INDIA IVD REGULATORY MAP

A practical orientation for global RA teams entering India

START HERE: WHAT IS THE PRODUCT IN INDIA?

1 Confirm Indian regulatory identity

Confirm the intended use, IVD status, and risk classification of the product under the Medical Devices Rules, 2017 (as amended), administered by the Central Drugs Standard Control Organization (CDSCO).

- IVD product
- IVD status under MDR 2017
- Risk classification (A–D)

2 Choose the regulatory route

CLASS A	CLASS B	CLASS C	CLASS D
Lowest risk	Low-to-moderate risk	Moderate-to-high risk	Highest risk
Low risk to patient and user. Inputs from well-established sources.	Moderate risk. Non-invasive or transient devices; some performance and QC requirements.	Higher risk devices; critical performance requirements and stronger evidence expectations.	Highest risk to patient or public health. Extensive evidence and regulatory scrutiny.
Imports generally require CDSCO import license processes.	Imports generally require CDSCO import license processes.	Imports generally require CDSCO import license processes and closer review.	Imports generally require CDSCO import license processes and highest level of review.

3 Build the India market-access infrastructure

CDSCO / MDR framework
Understand MDR 2017, IVD classification rules, import requirements, essential principles, and compliance obligations.

Indian Authorized Agent / importer setup
Appoint an Indian Authorized Agent (mandatory for foreign manufacturers) and establish compliant importer arrangements.

Licensing and dossier readiness
Prepare technical file per class, including performance evaluation, QMS, manufacturing details, Free Sale Certificate (FSC), and other required documents.

English labeling / commercialization readiness
Ensure English labeling, English IFU, UDI compliance, claims substantiation, and readiness for market launch.

4 Build the evidence stack

Administrative
Device details, FSC, Authorized Agent appointment, plant details, and other administrative documents.

Quality / QMS
ISO 13485 certified QMS, manufacturing controls, change management, CAPA, and continual improvement.

Analytical performance
Analytical sensitivity, specificity, accuracy, precision, robustness, reportable range, and method validation data.

Clinical / scientific performance
Clinical performance evidence appropriate to class, including clinical evaluation and literature support.

Labeling & IFU
English labeling and IFU, symbols, intended use, claims, precautions, and user instructions.

RA TRAP TO AVOID
Do not start with the timeline—start with classification (MDR 2017), import/manufacturing path, Authorized Agent, and evidence. Missteps early create costly delays later.

STRATEGIC INSIGHT:
In India, the import licensing route, device class, and local representation are the primary drivers of the timeline. Get them right early to move faster.

Training overview — verify current product-specific requirements with CDSCO and your Indian Authorized Agent. Not legal advice.

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INDIA IVD: HOW THE WORK ACTUALLY FLOWS

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

A Program flow

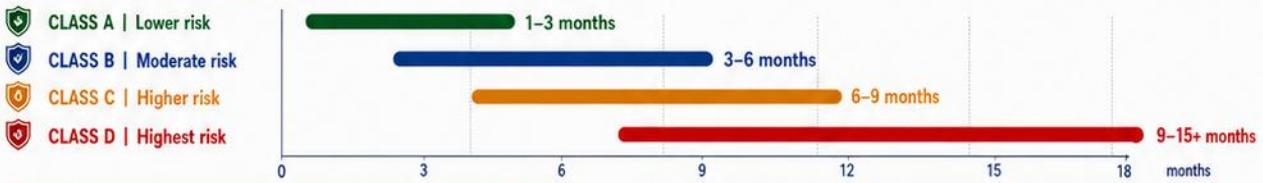
1. **Scope** — Define intended use and product family
2. **Classify** — Determine risk classification (Class A–D) per MDR 2017
3. **Route selection** — Confirm regulatory route (Import or Manufacture) and requirements
4. **Authorized agent / importer setup** — Appoint Indian authorized agent / importer and ensure registration
5. **Evidence** — Analytical performance, clinical performance, and evaluation
6. **Submit / license** — Submit application via SUGAM portal and obtain licence to import / manufacture
7. **Launch / maintain** — Market authorization, post-market controls, changes, vigilance

B What gets heavier as the class rises?

Signal	CLASS A	CLASS B	CLASS C	CLASS D
Pathway intensity	Lower ●○○○	Moderate ●●○○	High ●●●○	Very high ●●●●
Analytical performance	Basic ●○○○	Moderate ●●○○	High ●●●○	Very high ●●●●
Clinical / scientific support	Not usually required ○○○○	Limited / targeted ●○○○	Moderate ●●●○	Extensive ●●●●
QMS readiness	Basic ●○○○	Moderate ●●○○	High ●●●○	Very high ●●●●
Post-market control	Lower ●○○○	Moderate ●●○○	Higher ●●●○	Highest ●●●●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on CDSCO review timelines, completeness of submission, class, and import / manufacturing pathway.



Timelines are indicative and may vary by product class, submission quality, and CDSCO workload.

Early engagement, complete evidence, and accurate documentation can significantly reduce review cycles.

D Labeling & language essentials

English-language support
All labeling and instructions must be in English.

Product labeling
Include required details, intended use, warnings, precautions, and symbols.

Instructions for use
Provide complete and clear IFU in English as part of the submission.

Claims control
Claims must be supported by evidence and consistent with intended use.

Product identifier & traceability docs
Include UDI/device identifier, lot/batch, and traceability documentation.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- CDSCO – *Medical Devices*: https://cdsco.gov.in/opencms/opencms/en/MedicalDevices
- CDSCO – *In Vitro Diagnostics (IVD)*: https://cdsco.gov.in/opencms/opencms/en/IVD
- *Medical Device Rules, 2017 (MDR 2017)*: https://cdsco.gov.in/opencms/opencms/en/ActsRules
- SUGAM Portal (Licensing): https://sugam.cdsco.gov.in
- Hopestone Capital & Consulting: hopestonecapital.com

IMPORTANT

Product-specific Indian requirements, current CDSCO guidance, and applicable notifications govern.

Confirm current requirements before execution.

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