Common Confusion about ICH and its GCP Guideline

Writers -- not only student writers, but even some authors I worked with as a magazine editor -- often demonstrate confusion about the meaning of ICH. ICH is industry shorthand for **International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use** (clearly, an organization name so long begs for abbreviation.)

- I frequently see writers in clinical research treat ICH as a synonym for GCP. But, the ICH Guideline for Good Clinical Practice is but one of the ICH guidance documents.
- ICH spelling errors by U.S. writers are probably caused by overly "helpful" computer spelling tools, which inevitably tell us to spell *harmonization* the American way. Organizations, like authors, like to see their names spelled the way they do -- and the official name of ICH uses British spelling.

ICH guidelines fall into several categories. The Efficacy (E) category is most familiar to clinical research professionals.

- **Efficacy topics relate to clinical studies in human subjects.** Examples: E2 Clinical Safety Data Management; E4 Dose Response Studies, Carcinogenicity Testing; and E6 Good Clinical Practice

The Safety (S) category is most referred to by scientists involved in pre-clinical testing.

- **Safety topics relate to in vitro and in vivo pre-clinical studies.** Examples: S1 Carcinogenicity Testing, S2 Genotoxicity Testing

The Quality (Q) category is most in use by manufacturing personnel.

- **Quality topics relate to chemical and pharmaceutical quality assurance.** Examples: Q1 Stability Testing, Q3 Impurity Testing

Categories that cross specialties are **Multidisciplinary topics**, such as

- M1: Medical Terminology (MedDRA)
- M2: Electronic Standards for Transmission of Regulatory Information (ESTRI)
- M3: Timing of Pre-clinical Studies in Relation to Clinical Trials
- M4: The Common Technical Document (CTD)
- M5: Data Elements and Standards for Drug Dictionaries

Resources

ICH: www.ich.org
FDA guidance documents (including E6): http://www.fda.gov/oc/gcp/guidance.html
NIH institutes use E6, e.g., the National Institute of Allergy and Infectious Diseases: www.niaid.nih.gov/dmid/clinresearch/handbook.pdf
EMEA (The European Agency for the Evaluation of Medicinal Products): http://www.emea.eu.int/Inspections/GCPgeneral.html