Regulatory Pathways — CLIA, CAP, IVDR & NDC/GMP — Hands-on

Get a practical, high level view of how regulatory pathways such as CLIA, CAP, IVDR and NDC/GMP influence clinical genomics labs and tests. This module focuses on concepts, documentation expectations and readiness mindset so that teams can align their pipelines, validation evidence and reports with evolving regulatory frameworks. Content is for training and awareness, not legal or regulatory advice.

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Session Index

Session 1

Fee: Rs 8800 Apply Now

Regulatory Landscape for Genomic Testing

Why regulatory pathways matter for genomic tests

patient safety and reliability mindset | **market access and accreditation snapshot** | **evidence and documentation expectations (high level)**

High level view of key frameworks

CLIA and CAP (laboratory focussed) **IVDR (device and test focussed)** **NDC/GMP style ideas for products**

Where bioinformatics fits into regulatory thinking

pipeline as part of the test system **validation and change control snapshot** **data and report traceability mindset**

Session 2
Fee: Rs 11800 Apply Now

CLIA & CAP Concepts and Lab Impact

Clinical Laboratory Improvement Amendments (CLIA) — high level ideas

laboratory certification mindset **test complexity and oversight snapshot** **quality and proficiency testing concepts**

College of American Pathologists (CAP) programmes — overview

accreditation programme snapshot **proficiency testing schemes idea** **checklists and inspections (conceptual)**

Implications for NGS and clinical genomics labs

documented procedures and QMS linkage **validation and ongoing monitoring** **people, training and competency records**

Session 3
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IVDR, NDC/GMP & Global View (High Level)

In vitro diagnostic regulation (IVDR) — concept snapshot

device and test classification idea **performance and**

clinical evidence mindset | documentation families (high level)

NDC/GMP style ideas for marketed tests and kits

manufacturing quality concepts | lab developed tests vs kits mindset | lab obligations vs manufacturer obligations (conceptual)

Putting it together: global high level view

different regions, common principles | evidence, validation and documentation threads | when to seek specialist regulatory advice

Session 4

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Mini Capstone: Pathway & Documentation Map

Start from a simple genomic test use case

Theory + Practical

Sketch a high level regulatory pathway view

relevant frameworks checklist | lab vs product responsibilities (conceptual) | key evidence themes

Draft a documentation and readiness map

policies and SOPs snapshot | validation and QMS links | open questions for regulatory experts