

## ICH E6 R2: Guideline for Clinical Practice

Integrated Addendum



# Investigator Oversight Module

### **Investigator Oversight Module**

#### Section 1.63

"Certified Copy: A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original.

The expectation is that any documents used as source in lieu of the original record (e.g., electronic health records, faxes, emails, etc.) must have evidence that it has been verified to have the same information as the original (e.g. dated signature, validated stamp).



## **Certificate of Completion**

#### This is to certify that:

#### Has completed reviewing the Topic:

ICH E6 R2: Guideline for Clinical Practice Integrated Addendum; Investigator Oversight Module, on: (insert date below)

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