Most Common CI Deficiencies

• Failure to follow the investigational plan and/or regulations
• Protocol deviations
• Inadequate recordkeeping
• Inadequate accountability for the investigational product
• Inadequate communication with the IRB
• Inadequate subject protection – failure to report AEs and informed consent issues

Source: [http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm261409.htm](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm261409.htm)