

# HAVE YOU READ THE ICH E6 (R3) GCP GUIDELINE?



From 1 Oct 2025, NHG Health PI, Site PIs and Co-Is pending ICH E6 (R3) GCP training will NOT be able to submit new IRB applications and study amendments for clinical trials.

## **Enhanced GCP Concept**

### **What Should I Consider?**

- Have I identified the critical risks to participant safety?
- Which data points are essential for trial reliability?
- Have I planned appropriate oversight and monitoring for high-risk areas?

## PROPORTIONATE, RISK-BASED APPROACHES

#### **What Does It Mean?**

Take a strategic approach to identifying & managing risks. Focus efforts on areas with highest impact on participant safety & data integrity.

QUALITY BY DESIGN (QbD)

"Building quality into clinical trials from the start"



"Right tools to meet trial objective"





## **Complete Your CITI GCP Course Today!**



Recommended Course: GCP for Clinical Investigations of Drugs and Biologics (ICH)

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Scan here for <u>Step-by-Step</u> guide on how to update your ICH GCP Training





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