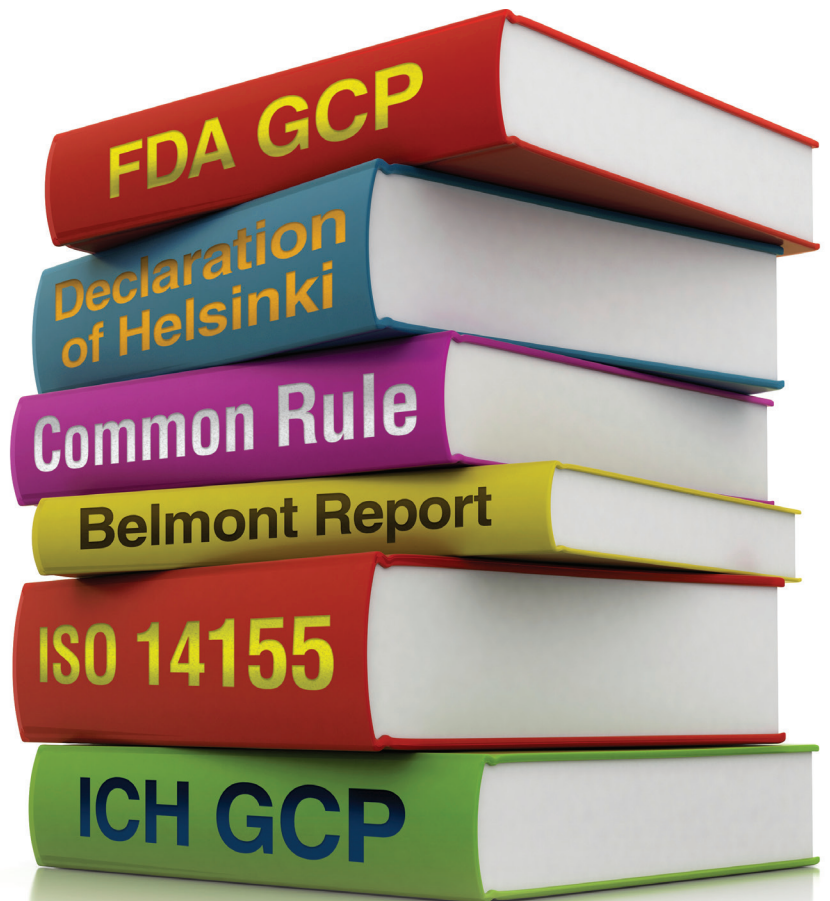


# GOOD CLINICAL PRACTICE

## What is GCP?

**Good Clinical Practice (GCP)** is an international ethical and scientific quality standard for the conduct of clinical research. GCP has a two-fold purpose: to protect human subjects and to assure accurate and credible data from clinical trials.

“**Good Clinical Practice is more than any one document; rather, it is a collective compilation of many thoughts, ideas and best practices spanning the globe over.**”



## Partnerships in GCP include:

- ✓ **Sponsors:** drug, device, or biologic manufacturers who design the study protocol
- ✓ **Investigators and Research Staff:** those who enroll subjects into studies at a site, and collect research data according to the study protocol
- ✓ **Contract Research Organizations:** organizations that are delegated some or all of the responsibilities of conducting the study
- ✓ **Institutional Review Boards/Ethics Committees:** organizations that provide oversight throughout the study
- ✓ **FDA:** regulatory authority with the power to approve or disapprove product

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