



B u s i n e s s C o n s u l t a n t s

Good Quality Control Laboratory Practices in a Global Environment			
Day 1			
From... To		Total	Course Content
8:30	8:45	0:15	Introduction
8:45	10:30	1:45	Overview of ISO17025, Eudralex Volume 4, and CFR Title 21, Parts 58, 210 and 211 Overview of 21 CFR 58 Good Laboratory Practices The Quality Control Laboratory: General requirements for design and construction of microbiological and analytical laboratories, Design and construction considerations - Part 211 Subpart C: Buildings and Facilities
10:30	11:00	0:30	Coffee Break
11:00	12:00	1:00	QC Laboratory Utilities - qualification requirements Safety and security Sample handling, qualification of sample storage locations Calibration and Qualification of instrumentation and equipment The Calibration Cycle Calibration and maintenance of QC lab equipment Identifying critical calibration parameters Writing calibration procedures Documenting calibration results Setting acceptance limits for calibrations using risk-based approaches Investigation of OOC - out-of-calibration and OOT out of tolerance Events and Consequences
12:00	13:00	1:00	Practical - Laptop with Minitab14 required (One month trial CD will be provided if required) Laboratory statistics for non-statisticians. Using Minitab14 to calculate trend analysis (CSUM, EWMA) Comparing data sets (Student T, ANOVA)
13:00	14:00	1:00	Lunch Break



B u s i n e s s C o n s u l t a n t s

14:00	15:30	1:30	Practical -continued Laptop with Minitab14 required (One month trial CD will be provided if required) Quality Tools (Capability six pack, Cp, Cpk) Histograms Basic quality control run charts, Pareto charts, N and P charts
15:30	15:45	0:15	Coffee Break
15:45	17:00	1:15	When things go wrong - investigation of Out of Specification results. OOS, OOL, OOT, OOC, OED Using method validation to check analytical capability, to determine statistical considerations for OOS results Deviations and test failures, Essential Documentation A basic root cause analysis primer - Conducting Effective Investigations using root cause analysis, causal tree analysis and Ishikawa 6M Effective handling of Deviations and Out Of Specification Results: how to stay out of regulatory hot water Corrective and Preventative Actions
17:00	17:15	0:15	Discussions, Questions and answers

Good Quality Control Laboratory Practices in a Global Environment			
Day 2			
From... To		Total	Course Content
8:30	10:30	2:00	Analytical method validation - What to validate, what to verify Analytical method verification How to organise Design of Experiment (DOE) for analytical method validation Approaches to Experimentation Factorials designs Taguchi Method Experimental Design Process Practical -using Excel spread sheets to generate results (Laptops required)



B u s i n e s s C o n s u l t a n t s

10:30	11:00	0:30	Coffee Break
11:00	13:00	2:00	Equipment Qualification Requirements Qualification of QC laboratory equipment: DQ/IQ/OQ/PQ Design Qualification Installation Qualification Operational Qualification Performance Qualification
13:00	14:00	1:00	Lunch Break
14:00	15:30	1:30	System Suitability Testing: an essential component of lab compliance Stability Dissolution apparatus / Maintenance and calibration Dissolution and Bioequivalence Notes on "In vitro" versus "in vivo" equivalence testing Applications of in vitro dissolution testing Mechanism of dissolution Multi point dissolution Comparative dissolution testing Examples on multi-point and comparative dissolution testing
15:30	15:45	0:15	Coffee Break
15:45	17:00	1:15	Documentation, records-keeping and change control Management of reagents, test solutions and reference standards Personnel development and training Example: development of a document how to establish the set-up, mechanical calibration, and operation checks for dissolution Apparatus. Document History, Purpose, Scope/Policy, Responsibility, Procedure, Supporting documents, Records, Reference information, Glossary, Attachments
17:00	17:15	0:15	Discussions, Questions and answers

Duration 14h