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Updates Published for ICH E6 GCP Guideline: GMP for IMP Principles - BLOG

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Updates to guidances on clinical trial development were recently published by the ICH Management Committee in a draft format. This updated document reveals principles that are currently under development by the ICH E6(R3) Expert Working Group (EWG).

According to ICH, the ICH E6 Good Clinical Practice (GCP) Guideline principles are "interdependent and should be considered in their totality to assure ethical trial conduct, participant safety, and reliable results of clinical trials". Public comments on the principles are not being taken at this time. Once the ICH E6(R3) Guideline reaches Steps 2 and 3 of the ICH guideline development process, the EWG will invite and consider public input.

Impact on GMP for IMPs

The current principles of the ICH GCP Guideline (ICH E6 (R2)) relating to GMP for Investigational Medicinal Products, IMPs, include the following:

- IMPs should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.

With the third revision of ICH E6 (ICH E6(R3)), these GMP for IMP principles are expected to be expanded to the following:

- IMPs used in a clinical trial should be manufactured in accordance with applicable GMP standards and be stored, shipped, and handled in accordance with the product specifications and the trial protocol. In particular the following applies:
    - IMPs should be manufactured under GMP.
    - Measures should be in place to ensure that the IMP provided to trial participants retains its quality.
    - IMPs should be used in accordance with the protocol and relevant study documents.
    - Manufacturing, handling, and labelling of IMPs should be undertaken in a manner that maintains blinding, and treatment assignment, where applicable.
    - IMP labelling should follow the appropriate regulatory requirements.
    - Risk-based approaches should be considered when implementing proportionate measures to ensure GMP and the appropriate shipping and handling of the IMP.

Previously, the WHO published two new draft documents relating to Development and GMP for IMPs: "Good Practices for Research and Development Facilities"

and "GMP for IMPs".

For More Information:

- Read the Draft Principles of ICH E6 GCP.
- Review the current guideline, ICH E6(R2): Guideline for Good Clinical Practice
- Learn more about the ICH work plan, expert list, and reports of prior public engagements on the ICH website - Efficacy Guidelines.
