

Privacy, Security, HIPAA & 21 CFR Part 11 for Bioinformatics — Hands-on

Build compliance-by-design pipelines for clinical and translational bioinformatics. This hands-on module covers HIPAA/HITECH and 21 CFR Part 11 essentials, global privacy context (GDPR/India DPDP — overview), de-identification and consent, technical/administrative controls, computer system validation, documentation, and day-to-day compliance operations for audit readiness.

Privacy, Security, HIPAA & 21 CFR Part 11 for Bioinformatics

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Bioinformatics**

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Validation** **Session 3 — Clinical Data Governance & Safe Analytics** **Session 4 — SOPs, Evidence &
Audit Readiness**

Session 1

Fee: Rs 22520 [Apply Now](#)

Regulatory Landscape & Data Protection

HIPAA/HITECH essentials

PHI & identifiers **covered entities & BAAs** **minimum
necessary**

21 CFR Part 11 scope

e-records & e-signatures **validation expectations**

audit trails/time stamps

Global privacy (overview)

GDPR principles **India DPDP Act** **DPIA/TRA basics**

Session 2

Fee: Rs 26720 Apply Now

Controls, Security Architecture & Validation

Access & identity

RBAC/ABAC **MFA/SSO** **least privilege**

Crypto & logging

TLS/at-rest encryption **KMS & key rotation** **tamper-evident logs**

CSV & GxP validation

VMP & risk-based approach **IQ/OQ/PQ** **change control**

Session 3

Fee: Rs 30920 Apply Now

Clinical Data Governance & Safe Analytics

De-identification & consent

Safe Harbor vs Expert **limited datasets & DUAs**
consent management

Secure environments

segmented VPC/VNET **data egress controls**
workspace hardening

Monitoring & incidents

SIEM & alerts **IR playbooks** **breach notification**

Session 4

Fee: Rs 36520 Apply Now

SOPs, Evidence & Audit Readiness

Documentation & training

policies/SOPs/WIs **role-based training** **competency records**

Vendors & contracts

BAAs & DPAs **right to audit** **SLAs & SLOs**

Audits & CAPA

checklists & evidence **findings → CAPA** **continuous improvement**