

GOOD QUALITY CONTROL LABORATORY PRACTICES IN A GLOBAL ENVIRONMENT

Which are the applied principles of Good Laboratory Practice and how to become a laboratory to offer your services for the benefit of the global market?

May 17&18, 2010
Limassol

Course Fee
HRDA Beneficiaries
SMEs:- €150-300* + ΦΠΑ
LEs:- €250-500* + ΦΠΑ
Non HRDA Beneficiaries:
€650 + VAT



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GMP/GLP Consultant

*The approved fee by the HRDA is €2000. The due fee by each participant depends on his/her company cost . How to calculate the exact fee? Please call in 22466500.

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Course Content

Overview of ISO17025, Eudralex Vo.4, and CFR for the GLP
 The QC Laboratory: design and construction of microbiological and analytical laboratories, Buildings and Facilities.
 QC Lab.: qualification requirements, Safety and security, Sample handling, sample storage locations.
 Calibration and Qualification of instrumentation and maintenance of equipment. The Calibration Cycle.
 Setting acceptance limits for calibrations. Investigation of out-of-calibration and out-of- tolerance events and consequences.
Practical:Laboratory statistics for non-statisticians.
 Minitab14 to calculate trend analysis.
 Quality Tools (Capability six pack, Cp, Cpk). Histograms. Basic quality control run charts, Pareto charts, N and P charts.

Investigation of Out of Specification results. Using method validation to check analytical capability. A basic root cause analysis primer.
 Method validation – What to validate, what to verify
 How to organise Design of Experiment (DOE) for analytical method validation. Factorials designs, Taguchi Method, Experimental Design Process.
 Qualification of QC laboratory equipment: DQ/IQ/OQ/PQ
 System Suitability Testing. Stability, Dissolution and Bioequivalence. Applications of in vitro dissolution testing. Mechanism of dissolution, Multi point dissolution, Comparative dissolution testing, Examples on multi-point and comparative dissolution testing.
 Documentation, records-keeping and change control. Management of reagents, test solutions and reference standards.

Course Benefits: Delegates will be able to

- Use advanced laboratory measurement systems to quantify the quality of the laboratory results.
- Apply the state-of-the-art Good Quality Control Laboratory Principles in their laboratories.
- Learn about the globally approved laboratory practices and implement the practices applied by well established analytical and microbiological laboratories in the universe during the application of the GQCLP regulations.
- Design experiments for analytical method validation and evaluate the experimental results using statistical tools and advanced software.



APPLICATION FORM

Company :.....

Tel..... Fax:..... Email:.....

Name and surname email Mobile Ph.one

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