



... training you can access, afford, assimilate and appreciate!

## 1-day Training Programmes offered at our Office

S/N	Topic	Course content
1	GMP Overview	CGMP- as a quality system; as a regulation; its core values; its primary areas of concern; Regulators' rationale; Regulators' expectations; Approaches to compliance; Patients' expectations; consequences of non-compliance; benefits of compliance; how you can contribute to improved compliance
	Pharmaceutical Contamination Control	Introduction to basics of contamination control followed by a discussion on initiatives necessary to minimise risk of contamination from Personnel; Buildings and Facilities; Equipment; Raw Materials; In-process and Finished Materials; Packaging and Labeling; Sampling and Testing
2	Pharmaceutical Facilities	Premises; HVAC and Water Systems
3	Sterilisation and Aseptic Processing	Comprehensive exposition of sterilisation concepts; sterilisation cycle development; Qualification/Verification of Autoclaves, DHS, Tunnel Sterilisers; Media Simulation Studies; Overview of Instant/Rapid Microbial Detection Methods
4	Good Biosafety Practice	Why Biosafety is so important, Risk Assessment and Risk Control, Proper selection and use of Biosafety Cabinets; Considerations in Design of Biosafe Facilities
5	Good Laboratory Practice & Measurement System Analysis	Overview of OECD GLP; Overview of ISO 17025 GLP; Overview of Schedule L-1 GLP; Checklist for Compliance Good (Statistically Valid) Sampling Plans and Practices Overview of Measurement System Analysis; Calibration Management; Importance of Correct Techniques; Verifying Compendial Methods; In-depth and practical coverage of Validation of in-house developed Analytical Methods; Validation of PCR family of Methods Handling "atypical" and "OOS" Test Results
6	Stability studies	Introduction; forced degradation studies; developing and validating stability indicating analytical method; stability protocol; test frequency; climatic zones; stability study of normal products, special products; practical issues; bracketing and matrixing; evaluation of data; closing remarks and general practical tips for a successful and meaningful study
7	Pharmaceutical Materials Management	Introduction; vendor qualification and vendor status rating; good (statistically valid) sampling practice; Practical situations; general regulatory expectations
	Pharmaceutical Production & in-process controls	Production and in-process controls; special issues in API production; Handling Manufacturing Deviations & Change Control; Packing and Labeling control; risk profiling and visual signage in production and packaging areas
8	Failure Investigation	All you wanted to know about carrying out effective failure investigation and CAPA
9	Conducting Pharmaceutical Audit	Introduction; types and purposes of audits; the auditor; organizing for audit; preparing for audit; Performing the audit; closing the audit; the audit report; overview of QSIT
10	Process Validation	FDA Guide to Process Validation Jan 2011: Stages 1, 2 and 3 including ASTM 2500E
11	Quality Risk Management	In-depth and practical coverage of ICH Q9 (QRM)
12	Cleaning Validation	In-depth and practical coverage
13	Quality with Productivity	Exploring strategies for improving both productivity and compliance levels simultaneously
14	OECD GLP	Presented along the requirements specified in USFDA's 21CFR58 and EPA's 40CFR806

**Group size** 6 participants from the same Organisation

**Timings** 0900 to 1800 hrs

### Center for GMP

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