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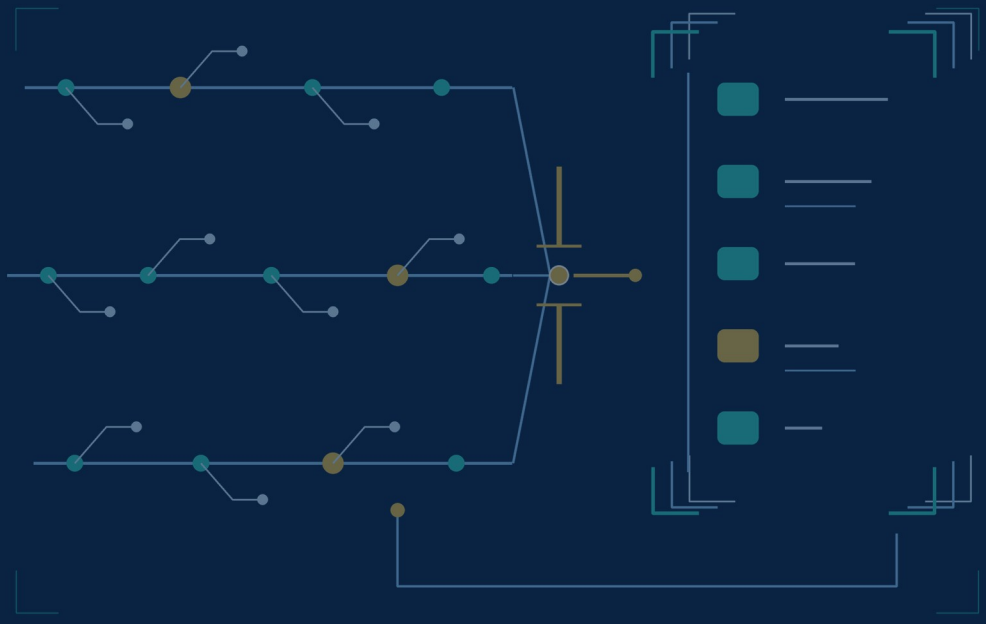
MEDDEV ADVISORY · PRACTITIONER HANDBOOK

CDSCO Medical Device Biological Safety Submission Playbook

Building defensible ISO 10993 evidence into India's Device Master File under the Medical Devices Rules, 2017



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Correction history — version 1.1.0 Version 1.0.1 described G.S.R. 269(E) and G.S.R. 270(E) as draft-only despite stating a source baseline through 21 August 2026. Their final instruments, G.S.R. 744(E) and G.S.R. 743(E), were notified on 14 August 2026 and published in the Official Gazette dated 19 August 2026. Version 1.1.0 corrects that missed source reconciliation in Chapters 1–3, 5, 7–9 and 15; the source and claim registers; the appendices; the public preview; release notes; manifests; and customer-package controls. Version 1.0.1 is preserved as a historical artifact but is superseded for current-use purposes. This critical MedDev Advisory correction is due without charge to every verified affected purchaser or resource licensee, irrespective of Update Assurance. Update Assurance remains a separate benefit for later external-change alerts, impact notes and eligible releases.

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How to use this playbook

Using the worksheets

The worksheets in this reading edition are reference structures, not fillable PDF forms. For live work, transfer the relevant fields into the manufacturer's controlled quality-management-system record or an approved editable template. Preserve the record identifier, revision, decision status, owner, approval and reopening trigger whenever a worksheet is copied or adapted. Any editable companion is a separate controlled product and is governed by its own licence and release status.

The operating method

Use the book as one connected workflow rather than a collection of India facts. Each stage answers a different question and produces an input for the next.

1. **Qualify the route.** Record the device, intended use, classification source, grouping, applicant, manufacturer, sites, authority and application context. Keep assumptions visible.
2. **Lock the applied device.** Reconcile the model and configuration list, labels, claims, contact, supply state, shelf life and manufacturing state to the application.
3. **Control sources and status.** Separate law, final amendments, guidance, FAQ/checklist interpretation, portal practice, standards and drafts. Record the check date.
4. **Map the dossier.** Show where device description, materials, risk, Essential Principles, verification and validation, biological evidence, clinical evidence and post-market information live and how they connect.
5. **Test evidence applicability.** For each record, name the article, model, lot, supplier, process, site, sterilisation, packaging/ageing state, use and claim that it can support.
6. **Choose an evidence route.** Evaluate the biological question, existing evidence, uncertainty and consequences before deciding whether literature, device knowledge, chemistry, toxicology, biological testing, clinical or post-market evidence—or a combination—is appropriate.
7. **Write for reconstruction.** Give the reviewer a direct, bounded narrative and exact approved-document locations. Do not force the reviewer to infer the device or assemble the argument.
8. **Maintain the position.** Reopen the assessment when the device, process, supplier, site, sterilisation, packaging, intended use, evidence, complaints, sources or standards change.

For the fictional sterile fluid-path set, the workflow begins with a provisional domestic Class B route. The charter then fixes the applied configurations, assembly site and outside sterilisation site. The source register separates the Rules from an administrative sterilisation letter, its historical draft record and the later final amendment. The dossier crosswalk shows where the device description, risk, biological evidence, sterilisation and stability records connect. The device-state map then tests whether resin plaques and legacy finished-device reports represent the current sterile, packaged set. The example ends with open work because the evidence does not yet justify a broader conclusion.

Steps may overlap, and specialist or authority clarification may redirect the work. The sequence prevents a report, certificate, test result or foreign-market decision from silently answering a different India question.

Chapter 1 — One India Market, Several Regulatory Routes

Chapter outcome Decide the India route, authority and applicant role, then record the governing sources, assumptions and escalation points in a dated route-and-authority record.

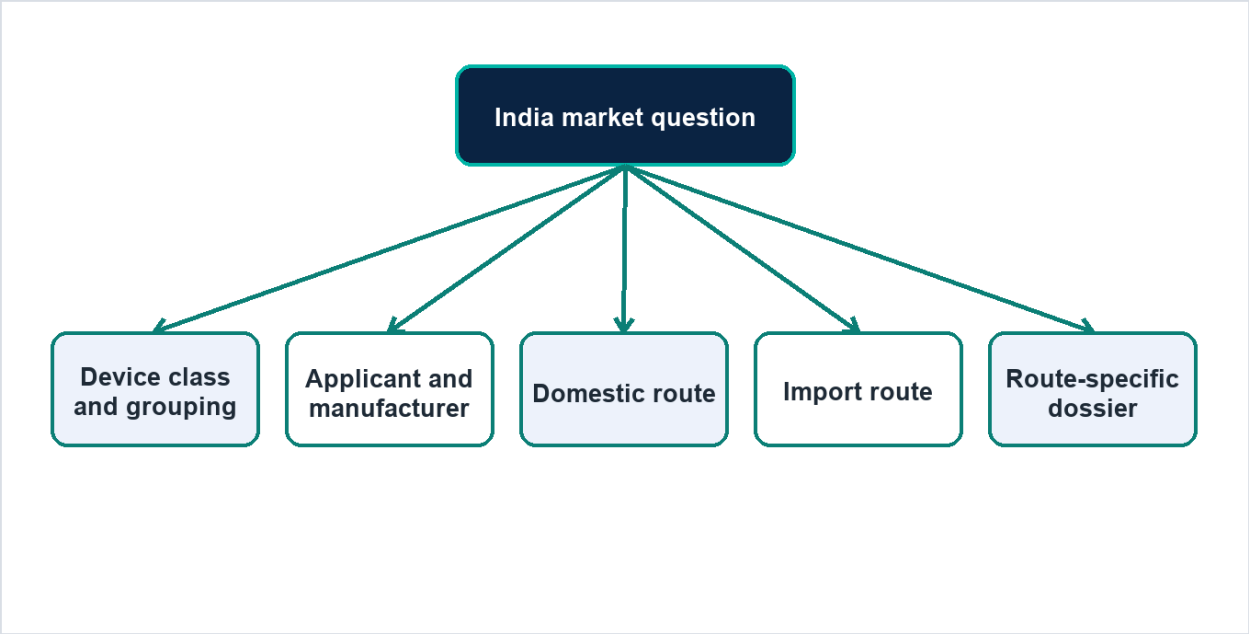

Figure 1. An India submission begins by separating route, authority and applicant role

Why route labels fail

The common failure is not ignorance of the four risk classes. It is starting the technical file after attaching a familiar route label to an incomplete product description. A manufacturer may say “Class B domestic”, an importer may say “already CE marked”, or a founder may say “Class A, therefore exempt”. Each phrase hides decisions about scope, intended use, sterile or measuring status and current India classification. It can also hide the transaction, applicant, loan-licence arrangement or an investigational-device boundary.

When these decisions remain implicit, the biological file is built for a route that may not exist. A full Device Master File may be assembled for a product using the Class A non-sterile/non-measuring registration pathway, while another team may treat that registration pathway as permission to retain no supporting evidence. A foreign manufacturer may send a global technical file without defining the Indian authorised agent or applied sites. A domestic team may treat a test licence used to generate data as if it were the eventual manufacturing licence. None of these errors is corrected by adding more laboratory reports.

The route decision is therefore an evidence-control decision. It defines the authority context, application or registration mechanism, route-specific document architecture and later maintenance obligations. It does not answer the biological-safety question by itself.

Before opening a Device Master File template, establish scope, submitted product, current India class, transaction, applicant, authority, dossier structure and any fact that could change the route. The eight-question screen below turns those decisions into a record. An unresolved route-changing fact leads to escalation, not a guessed pathway.

Chapter 3 — Control Legal Sources, Status, Standards, and Claims

Chapter outcome Decide which source supports each statement, how strongly it may be written and when it must be rechecked, then capture the answer in a source-status map and claim register.

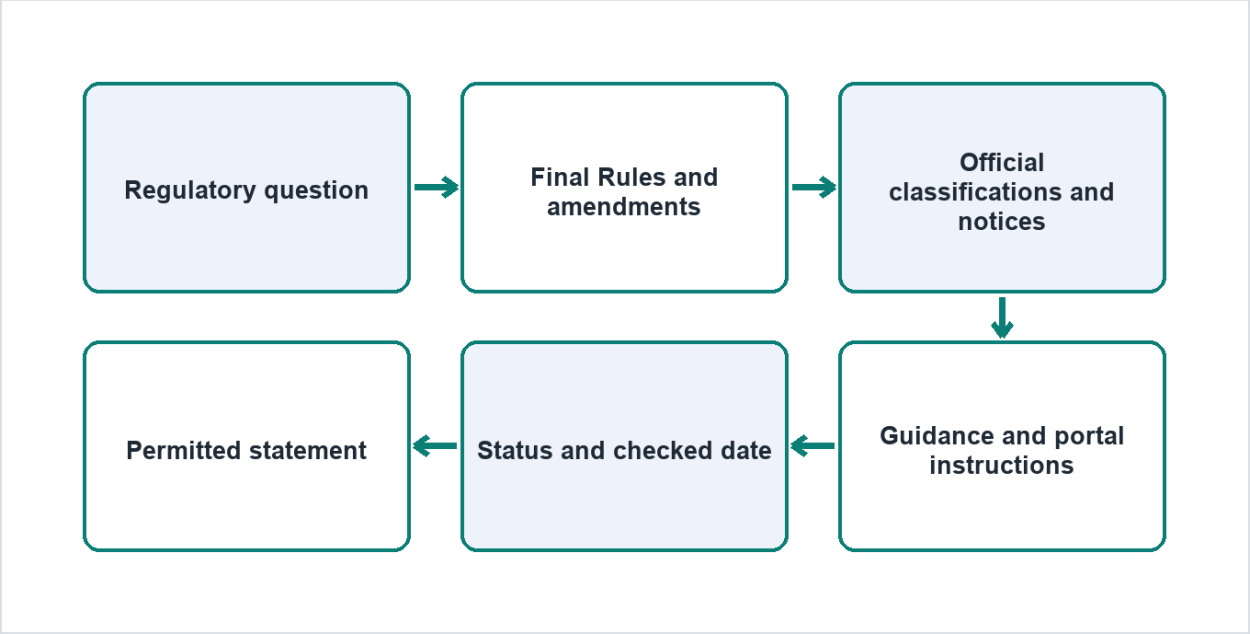

Figure 3. A reliable claim shows which source controls it and what that source can support

Why official-looking sources mislead

The weak source habit is to ask whether a document is “official” and stop there. Many different materials can be hosted on an official domain: a Gazette-notified final rule, an administrative republication, a signed guideline, a public-awareness FAQ, a classification list, meeting minutes, a portal checklist and a draft notification. They do not carry the same legal or interpretive weight.

The resulting error is often subtle. A team downloads the Medical Devices Rules PDF from CDSCO and calls it the “current consolidated MDR”. A writer finds a helpful FAQ answer and converts it into “the Rules require”. A portal field becomes a permanent dossier obligation. A draft amendment appears in a presentation without the word “draft”. An international ISO edition is treated as automatically controlling in India even though Rule 7 gives priority to an applicable BIS standard. Each statement may sound reasonable; together they create a dossier whose claims cannot survive source review.

Source control is not a bibliography exercise. It governs the strength of every statement. The relevant question is not merely “where did this come from?” but “what kind of source is it, what does it actually say, what has amended or qualified it, and what can it safely support here?”

Source status in plain language

A document does not become law simply because it is hosted on an official website. Its type controls the words the dossier may use.

Chapter 4 — Read the Fourth Schedule as an Evidence Architecture

Chapter outcome Place each biological-safety question, supporting record, limitation and open action in a Fourth Schedule crosswalk that a reviewer can follow without reconstructing the file.

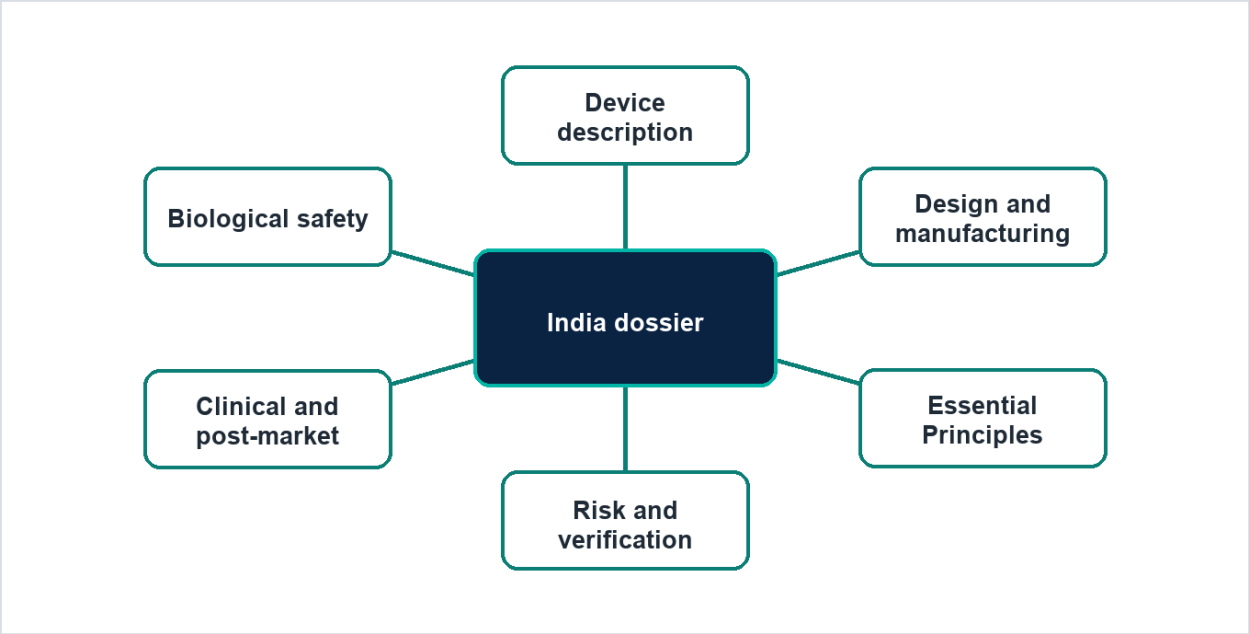

Figure 4. Read the Fourth Schedule as connected evidence architecture

Why a biocompatibility folder is not enough

The most familiar failure is the “biocompatibility folder”. It contains laboratory reports, perhaps a biological evaluation report and several supplier declarations. The folder may be technically substantial, yet the Device Master File does not show which applied models those records represent, how manufacturing and sterilisation affect the final state, which risks they address, where conformity is claimed, or what remains unresolved.

The opposite failure is a beautifully formatted Device Master File that summarises evidence too aggressively. It says “biocompatible as per ISO 10993”, gives a list of report titles and marks an Essential Principle “complies”. The underlying reports may concern a different configuration, raw material or legacy process. The reviewer sees a conclusion but not the chain that makes it defensible.

Both failures come from treating the Fourth Schedule as a packing list. Appendix II is better read as an evidence architecture. Device description establishes the subject, while design and manufacturing establish the made state. The Essential Principles checklist states applicable questions and methods; risk analysis identifies hazards, controls and residual uncertainty; and verification and validation supply evaluated evidence. Clinical and post-market records then test the conclusion against use experience. A report can support more than one connection without being copied into every section.

In plain language, the Device Master File must answer five connected questions:

1. What exact device is India being asked to accept?
2. How is that device made and supplied?

Where does this part of the biological-safety story belong?	Question the node should answer	Typical reference—not a universal submission prescription
Medicinal substances, section 7.3	If the device incorporates a medicinal substance, are its identity, source, reason for presence, safety and performance in the intended application addressed?	Substance identity/source record; intended role; device–substance compatibility and applicable safety/performance evidence
Biological safety, section 7.4	If animal- or human-origin cells, tissues or derivatives are used, are origin, sourcing and relevant biological-safety controls addressed separately?	Origin/material inventory; source/donor and process traceability; applicable biological-safety evidence and specialist assessment
Sterilisation and stability, sections 7.5 and 7.8	Does the claimed final state and shelf life match the evidence subject?	Sterilisation/packaging/ageing validation references; finished-device/test-article link; residuals interface
Animal and clinical evidence, sections 7.7 and 7.9	What distinct in vivo or clinical evidence contributes, and what are its limits?	Study/evaluation reference; relevance rationale; unresolved clinical or model limitations
Post-market surveillance, section 7.10	Does real-world experience support or challenge the current conclusion?	Complaint/adverse-event/FSCA trend references; corrective actions; reassessment triggers

Interpretation. The same approved record can support more than one node, but each use should state the proposition it supports. Repetition of a filename is not an architecture.

4. Connect each hazard to a control and evidence item

Use the risk summary to identify biological hazards or hazardous situations relevant to the submitted state. For each, record the control strategy and the evidence that evaluates either the control or the resulting risk. Keep scientific streams distinct: a material certificate identifies specified material attributes; a chemical-characterisation study describes detected constituents under its conditions; a toxicological assessment evaluates exposure and hazard; a biological test observes a defined response; clinical and post-market evidence describe performance and harms in use. None automatically replaces the others.

The crosswalk does not need to teach each specialist method. It should show why an item is in the dossier and what it cannot establish. Where a conclusion depends on qualified toxicology, clinical evaluation, sterilisation validation or animal-study interpretation, cite the approved specialist record and its responsible reviewer.

Do not create a row for every test merely because a laboratory report exists. Start with the device-specific question and show the evidence route. This prevents the dossier from converting historical testing into a mandatory endpoint matrix.

5. Evaluate applicability, not just existence

For each evidence item, record the studied article, model/configuration, materials and supplier state, manufacture, cleaning, sterilisation, packaging/ageing condition, use/contact context and date. Compare those facts with the submitted device state. Classify the result as applicable; applicable with a bounded bridge; informative but not dispositive; or not applicable. State the reason.

Appendix II allows a rationale where no new testing has been undertaken and gives an example involving identical materials in a previous legally marketed version. That provision is not a blanket

3. Assemble the proportionate architecture

For the Class A non-sterile and non-measuring route, distinguish three layers:

1. **registration information** expressly identified in Chapter IIIB;
2. **retained supporting evidence** behind the class, non-sterile/non-measuring, Essential Principles and standards self-certifications; and
3. **lifecycle records** for manufacturing, sale or distribution, labels, complaints, changes and authority verification.

The support layer should contain device identity, classification and route reasoning, Essential Principles and the standards basis under Rule 7, materials/contact information, biological evaluation, relevant QMS/release and complaint records, approvals and gaps. It is not a list of mandatory upload fields.

For other Class A devices, use the Fourth Schedule Part II paragraph (i) architecture. For non-IVD devices, it identifies device description and intended use, specifications including variants and accessories, materials, working principle or novel technology where present, labels and instructions, reported serious adverse-event information, Site Master File, firm constitution details, Essential Principles checklist and a Fifth Schedule undertaking.

For Class B, use the paragraph (ii) architecture and Appendix II Device Master File. The Device Master File is not simply “more documents”. It requires an organised account of the applied device, design and manufacturing, Essential Principles, risk analysis, verification and validation, materials/contact, sterilisation where applicable, shelf life, clinical evidence where applicable and post-market information.

4. Link the evidence to QMS and manufactured state

The biological narrative must describe the device that the QMS controls. Link every relied-on material, supplier, process, outsourced activity, sterilisation state, package and model to its specification and owner. The Site Master File describes site and contract activities; the Device Master File describes the product and process; the biological evaluation explains applicability.

Use the same approved identifiers across these records. If a conclusion relies on a specified tubing formulation from a named supplier, the Device Master File, purchasing control, production record and applicability assessment should cite the same formulation and supplier state. The QMS does not repeat the scientific conclusion; it shows that the manufacturer can identify and reproduce the state on which that conclusion depends.

For Class B, check that relevant supplier, specification, process, validation, release, change, non-conformance and complaint controls maintain the state relied on in the dossier. The dossier should not depend on a state the manufacturing system cannot identify or reproduce.

If a critical process is outsourced, record the legal manufacturer’s responsibilities, the external site and activity, the applicable licence and QMS evidence, incoming or release controls, change notification, record access and dossier cross-reference. In the fictional sterile fluid-path case, the 24 June 2025 administrative letter provides context only. It does not decide the applied route or remove the need to confirm the actual arrangement before filing.

5A. Evaluate scientific sufficiency without using class as a shortcut

Define each biological question from contact, exposure, materials and manufactured state, then assess existing evidence, applicability and gaps. Class affects route and scrutiny; it does not itself decide endpoints or require a new test.

Do not confuse the parties and records

Element	Role in the handoff	Typical failure
Foreign legal manufacturer	Owns or controls the submitted device, technical documentation and manufacturer conclusions	Sends a static export without defining its controlled status or India scope
Manufacturing or critical process site	Performs identified activities within a documented site scope	Site appears in a report or label but not in the applied site/certificate map
Indian authorised agent	Acts in the India representative/applicant context established by the Rules and controlled authorisation	Is asked to validate technical facts it cannot access or control
Evidence owner	Maintains the authoritative report, assessment or source data and controls disclosure	A PDF copy is shared, but no owner can answer applicability questions
India dossier owner	Controls the assembled India narrative, cross-references and current submission version	Copies the global table of contents and calls it the Device Master File

One organisation may perform several functions, but the functions should remain explicit. “Manufacturer file” and “agent file” are not adequate ownership fields.

The HANDOFF method

The **HANDOFF method** is an original MedDev Advisory structure for import-dossier governance. It is not a power of attorney, authorised-agent contract, prescribed checklist or legal opinion. It provides one shared working record so the manufacturer and agent do not maintain competing versions of the India application.

1. Harmonise the applied identity

Define the India scope before requesting documents: names, intended use, users/contact, dated class source, models/configurations, accessories, shelf life, sterile status, grouping rationale, manufacturer, sites and authorised agent.

Create a model-alias table across India codes, global catalogue numbers, regional authorisation records, biological reports, complaint databases, labels and certificates. An alias is a reconciled identity, not permission to assume two devices are equivalent. Where a family name conceals different manufacturing or sterilisation states, create separate lines.

Use the applied-model register for MD-14 data, Part I authorisation, certificates, master files, labels, market history and evidence applicability. Reopen it before adding a model anywhere.

2. Assign responsibility and authority

For each dossier element, record who prepares it, owns the source facts, technically approves the conclusion, approves it for India use and answers a query. The evidence owner and India submission owner may differ; a single “responsible” column does not make that distinction.

The manufacturer controls design/manufacturing facts and authorises its technical position; the agent controls the India application within its role and confirms document versions; qualified specialists approve domain conclusions. Regulatory coordination cannot replace verification.

Chapter 11 — Testing, Prior Evidence, and the Rationale for No New Testing

The Decision Decide, for each biological question raised by the device or model set in the India application (the **applied device** in this playbook), whether the available evidence is applicable and sufficient, whether a defined gap remains, and whether generating new test data is justified.

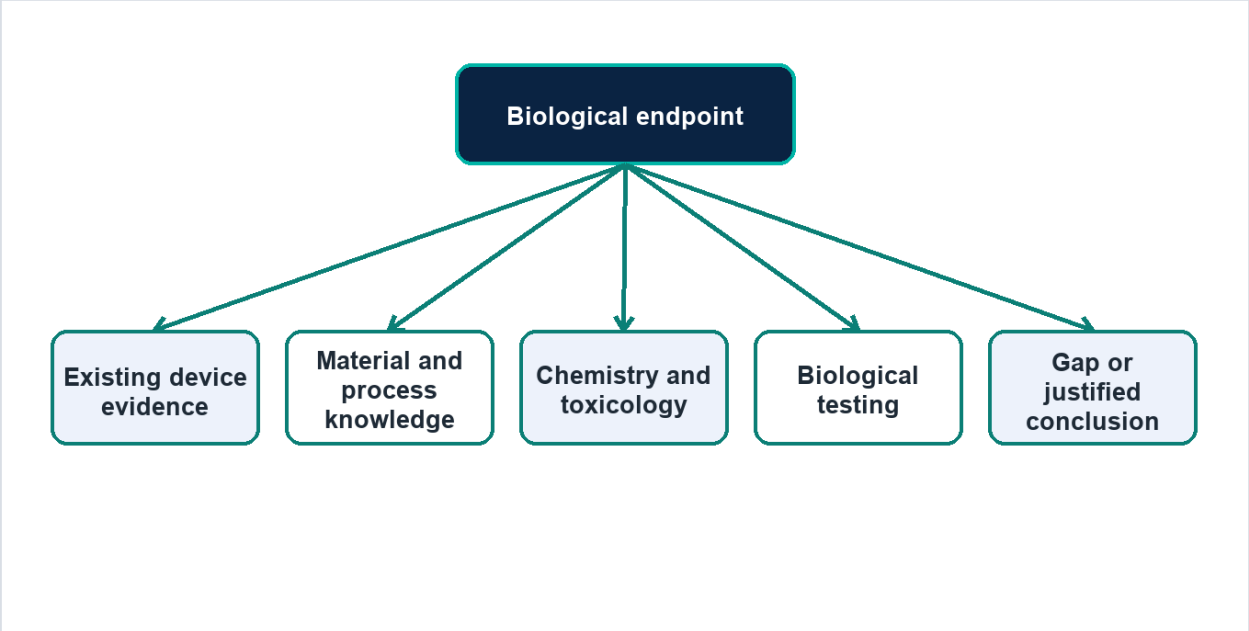

Figure 11. Endpoint evaluation and the evidence route are separate decisions

Reading the figure. Follow each biological question to the evidence route that resolves it or leaves a controlled gap.

Why evidence-route decisions go wrong

Testing decisions are often made too early. A team identifies a contact category, finds a familiar list of endpoints and asks a laboratory for a quotation. Another team starts from the opposite direction: it owns an old report with a favourable conclusion and declares that no further work is needed. Both approaches bypass the professional decision. The first mistakes endpoint relevance for a test instruction. The second mistakes possession of data for applicability and sufficiency.

Prior evidence creates a particular temptation. “Same material” may mean only the same generic polymer name. It may conceal a different grade, colourant, supplier, processing aid, bonding system, manufacturing site, sterilisation state, package, age, geometry or exposure. Conversely, a visible difference does not automatically invalidate the evidence or compel repetition. It creates a question that needs controlled comparison.

A defensible India dossier therefore does not argue for fewer tests as a commercial objective. It explains how every applicable biological question is addressed, what the evidence actually represents, why the combined evidence is sufficient or insufficient, and what would cause the conclusion to be reopened. A no-new-testing rationale is the result of that analysis, not its starting instruction.

Chapter 13 — Write the Biological-Safety Narrative and Audit-Ready Cross-Reference System

The Decision Decide whether the India dossier gives a reviewer one controlled route from the device or model set in the India application (the **applied device** in this playbook) through biological questions, evidence applicability and limitations to a defined conclusion and exact supporting records.

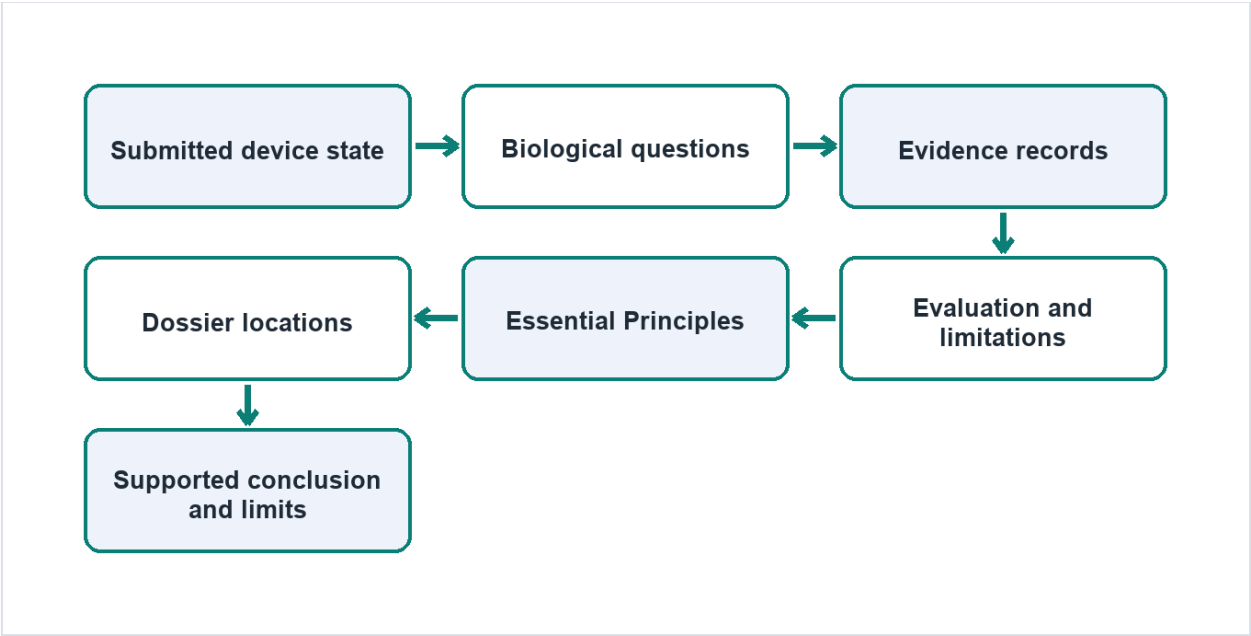

Figure 13. The biological-safety narrative needs a review-ready navigation chain

Reading the figure. Trace each conclusion to its controlled evidence, then trace a changed record back to every affected conclusion.

Why complete files remain untraceable

Many dossiers contain the necessary documents but make the reviewer reconstruct the argument. The device description uses a family name, the risk file uses a platform name, laboratory reports use development codes, and the application lists catalogue numbers. The Essential Principles checklist says “see biocompatibility report”, while the report covers a legacy article. The biological summary announces a conclusion but does not identify excluded models or unresolved real-time ageing.

The attempted cure can be equally damaging: copying large blocks from reports into a new document. Duplication creates inconsistent versions, obscures the authoritative source and makes change control harder. A narrative is valuable because it explains relationships, applicability and boundaries. It should not become an uncontrolled archive of technical results.

An audit-ready system therefore needs two things. The **narrative** answers what was evaluated, how, and with what limits. The **navigation map** answers where each controlled fact and evidence item resides. Neither can compensate for an undefined device, weak evidence or a conclusion outside competence.

Chapter 15 — Control Post-Approval Change, Vigilance, and Dossier Maintenance in India

The Decision Decide whether a change, field event or source update requires biological reassessment, a controlled India dossier update, a post-approval regulatory action, vigilance/field safety corrective action (FSCA) escalation, or more than one of these.

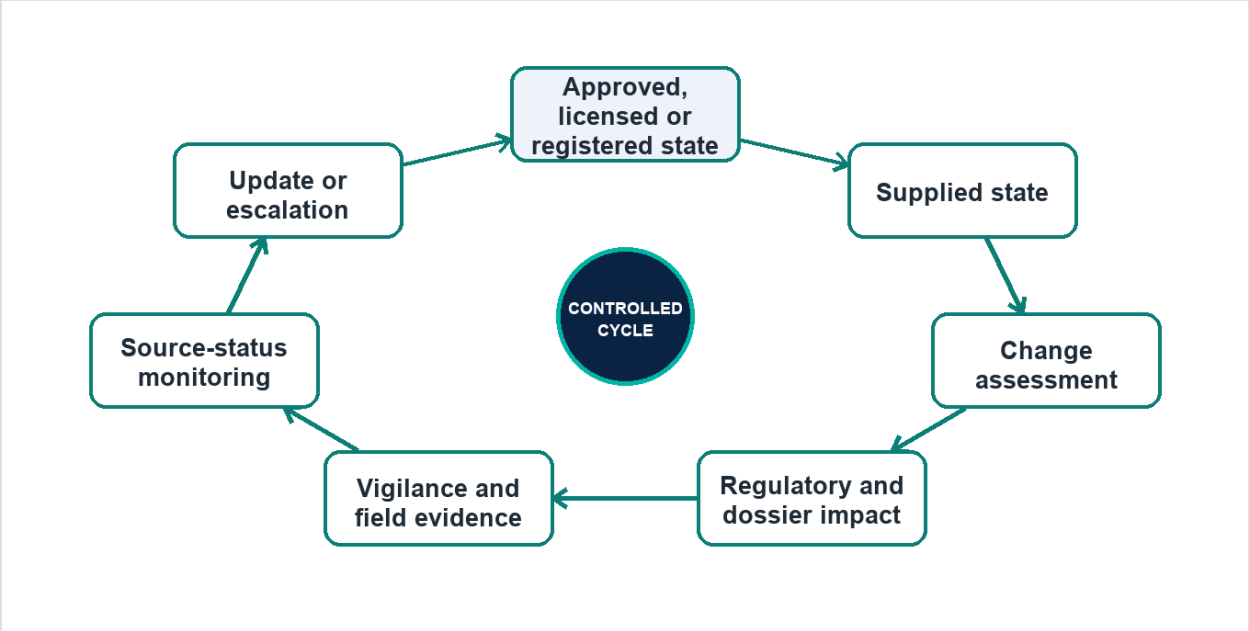

Figure 15. India dossier maintenance links change, vigilance and source monitoring

Reading the figure. Compare each change, signal or source update with the approved, supplied and evaluated states before setting a new baseline.

Why approval is not the end of the biological dossier

A biological-safety conclusion is bounded by a device state, evidence set, intended use and date. Suppliers change formulations, processes drift, manufacturing or sterilisation moves, packaging ages, models are added, complaints accumulate and standards are revised. Any of these can alter the reasoning even when the commercial product name remains unchanged.

A change does not automatically require new biological testing. It requires controlled comparison of affected biological questions and available evidence, followed by a competent evidence-route decision. Confusing reassessment with retesting creates unnecessary work; confusing “no test” with “no action” leaves the dossier unsupported.

Lifecycle control must also separate four questions that teams often collapse:

1. Has the biological-risk position changed or does it need reassessment?
2. Must an authoritative dossier record be revised?
3. Is prior regulatory action, endorsement, notification or another post-approval route implicated?
4. Does a complaint, adverse event, trend or field action trigger vigilance, FSCA, recall or other escalation?

Trigger	Minimum biological comparison	India dossier consequence	Separate escalation question
Material/formulation or colourant	Composition, impurities/additives, contact, exposure, prior evidence	Update material map, risk questions, evidence applicability and conclusion	Current post-approval route; supplied-lot exposure
Supplier or manufacturing process	Specification equivalence, process aids/residues, controls, site state	Update supplier/process evidence and bridge; revise risk/Essential Principles links	Site/device change route; quality management system (QMS) action
New model or grouping change	Contacting construction, geometry, dose, duration, worst-case representation	Update model scope, grouping record and evidence perimeter	Licence/application scope and portal category
Manufacturing/testing site	Activities, process/equipment, materials, quality scope, device state	Reconcile site in DMF and every relied-on report/certificate	Authority action, audit and licence scope
Sterilisation method/site/cycle	Method, cycle family, residuals, material effects, package and ageing	Reassess sterile finished device and affected reports/conclusions	Endorsement/current route; outsourced-site legality
Packaging or shelf-life change	Barrier/contact, extractables contribution, transport, accelerated/real-time state	Revise stability, representation and expiry-linked conclusion	Scope/timing and already distributed lots
Intended use/contact/population	Contact route/duration, users, anatomical site, claims and exposure	Rebuild question set, risk links and evidence scope	Classification, grouping and new/investigational boundary
Complaint/adverse event/trend	Event coding, device state, exposure, causality limits, affected lots	Reopen relevant risk proposition and post-market section	Reportability, medical action, FSCA/recall
Standard or official-source update	Edition/status, transition, India adoption/recognition and method impact	Assess reports, Essential Principles method and narrative references	Regulatory commitment or authority communication

An event can occupy several rows. For example, moving ethylene-oxide sterilisation may change site, cycle, residuals, packaging logistics, label information and regulatory route simultaneously.

Completed practitioner artifact — four-decision change assessment

This fictional worked record uses a proposed flexible-tubing supplier change for the sterile fluid-path set. No implementation date, affected lot or market exposure is invented; those are intake facts that must be established before the record can pass its gate.

Intake field	Completed fictional entry
Trigger	Proposed change to the flexible-tubing supplier and potentially the supplied composition/process state
Potential scope	All three configurations; confirm whether the tubing specification and use are common before treating them alike

Appendix A — Route and Authority Decision Record

Purpose

Use this annotated record to make the regulatory context of the biological-safety dossier visible before evidence is selected or written. It is a reasoning structure, not an application form, legal opinion, classification engine or substitute for the current Medical Devices Rules, Gazette notifications, official classification sources and route-specific CDSCO or State Licensing Authority instructions.

Biological evidence cannot be reviewed in isolation from the device that is being submitted, the applicant, the proposed Indian route and the authority involved. The same laboratory report may have a different place in a Class A non-sterile, non-measuring registration record, a domestic manufacturing-licence dossier, a Class C or D application, or an import application. Route does not decide biological safety, but it does decide the filing context, the accountable parties and the records that must remain aligned.

Completion sequence

1. Freeze the decision date and source baseline

Record the date on which the route assessment is made, who made it, who reviewed it, and the controlled sources used. Cite the applicable Rules and final amendments separately from guidance, FAQs, checklists and portal instructions. If a current official page is undated, record the access date and retain a controlled copy. If a draft proposal could alter the route later, place it in a monitoring field; do not use it as current law.

2. Identify the submitted device

Record the generic device name, intended use, indications, user, patient population, anatomical site, mode of action, duration and frequency of use, sterile/measuring status, models and accessories. Distinguish a medical device from an IVD, drug, cosmetic, general wellness product or another regulated article. If a product is borderline or its principal intended action is uncertain, stop and obtain appropriately qualified regulatory or legal input.

3. Record the provisional India classification and grouping

State the A, B, C or D classification as a controlled, source-linked conclusion. Record the rule or current official classification source, the intended-use assumptions on which the conclusion depends, and any unresolved ambiguity. Then record the proposed grouping—single, family, system, group or another applicable construct—and its separate basis. Grouping may organise an application; it does not automatically establish that one biological dataset represents every model.

4. Identify the applicant and sites

For a domestic route, identify the manufacturer, legal manufacturer where relevant, each manufacturing site, critical outsourced activity and the proposed State or Central authority interface. For an import route, identify the foreign manufacturer, manufacturing sites, Indian Authorised Agent, licence relationship and products to be included. Record sterilisation, testing and packaging sites separately when they influence the finished-device state or licence architecture.

5. Select the route without collapsing distinct pathways

Record whether the current working route is Class A non-sterile/non-measuring registration, domestic Class A or B manufacturing licence, domestic Class C or D manufacturing licence, import licence, test/evaluation route, clinical investigation route, new/no-predicate route, or another identified pathway. Pair each route with its current application and outcome form only after checking the operative source. Do not infer an Indian route from an EU, U.S., UK or other foreign classification.

6. State what the route decision changes in the biological dossier

Record the expected dossier location, review depth, responsible dossier owner, applicable checklist or interface, inspection considerations and the biological-evidence outputs that need to be controlled. Keep this description proportionate. A lower-risk route does not erase the manufacturer's responsibility to understand contact, materials, foreseeable biological hazards, existing evidence and lifecycle signals.

7. Preserve uncertainty and recheck triggers

List every assumption that could change the route, authority or dossier presentation: intended-use wording, sterile status, measuring function, software role, duration, invasiveness, implant status, medicinal substance, biological material, novelty, grouping, manufacturing site or foreign licence history. Name the owner and the event that requires the decision to be reopened.

Control field	Completed entry
Owner/closure	India regulatory and qualified technical reviewers confirm current BIS status, applicable basis and technical impact using lawful standards access; document the decision and update all affected references.

Limitations and competence boundary

This register does not provide legal consolidation, continuous monitoring, a legal opinion or automatic notification of every change. Official pages can be incomplete, moved or delayed. A current India regulatory professional must verify route and procedural implications. Legal-effect questions require appropriate Indian legal review. Scientific standards changes require competent technical review, including lawful access to the complete standards.

Use this appendix with Chapter 3 for source hierarchy and claims control and Chapter 15 for dossier maintenance. It should govern dossier revisions, regulatory-intelligence alerts and device-specific source-impact assessments.

Source and status note

- **CDSCO Rules/amendment and Gazette-notification indexes — monitoring indexes.** Official monitoring routes; neither is itself a legal consolidation. Rules index and Gazette-notifications index
- **S.O. 3286(E) — final notification with future commencement.** It appoints 30 June 2027 for the identified Drugs and Cosmetics Act-related Jan Vishwas provisions and has no current August 2026 route effect. Official CDSCO-hosted notification
- **G.S.R. 743(E) and G.S.R. 744(E) — final amendments.** Both were notified 14 August and published in the Official Gazette dated 19 August 2026. Apply only their exact effects and qualifications. G.S.R. 743(E) and G.S.R. 744(E)
- **BIS dual monitoring routes and dated 2025 MHD snapshot — standards monitoring records.** Search both the new BIS standards portal and the legacy BIS route. Use the snapshot only as dated evidence; the identified ISO 10993-17 edition gap requires specialist review. Dated CDSCO-forwarded MHD list
- **Draft amendment records at the controlled cut-off — proposals only.** G.S.R. 269(E) and 270(E) are historical drafts finalized by G.S.R. 744(E) and 743(E); search the remaining draft records for matching final Gazette instruments before live use and do not use draft content as current law.

Closing note — Build the India dossier as a traceable argument

A defensible biological-safety submission is not the largest possible collection of reports. It is a controlled argument about a defined device, placed in the correct India route, supported by applicable evidence and bounded by what remains uncertain.

The practical discipline is consistent throughout this book. Identify the submitted state and separate law from interpretation and current practice. Map biological questions into the Device Master File and risk architecture, then test whether the evidence represents the device. Integrate different evidence types without double counting, disclose limitations and maintain the conclusion after change.

The four fictional dossiers deliberately end with controlled decisions, open conditions and monitoring triggers—not fictional approvals. Real devices require the same honesty. Where competence ends, escalate. Where a source is volatile, recheck it. Where evidence does not represent the submitted device, do not make the report say more than it can support.

That discipline is what turns biological information into a reviewable India dossier.

Final readiness checklist

Use this checklist only after the underlying records have been completed. A checked row records a verified state and its evidence; it is not a substitute for the responsible review.

Readiness checkpoint	Evidence of pass	Stop or limit condition
Route and applied scope are current	Dated route record and submission charter reconcile class, grouping, applicant, authority, models, sites and claims	A provisional route or scope fact could change the dossier or evidence claim
Submitted contacting device state is defined	Component/material/contact/ process/sterile/package/age map with unknowns resolved or controlled	A material contacting pathway or supplied state is undefined