UNITED KINGDOM IVD REGULATORY MAP

A practical orientation for global RA teams entering the UK

START HERE: WHAT IS THE PRODUCT IN THE UK?

1 Confirm UK regulatory identity

Confirm the intended use, how the product will be supplied (professional use or self-test), and whether it falls within a higher-risk category under the UK framework (Annex II List A or List B). This determines the conformity assessment involvement where applicable, evidence expectations, and MHRA oversight.

General IVD | Self-test IVD | Annex II List B IVD | Annex II List A IVD

2 Choose the regulatory route (Great Britain framework)

GENERAL IVD	SELF-TEST IVD	ANNEX II LIST B IVD	ANNEX II LIST A IVD
Lowest risk	Low–moderate risk	Higher risk	Highest risk
Self-declaration No conformity assessment body involvement. Lower regulatory scrutiny and evidence expectations.	**Self-declaration** Additional requirements for lay user safety, usability and performance evidence compared with General IVDs.	**Conformity assessment *(where applicable)*** Requires involvement of a UK Approved Body (AB) for assessment against the UKCA Technical Documentation requirements.	**Conformity assessment *(where applicable)*** Requires involvement of a UK Approved Body (AB) and the most extensive scrutiny and evidence to demonstrate device safety and performance.

3 Build the UK market-access infrastructure

MHRA framework
Understand UK IVDR as it applies in Great Britain and MHRA expectations for the IVD lifecycle.

UK Responsible Person / local setup *(where applicable)*
Identify and appoint a UK Responsible Person if required. Ensure PRRC availability and UK contact arrangements.

MHRA registration
Register the manufacturer and devices with the MHRA via the Devices REG service and maintain records and post-market obligations.

English labeling / commercialization readiness
Prepare English labeling, IFU and marketing content that meet UK requirements for legal manufacturer and device information.

4 Build the evidence stack

Administrative
QMS documentation, product specification, GSPR checklist, risk management, PMS plan.

Quality
QMS to ISO 13485, process validation, supplier control, traceability and change control.

Analytical performance
Performance, accuracy, precision, interference and robustness studies per product claims.

Clinical / scientific
Clinical performance or scientific evidence supporting intended use and claims; literature as applicable.

Labeling & IFU
English labeling and IFU meeting UK requirements for content, symbols, UDI and traceability.

RA TRAP TO AVOID
Do not begin with "What is the UK timeline?" Begin with product identity → correct category (General, Self-test, List B, or List A) → conformity assessment involvement (where applicable) → MHRA registration → labeling & evidence. The timeline is the result of these decisions.

STRATEGIC INSIGHT:
Category, conformity assessment involvement (where applicable), and MHRA registration drive the timeline. Getting these right early prevents rework and delays.

UNITED KINGDOM IVD: HOW THE WORK ACTUALLY FLOWS

From classification to commercialization — with the decision points a newer RA professional should watch

A Program flow

1. **Scope** — Confirm intended use, product, & user.
2. **Classify** — Determine UK classification (General, Self-test, Annex II List B or A).
3. **Conformity assessment strategy** — Select route & evidence approach.
4. **UKRP / local setup** — Appoint UK Responsible Person (UKRP) and ensure local presence.
5. **Evidence** — Assemble technical documentation & performance evidence.
6. **Register** — Register device with MHRA (Part 4 of UK MDR 2002).
7. **Launch / maintain** — Place on GB market, maintain vigilance & post-market processes.

B What gets heavier as the category rises?

Signal	GENERAL IVD	SELF-TEST IVD	ANNEX II LIST B	ANNEX II LIST A
Pathway intensity	Lower ●	Moderate ●●	Higher ●●●	Highest ●●●●●
Analytical performance expectations	Basic ●	Core ●●	Enhanced ●●●	Extensive ●●●●●
Clinical / scientific support	Limited ●	Moderate ●●	Substantial ●●●	Extensive ●●●●●
Quality / conformity assessment readiness	Basic ●	Core ●●	Advanced ●●●	Comprehensive ●●●●●
Post-market control & surveillance	Lower ●	Moderate ●●	Higher ●●●	Highest ●●●●●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on device complexity, evidence quality, QMS readiness, translation/localization, UKRP readiness, MHRA processing, and other factors.

Ranges are indicative and not legal commitments. Expect variation by product, evidence, translations, and MHRA workload.

Both UK Approved Bodies (for certain classifications) and self-assessment (for others) are used. Check current rules by classification.

D Labeling & language essentials

- ☑ **English-language support** — All labeling, IFU and information provided in English.
- ☑ **Product labeling** — Labels must include mandatory information per UK MDR 2002 (Part 3 & 4).
- ☐ **Instructions for use** — Clear, accurate IFU, including intended user, limitations, performance, and warnings.
- ☐ **Claims control** — Claims must be evidence-based, balanced, and not misleading.
- ☑ **Product-specific ID & documentation** — Maintain UDI (where required), batch/lot, and technical documentation.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- MHRA — Overview of the UK Medical Devices Regulations 2002 (*as amended*): *gov.uk/guidance/overview-of-the-uk-medical-devices-regulations-2002*
- MHRA — IVD classification guidance: *gov.uk/guidance/ivd-classification*
- MHRA — Register a medical device: *gov.uk/guidance/register-a-medical-device*
- MHRA — UK Responsible Person (UKRP) guidance: *gov.uk/guidance/uk-responsible-person*
- GOV.UK — Medical devices information hub: *gov.uk/medical-devices*
- Hopestone Capital & Consulting: hopestonecapital.com

Important: Product-specific UK requirements, guidance, standards, and recent regulatory changes govern. Confirm current requirements before execution.

