



PREMIER ISSUE
NOVEMBER
2009

GMP TRAINING CONTENT

Meeting FDA Requirements for Subpart C: Buildings and Facilities

GMP Pharmaceutical Regulations: An Introduction
to Interpretation and Enforcement

Understanding GMP Part 210: A Baseline Document
for Interpreting Part 211 Regulations

GLP TRAINING CONTENT

FDA GLP Inspections: A Handbook to Preparing
for a Successful Inspection - Part 1

GLP vs. GMP Regulations: A Review of Their
Intended Purposes and Requirements

How to Effectively Utilize SOPs for GMP, GCP and GLP Operations
in an FDA-Regulated Environment: A Lifecycle Review

GCP TRAINING CONTENT

Drug Safety and Adverse Events for Clinical Trials: An Introduction

A Plan for Ensuring Quality is Built Into your Clinical Trial - Part 1

COMPUTER VALIDATION CONTENT

Regulatory Documentation for Quality Systems and
Computer System Validation Explained: The Basics

LIMS Validation Projects: Critical Considerations
for Successful Execution

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PUBLICATION DATES

November, January, March, May, July, September

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