO) program
- Describe what could be covered during an FDA inspection
- Explain regulatory actions, fraud and the consequences



Purpose of Research

- Determines
 - If product is safe and **effective**
 - What dose (for drugs) works best
 - What are the side effects
 - New screening and diagnostic tests
- Conducted
 - With investigator blinded or unblinded to test article and/or dose



Why Conduct Clinical Trials?

- Further emerging technologies
- Recognition in the blood community
- Revenue
- Job security if there is a research department within your facility



Which Regulations Apply?

- Research funding
- Which government agency will review the study
 - HHS regulations apply to studies that are federally funded
 - HHS and FDA regulations can apply to federally funded studies that will be submitted to FDA
 - FDA regulations apply to studies that are submitted to FDA
 - Institutional policies apply to university or private research