



Good Clinical Practice (GCP)—Everything You Always Wanted to Know but Were Afraid to Ask

**San Diego Convention Center • San Diego, CA
December 5, 2010 • 8:30 AM-12:30 PM***

FACULTY

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When a principal investigator signs the FDA form 1572 (for IND studies) or the "Statement of the Investigator (for IDE studies), one signs a legally binding commitment to comply with all relevant regulations and the principles of Good Clinical Practice (GCP). These responsibilities are clearly described in the International Conference on Harmonization (ICH) GCP Guidelines. While many US-based investigators and ethics review boards are familiar with the Belmont Report, the Common Rule and the FDA Regulations, many are less familiar with international GCP guidelines and practices. This session is designed to fill the gaps, offering an intensive, interactive introduction to the ICH GCP policies and practices that now apply to the vast realm of international clinical research and investigator certification.

Agenda*

7:00 AM	<i>Registration</i>
7:00-8:30 AM	<i>Continental Breakfast</i>
8:30-8:45 AM	Welcome and introduction to ICH GCP <i>Making History--The Who's, How's, When's and Why's of the International Conference on Harmonization and Good Clinical Practice Guidelines</i>
8:45-9:45 AM	The Dirty Dozen Plus One: Getting into ICH GCP E6 Guidelines <i>A Detailed Look at the Words and What's Behind Them</i>
9:45-10:45 AM	"Show Me Some of that Pilot Stuff, Mav" <i>Responsibilities: Investigators, Sponsors, Ethics Review Boards and Competent Authorities</i>
10:45 AM-11:00 PM	<i>Break</i>
11:00-12:00 PM	"When Things Ain't Right in the Neighborhood, Who

Agenda

Ya Gonna Call?”

All about Monitors, Audits, DSMBs and Adverse Event Reporting

12:00–12:30 PM

“Toto, I Don’t Think We’re in Kansas Anymore...”

Closing Dialogue, Questions and Honest Answers

12:30 PM

Adjournment

** Please note that lunch will not be provided.*