A practical guide to writing robust chemistry, manufacturing, and controls dossier modules to support first-in-human trials

Get your first-in-human (FIH) paperwork in order by drafting informative, phase-appropriate chemistry, manufacturing, and controls (CMC) modules for the common technical document (CTD).

GENERAL TIPS

- [ ] Don't reinvent the triangle—follow published guidelines
- [ ] Highlight patient safety considerations throughout the CTD

CHARACTERIZATION

- [ ] Characterize the drug product and its critical quality attributes (CQAs)

MANUFACTURING AND PROCESS CONTROLS

- [ ] Focus on the health and safety angles of manufacturing

REFERENCE STANDARDS AND CONTROLS

- [ ] Provide data supporting drug standards and controls

DRUG PRODUCT DEVELOPMENT

- [ ] Emphasize safety in drug product description and development sections

STABILITY

- [ ] Provide data on product stability based on selected manufacturing and dosage methods

PLANNING AND PROCEEDING

- [ ] Identify your gaps and areas of concern
- [ ] Update as the details change

View our webinar on demand and download our whitepaper to learn more.

References

1. International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). M4: The Common Technical Document. ICH.org. Accessed December 15, 2022.
2. European Medicines Agency. ICH Q8 (R2) Pharmaceutical Development. Committee for Human Medicinal Products, EMA/CHMP/ICH/167068/2004. June 2017.
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