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COURSE BROCHURE

Diagnostic Test Regulation and Performance Evidence Training Course

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Kuala Lumpur

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Registered in the United Kingdom and Saudi Arabia

Diagnostic Test Regulation and Performance Evidence Training Course

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Diagnostic Test Regulation and Performance Evidence is a 1-week training course for regulatory affairs specialists, quality managers and laboratory product managers, and each participant builds a diagnostic test regulatory dossier with a linked post-market surveillance plan. Diagnostics makers now face tighter scrutiny of clinical claims, more tests moving into higher risk classes and closer follow-up after launch. Jupiter Prime Training treats diagnostic test regulation and performance evidence as one connected discipline.

Why Diagnostic Test Regulation and Performance Evidence Matters Now

Three forces shape the field. Regulators in many markets have moved from self-declaration towards independent assessment for a larger share of diagnostic tests. Clinicians and laboratories expect published sensitivity, specificity and limits of detection to hold up in routine use. A manufacturer that plans evidence early reaches markets with fewer questions and recalls fewer lots. One that treats the dossier as paperwork faces delayed approvals, restricted claims and field safety actions. The course rests on general principles of risk-based classification, analytical and clinical performance evaluation and quality system control.

Who Gains Most from Diagnostic Test Regulation and Performance Evidence

- Specialists who classify new assays and choose the route to market
- Staff who plan and report analytical and clinical performance studies
- Quality leads who keep design records, labelling and change control aligned
- Product owners who translate intended purpose into claims and study scope
- Vigilance officers who track complaints, trends and field corrective actions

Cross-functional launch teams in diagnostics companies gain most when several members attend together because classification, evidence and labelling decisions interlock.

Diagnostic Test Regulation and Performance Evidence Capabilities

Participants learn to connect an assay's intended purpose to the evidence, files and monitoring regulators expect.

- Assign a risk class to a diagnostic test from its intended purpose — route to market
- Specify analytical performance studies for accuracy, precision and interference — design verification sign-off
- Design a clinical performance study with suitable specimen populations — evidence reviewers
- Build a technical file structure that traces claims to evidence — assessment bodies
- Test labelling and instructions for use against stated performance — laboratories and patients
- Apply trend analysis to complaint and vigilance data — field safety decisions

Key Diagnostic Test Regulation and Performance Evidence Terms

- Intended purpose — the manufacturer's statement of what a test detects in which specimen and for which clinical use.
- Analytical performance — how accurately and consistently a test measures its target.
- Clinical performance — the ability of a test to give results that correlate with a clinical condition.
- Scientific validity — the established link between the measured marker and the clinical condition the test addresses.
- Conformity assessment — the process showing that a test meets applicable requirements before it is placed on the market.
- Post-market surveillance — the planned collection and review of real-world data on a test after release.

Diagnostic Test Regulation and Performance Evidence Day by Day

Day 1: The Regulatory Landscape for Diagnostic Tests

- Intended Purpose Statements — Defining Target, Specimen, Population and Clinical Use
- Risk-Based Classification Rules — Placing Assays, Self-Tests and Companion Tests
- Conformity Assessment Routes — Choosing Between Self-Declaration and Independent Review
- Economic Operator Roles — Assigning Duties to Makers, Importers and Distributors
- General Safety and Performance Requirements — Mapping Obligations to Product Features

Day 2: Building Performance Evidence

- Scientific Validity Reports — Linking Marker to Clinical Condition
- Analytical Study Protocols — Measuring Accuracy, Precision, Interference and Detection Limits
- Clinical Performance Study Design — Selecting Specimens, Comparators and Sample Size
- Performance Evaluation Plans — Sequencing Evidence Across the Product Lifecycle
- Literature and Existing Data Appraisal — Deciding When Published Evidence Suffices

Day 3: Technical Files and Quality Controls

- Technical File Architecture — Tracing Every Claim to Supporting Evidence
- Design and Change Control Records — Judging When Changes Need Fresh Evidence
- Labelling and Instructions for Use — Aligning Stated Performance With Results
- Risk Management Files — Linking Hazards, Controls and Residual Risk
- Supplier and Reagent Lot Controls — Protecting Consistency Between Batches

Day 4: Life After Market Release

- Post-Market Surveillance Plans — Choosing Data Sources and Review Frequency
- Performance Follow-Up Studies — Confirming Claims in Routine Laboratory Use
- Complaint Trend Analysis — Separating Signals From Background Noise
- Vigilance Reporting Decisions — Classifying Serious Incidents and Field Actions
- Periodic Safety Summaries — Communicating Benefit and Risk to Reviewers

Day 5: Practising the Regulatory Dossier

- Classification Rationale Drafting — Applying Rules to a Participant Assay
- Evidence Gap Assessment — Testing Existing Studies Against Stated Claims
- Labelling Consistency Check — Reconciling Instructions With Performance Data
- Surveillance Plan Assembly — Defining Indicators, Thresholds and Reporting Lines
- Regulatory Dossier Completion — Combining Classification, Evidence, File and Surveillance Plan

Applying Diagnostic Test Regulation and Performance Evidence After the Course

- Run an evidence gap assessment on one marketed or late-stage assay and log each unsupported claim.
- Review the post-market surveillance plan of one product line and add trend indicators with escalation thresholds.

Diagnostic Test Regulation and Performance Evidence Questions FAQ

What is diagnostic test regulation and performance evidence, and why does it matter now?

It is the set of rules and studies that show a diagnostic test is safe and performs as claimed. It matters now because more tests require independent assessment, and clinicians expect stated performance to hold in practice.

Which roles gain most from diagnostic test regulation and performance evidence skills?

Regulatory affairs specialists, quality managers and laboratory product managers gain most. Study planners and vigilance officers also benefit, from hospital analysers to home self-tests.

How does diagnostic test regulation and performance evidence differ from a general medical device course?

It concentrates on the evidence specific to tests that examine specimens rather than treat patients. You work on scientific validity, analytical and clinical performance and specimen-based studies, which general device courses cover only briefly.

What will I bring back from diagnostic test regulation and performance evidence training?

You bring back a regulatory dossier outline for a real assay. It holds a classification rationale, an evidence map, a labelling check and a post-market surveillance plan your team can extend.

Diagnostic Test Regulation and Performance Evidence: The Way Forward

The diagnostic test regulatory dossier first informs which conformity route a product takes and which studies must run before submission. Regulatory, quality and product staff all use it. After its first use, the surveillance indicators are worth revisiting, because real complaint patterns often show which performance claims need closer follow-up.