Clinical Quality Management & Validation (IQ/OQ/PQ) — Hands-on

Understand how quality systems and validation activities are applied to clinical genomics pipelines. This module focuses on IQ/OQ/PQ style validation thinking, SOPs, controlled documents, traceability and how to generate audit ready evidence for pipelines, software and reporting workflows in regulated or pre regulated settings.

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Help Desk · WhatsApp

Session Index

Session 1 — Clinical QMS Foundations   Session 2 — Validation Concepts & IQ/OQ/PQ Logic

Session 3 — Method & Pipeline Validation Evidence   Session 4 — Mini Capstone: Validation Pack Snapshot

Session 1
Fee: Rs 8800 Apply Now

Clinical QMS Foundations

Why quality systems matter in clinical genomics

patient safety mindset reproducibility and traceability regulatory expectations snapshot

Core QMS building blocks (high level)

SOPs and controlled documents roles and responsibilities change control and deviations

Process mapping for sample to report workflows

pre analytic, analytic, post analytic view | hand offs and interfaces | risk points identification mindset

Session 2
Fee: Rs 11800 Apply Now
Validation Concepts & IQ/OQ/PQ Logic

What validation means for NGS pipelines and tools

fit for intended use mindset | analytical vs clinical validation (conceptual) | prospective vs retrospective data usage

IQ, OQ and PQ — high level view

installation qualification idea | operational qualification idea | performance qualification idea

Linking validation activities to documentation

plans and protocols | raw results and summary reports | sign off and archiving

Session 3
Fee: Rs 14800 Apply Now
Method & Pipeline Validation Evidence

Designing validation studies for pipelines and reports

reference materials and benchmark datasets | positive and negative controls mindset | repeatability and reproducibility snapshot

Key performance characteristics (high level)

sensitivity and specificity idea | precision and accuracy idea | reportable range and limits concept

Capturing results in validation summary tables

metrics tables exceptions and deviations notes conclusions and residual risks

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Session 4
Fee: Rs 18800 Apply Now

Mini Capstone: Validation Pack Snapshot

Start from a simple pipeline or report change scenario

Theory + Practical

Draft a mini validation plan and summary table

scope and acceptance criteria test matrix snapshot conclusion statement

Assemble a simple validation documentation bundle

plan and protocol files results and summary page sign off and archive checklist