In Vitro Diagnostic Regulatory Affairs Training Course

11 – 15 October 2027
Kuala Lumpur

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Overview

In Vitro Diagnostic Regulatory Affairs Training Course is a one-week advanced programme for professionals who plan, assemble, review, or maintain regulatory evidence for in vitro diagnostic devices. Participants connect intended purpose, qualification, classification, conformity assessment, quality management, risk management, performance evaluation, technical documentation, economic-operator responsibilities, market access, post-market surveillance, vigilance, and lifecycle change control. The course uses the European IVD regulatory framework as a structured case environment while requiring every participant to verify current jurisdiction-specific obligations with authorised regulatory and legal specialists.

Each participant develops an IVD Regulatory Pathway Dossier for a selected diagnostic product. The dossier brings together a regulatory strategy, classification rationale, evidence map, quality and risk interfaces, performance-evaluation plan, submission readiness review, surveillance design, and governance calendar. Agile Leaders Training Center presents regulatory affairs as a traceable lifecycle system rather than a one-time submission exercise.

Who Should Attend

- Regulatory-affairs professionals responsible for diagnostic product strategy, submissions, registrations, and change assessment
- Quality-assurance professionals maintaining an IVD quality management system and regulatory records
- Clinical, scientific, and performance-evaluation teams responsible for analytical and clinical evidence
- Risk-management and product-safety specialists linking hazards, controls, performance, and surveillance
- Research, development, engineering, and product-management teams preparing IVD products for market
- Manufacturing, supply-chain, and authorised-representative teams supporting economic-operator obligations
- Internal auditors and compliance professionals reviewing regulatory readiness and lifecycle controls

This advanced course assumes familiarity with medical-device or diagnostic product development. It does not provide legal advice, certification, notified-body approval, or a jurisdiction-specific market authorisation.

Departments and Industries

The course supports in vitro diagnostic regulatory affairs across:

- Regulatory affairs, quality assurance, clinical affairs, medical affairs, product safety, and compliance
- Diagnostic manufacturers, laboratories, biotechnology companies, software-enabled diagnostic developers, and contract organisations
- Importers, distributors, authorised representatives, research institutions, and healthcare technology organisations
- Product development, manufacturing, supply chain, post-market surveillance, and executive governance functions

Learning Objectives

- Map the IVD ecosystem, relevant actors, and regulatory responsibilities across the product lifecycle
- Define intended purpose and document qualification and classification decisions
- Select and justify a conformity-assessment and market-access pathway
- Connect quality-system processes, risk management, and regulatory evidence
- Structure analytical, clinical, and scientific performance-evaluation evidence
- Plan technical documentation and conduct an evidence-readiness review
- Design post-market surveillance, vigilance, trend reporting, and corrective-action interfaces
- Govern regulatory changes, renewals, registrations, and continuing obligations

Practical Work Product

Participants build an IVD Regulatory Pathway Dossier containing:

- Product and intended-purpose profile
- Qualification and classification decision record
- Actor and responsibility map
- Conformity route and evidence requirements matrix
- Quality and risk-management interface map
- Performance-evaluation evidence plan
- Technical-documentation readiness tracker
- Post-market surveillance and vigilance framework
- Regulatory change and governance calendar

Day 1: IVD Regulatory Ecosystem and Product Scope

- Diagnostic product lifecycle and the roles of manufacturers, authorities, notified bodies, laboratories, representatives, importers, and distributors
- Product concept, intended purpose, target population, specimen, user, setting, and claimed benefit
- IVD qualification boundaries and interfaces with medical devices, laboratory-developed activities, research-use products, and software
- Regulatory intelligence sources, controlled assumptions, and evidence traceability
- Responsibility assignment through a regulatory actor map and decision log

Workshop: create the product profile, stakeholder map, and regulatory-question register for the IVD Regulatory Pathway Dossier.

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Day 2: Classification and Market-Access Pathway

- Risk-based classification logic and the evidence needed to support a classification rationale
- Classification rules, special characteristics, companion diagnostics, self-testing, near-patient testing, and software considerations
- Conformity-assessment routes and the consequences of product class for external assessment
- Economic-operator readiness, registration, identification, labelling, and language considerations
- Market-access sequencing, dependency mapping, and regulatory milestone planning

Workshop: produce a documented classification rationale, conformity route, and milestone map with explicit assumptions and escalation points.

Day 3: Quality, Risk, and Technical Documentation

- IVD quality management system interfaces with design, suppliers, production, verification, release, complaints, and corrective action
- Risk-management planning, hazard identification, risk controls, benefit-risk reasoning, and residual-risk communication
- Traceability between intended purpose, requirements, risks, verification, validation, labelling, and claims
- Technical-documentation architecture, document ownership, version control, and evidence-status tracking
- Submission-readiness reviews, evidence gaps, remediation priorities, and governance checkpoints

Workshop: build a quality-risk-regulatory traceability matrix and a technical-documentation readiness tracker.

Day 4: Performance Evaluation and Evidence Governance

- Scientific validity, analytical performance, and clinical performance as connected evidence streams
- Performance-evaluation planning, acceptance criteria, data provenance, protocol controls, and report structure
- Study governance, specimen considerations, bias, limitations, deviations, and evidence quality
- Claim-evidence alignment and disciplined review of labels, instructions, promotional statements, and intended users
- Evidence maintenance, literature monitoring, performance follow-up, and lifecycle updates

Workshop: create a performance-evaluation evidence map that links claims, endpoints, data sources, gaps, owners, and approval decisions.

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Day 5: Post-Market Control and Regulatory Governance

- Post-market surveillance planning, complaint inputs, performance signals, trend review, and periodic reporting
- Vigilance assessment, reportability decisions, timelines, field actions, and authority communications
- Corrective and preventive action interfaces with risk files, performance evidence, labelling, and product changes
- Change assessment for design, supplier, manufacturing, software, intended purpose, claims, and market expansion
- Regulatory governance dashboard, renewal calendar, management review, escalation, and audit readiness

Capstone: present and challenge the completed IVD Regulatory Pathway Dossier through a simulated cross-functional regulatory review board.

Training Methods

- Facilitated regulatory pathway mapping and decision exercises
- Diagnostic product case studies with incomplete or conflicting evidence
- Classification, traceability, and performance-evaluation workshops
- Cross-functional review-board simulation and peer challenge
- Templates for evidence mapping, readiness tracking, surveillance, and change governance

Course Outcomes

Participants leave able to organise a defensible regulatory pathway, expose evidence gaps early, assign accountable owners, and maintain product compliance throughout the IVD lifecycle. They also leave with a practical dossier structure that can be adapted to their organisation only after review against current laws, guidance, quality procedures, and market-specific requirements.

Frequently Asked Questions

Does the course cover the European IVD regulatory framework?

Yes. It uses the European framework and related guidance as a structured learning environment, while distinguishing regulatory principles from advice for a specific product or market.

Is this an introductory IVD course?

No. It is designed for experienced professionals who need to integrate regulatory, quality, risk, performance, and post-market work into one governed pathway.

Does completing the course confer certification or market approval?

No. Course completion does not constitute certification, conformity assessment, regulatory authorisation, or legal advice.

What practical document will I produce?

You will build an IVD Regulatory Pathway Dossier containing the core decision records, evidence maps, readiness controls, and lifecycle governance tools developed during the one week.