Quality Systems: CLIA/CAP Readiness for Bioinformatics Labs — Hands-on

Build a pragmatic, audit-proof Quality Management System (QMS) for clinical bioinformatics. This module translates CLIA/CAP expectations into day-to-day workflows across validation/verification, documentation, data integrity (ALCOA+), training & competency, supplier qualification, change control, internal audits, and CAPA—so your pipelines and reports can withstand inspections.

Quality Systems: CLIA/CAP Readiness for Bioinformatics Labs

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Session Index **Category 5 · Clinical & Translational Bioinformatics**

Session 1
Fee: Rs 23120 Apply Now

QMS & CAP/CLIA Foundations

Quality system architecture

policy → SOP → WI → forms **roles & responsibilities** **quality manual**

CAP checklist mapping (high-level)

bioinformatics-specific items **pre-analytical → post-**

analytical risk-based priorities

CLIA applicability (overview)

LDTs & reporting personnel & supervision proficiency testing

Session 2

Fee: Rs 27320 Apply Now

Validation/Verification & Data Integrity

Method validation & verification

accuracy/precision/LoD/LoQ linearity/reportable range reference materials & QC

Bioinformatics pipeline V&V

truth sets/coverage change impact analysis re-validation triggers

ALCOA+ data integrity

attributable/legible/contemporaneous original/accurate/complete consistent/enduring/available

Session 3

Fee: Rs 31520 Apply Now

Documentation, Training & Change Control

Doc control & templates

SOP/WI/forms/versioning traceability & records electronic signatures

Training & competency

matrices & curricula assessments/attestations continuing education

Change control & suppliers

software/hardware changes **vendor qualification** **service level oversight**

Session 4

Fee: Rs 37120 Apply Now

Internal Audits, CAPA & Inspection Readiness

Internal audit program

plans/checklists **objective evidence** **reports & follow-ups**

Deviations, incidents & CAPA

root-cause analysis **effectiveness checks** **trend reviews**

Inspection readiness

war room & SME prep **mock inspections** **continuous improvement**