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Medical Device Change Control and Evidence Decisions

Arvind Rathore

ISO 10993 Biocompatibility Consultant · Founder, MedDev Advisory

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SELECTED AUTHENTIC PAGES

This preview shows selected non-consecutive pages that demonstrate the writing, contents, figures and evidence-control method.

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CURRENT PUBLICATION STATUS

www.meddevadvisory.com/medical-device-change-control-handbook

Contents

How to use this book

The operating sequence

Use the chapters as one decision pathway:

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charter and hold → approved/marketed baseline → atomic and cumulative deltas → impact domains → evidence applicability → decision questions → risk and V&V plan → separate market routes → decision memo → controlled implementation → monitoring and reopening
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The pathway is intentionally not a universal flowchart. Real organizations use different quality systems, roles and records. The value lies in the questions and evidence relationships, not in copying a form.

Choose a reading route

Quality and regulatory leaders

Read Chapters 1–4 to establish authority, holds and baseline control; Chapters 7–14 to separate evidence and market decisions; and Chapters 18–20 to control authorization, implementation and monitoring. Use the jurisdiction chapters as source-dated orientation before obtaining device-specific review.

Engineering, manufacturing and supplier-quality teams

Begin with Chapters 3–8. Concentrate on the approved and marketed baseline, atomic change decomposition, physical and process deltas, impact domains and evidence provenance. Then use Chapters 9–13 to convert uncertainty into a reviewable verification-and-validation plan.

Biological, clinical, software, sterilization, packaging and other specialists

Read Chapters 5–10 and 13–14. The book does not replace your discipline's methods. It is designed to improve the facts and decision questions you receive and to preserve your conclusion's scope when it enters the wider change file.

Executives and implementation owners

Read Chapters 1, 2, 14 and 18–20. These chapters distinguish evidence status from authorization, expose unresolved conditions, and connect the approval to inventory, training, release, monitoring, containment and rollback.

Use the case system critically

The longitudinal **AsterFlow** dossier follows a fictional sterile fluid-path family through interacting supplier, material, process, sterilization, labeling and configuration changes. Shorter dossiers address packaging and shelf life, the **PulsePatch** wearable, software, site transfer and a change that becomes a field-action question.

Each case begins with a plausible but defective decision record. The corrected path shows how to frame and challenge the work; it never supplies a transferable regulatory or safety conclusion. Look for three recurring prompts:

- **Reviewer's question** — what an independent reviewer may ask the team to demonstrate;

Chapter 1 — One Change Request, Several Different Decisions

Chapter purpose Learn to separate the decisions concealed inside a single change request, so that one approval, test result, market conclusion or project status cannot be mistaken for authority it does not possess.

Practical output A decision map that names the required dispositions, owners, evidence, dependencies, holds and reopening triggers for the proposed change.

It sounds like a routine request: “Approve the alternate tubing supplier.” Purchasing has a continuity problem. The new supplier says the polymer grade is equivalent. Engineering sees the same nominal dimensions. Operations wants a date. A change form is opened, several departments select *no impact*, and a manager asks when the first production lot can be released.

Yet the administrative title has compressed a much larger decision. The actual proposal may include a different raw-material source, manufacturing site, extrusion history, processing aid, dimensional distribution and supply-chain traceability. It may affect an assembly that is sterilized, packaged, labeled and marketed in several configurations. Existing performance, biological, sterilization, packaging and clinical evidence may represent different versions of that assembly. The United States, European Union and India may not ask the same regulatory question. Inventory from the old and new routes may coexist.

None of those facts proves that the proposal is unacceptable. They show why the word *approve* is too small for the work.

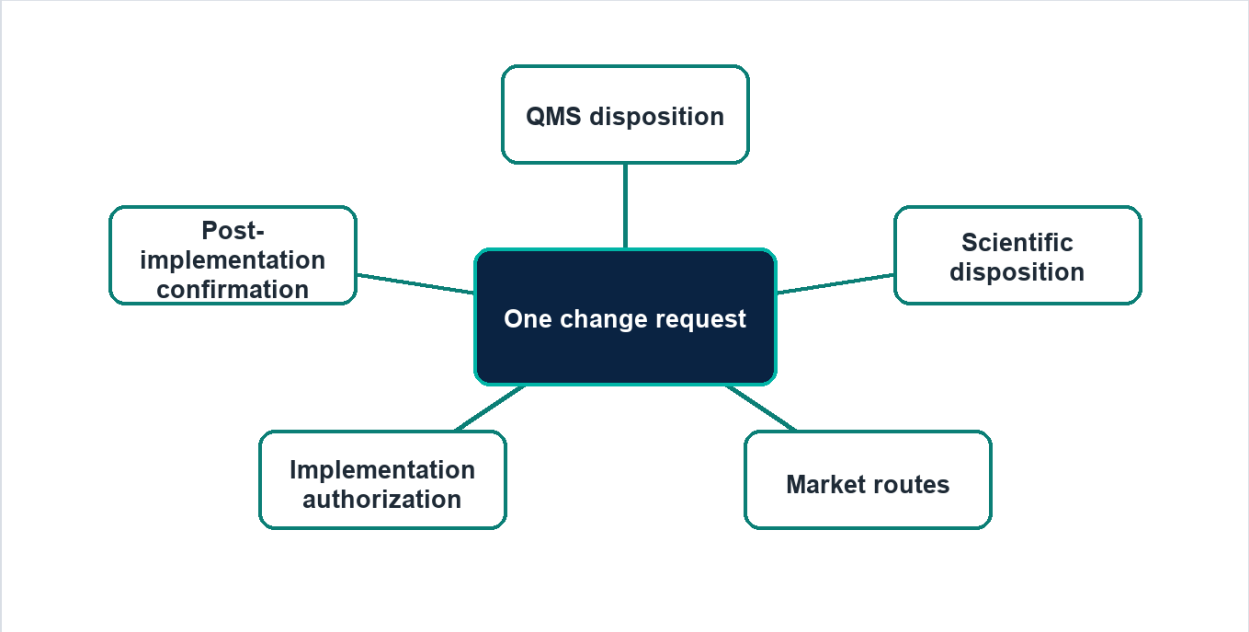

Figure 1. One change request creates five controlled dispositions

The management error is not change—it is decision compression

Teams rarely set out to hide uncertainty. Compression usually begins because the quality system needs one record, the project needs one milestone, or a dashboard needs one status. A single field

Chapter 3 — Reconstruct the Approved and Marketed Baseline

Chapter purpose Establish the controlled state against which a proposed change will be assessed, while exposing differences among design records, manufacturing reality, evidence history, market authorization and actual supply.

Practical output A question-specific baseline statement that identifies represented products, configurations, sites, suppliers, processes, evidence, markets and time periods, together with discrepancies, holds and unresolved ownership.

A change cannot be assessed against “the current device” until the organization can say what that phrase means. The drawing system may describe one state. The bill of material may describe another. A validation report may represent a limited configuration made three revisions ago. A submission may contain the device state presented to an authority at a particular time. A certificate or license may cover a named family but depend on controlled technical documentation and conditions that are not visible in the certificate title. Production records show what was built. Distribution records show what was actually supplied.

These records are related, but they are not interchangeable.

Baseline reconstruction is the disciplined work of bringing them into a traceable comparison. Its purpose is not to create a perfect history of the company. It is to identify the state that matters to the present decision, show where that state is supported, and prevent an unresolved discrepancy from being converted into an assumption.

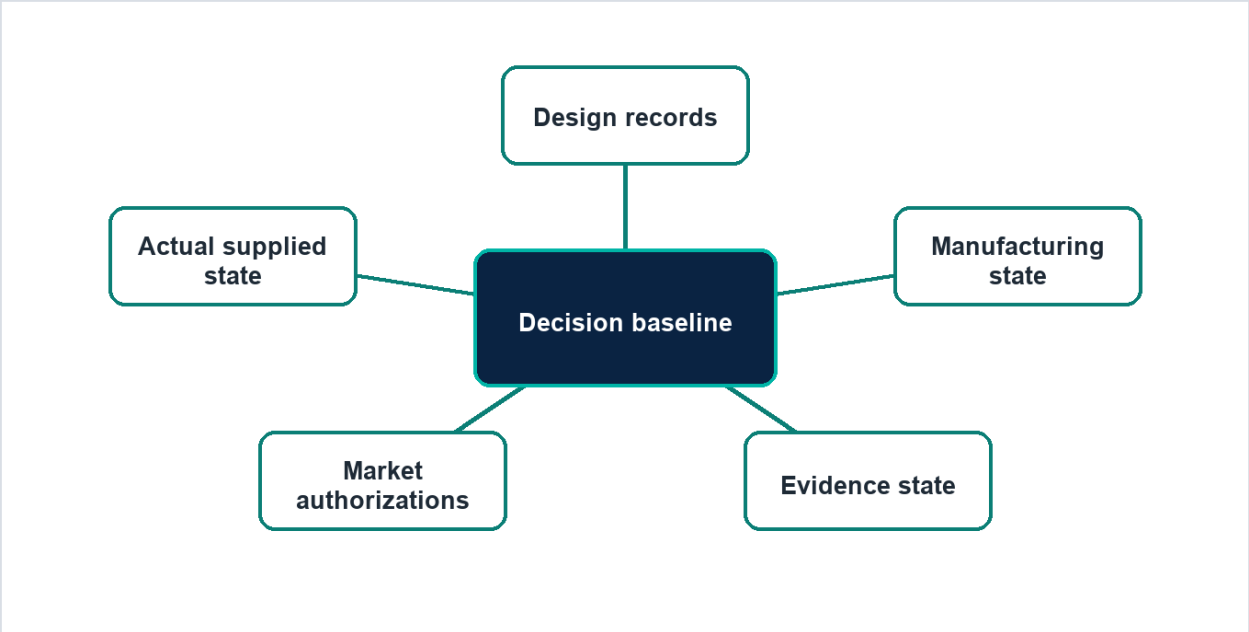

Figure 3. Reconstruct the approved and marketed baseline

Chapter 4 — Decompose Atomic, Concurrent, and Cumulative Changes

Chapter purpose Replace the administrative project title with a controlled set of physical, functional, procedural and informational deltas, then show how those deltas interact with concurrent work and earlier product history.

Practical output A change decomposition that links each atomic and cumulative delta to the relevant baseline, affected questions, owner, evidence needs, authorization context and implementation hold.

Projects are named for budgets and schedules. “Alternate supplier,” “site transfer,” “cost reduction,” “software update” and “label refresh” are useful management labels. They are weak scientific descriptions.

An alternate supplier may bring a new raw-material source, formulation detail, manufacturing site, equipment train, process window, inspection method, packaging route and change-notification practice. A site transfer may include new utilities, operators, environmental controls, fixtures and data systems. A software update may alter an algorithm, dependency, user message, network behavior and cybersecurity control. Even when each difference is modest, the finished state is the combination.

Change decomposition is the work of stating those differences separately enough that competent reviewers can see their mechanisms, while keeping them connected enough that interaction and cumulative history are not lost.

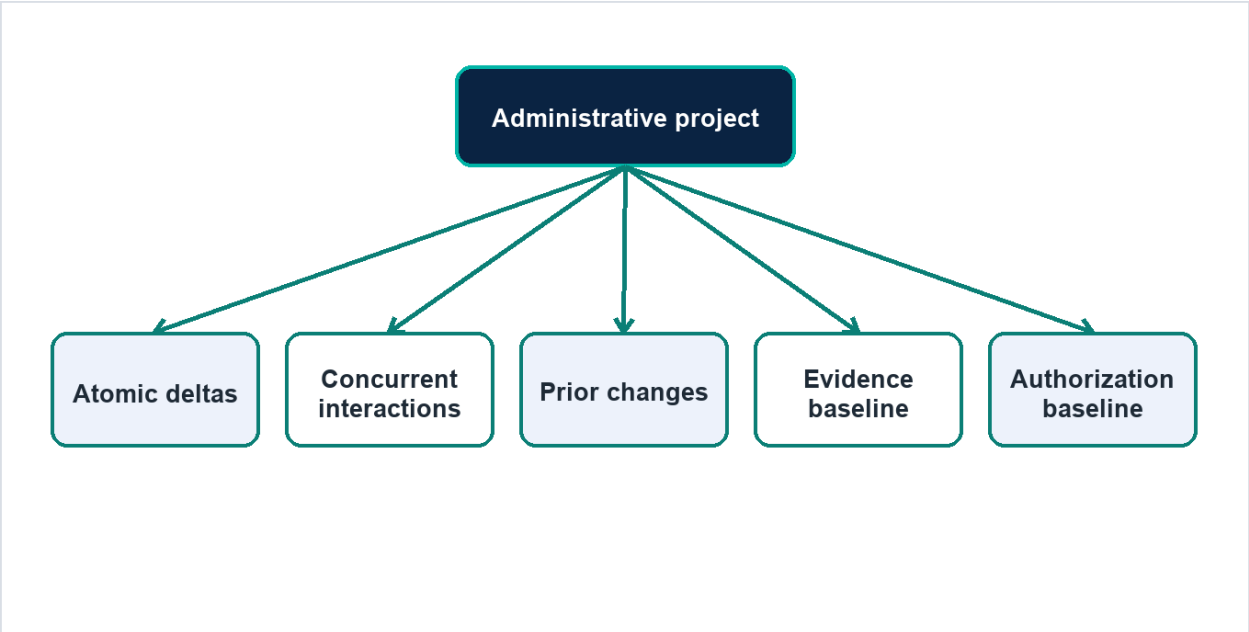

Figure 4. Decompose the project into atomic, concurrent and cumulative deltas

The administrative unit is rarely the assessment unit

One change-control record may contain several assessment units. Conversely, several organizational projects may converge on one product configuration. If the assessment follows record boundaries, an interaction can fall between owners.

Chapter 7 — Map the Cross-Functional Impact Domains

Chapter purpose Route each material change question to the discipline competent to answer it, while preserving interfaces, dependencies and the limits of every conclusion.

Practical output A cross-functional impact map that names questions, owners, evidence, handoffs, exclusions, holds and reopening triggers without producing an automatic approval state.

A cross-functional review can look impressive and still miss the decision. Twelve departments may sign a form, each believing the change was evaluated by someone else. A materials reviewer sees no drawing change. Engineering sees conforming dimensions. Regulatory sees no intended-use change. Quality sees all signatures present. The space between those reviews—the changed process history of a patient-contacting component—has no owner.

The purpose of an impact map is not to collect departmental consent. It is to make sure each affected question reaches a competent reviewer, and that the answer returns with enough scope and evidence for the other decisions to use.

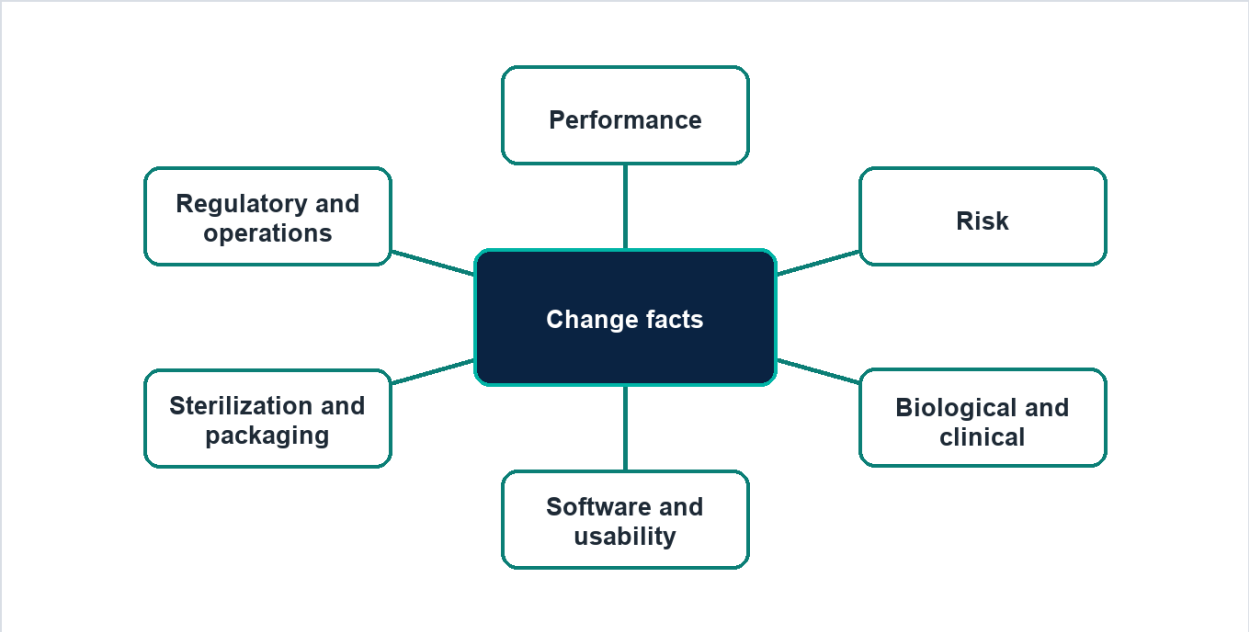

Figure 7. Cross-functional impact domains receive distinct questions

Route questions, not project titles

“Please assess the supplier change” invites a functional checkbox. A useful request identifies the source fact, affected state and decision question.

Chapter 8 — Judge Evidence Provenance, Applicability, Equivalence, and Bridging

Chapter purpose Determine what an evidence item actually represents, which question it can answer, how known differences affect its use and where a bounded bridge is supportable or must remain open.

Practical output An evidence-use rationale that links source and target states, original and current questions, relevant differences, competent judgment, residual uncertainty, scope and reopening triggers.

An old report is not weak because it is old. A new report is not strong because it is new. The useful question is whether the evidence is authentic, traceable, suitable for its original purpose and applicable to the decision now being made.

Evidence loses meaning when separated from the state that produced it. A performance result belongs to a defined article, method and condition. A supplier declaration belongs to a stated source and knowledge boundary. A clinical or post-market data set belongs to a population, exposure period and configuration history. A regulatory record belongs to an authorization context.

The team's responsibility is to preserve that provenance, then make any bridge to the proposed state explicit.

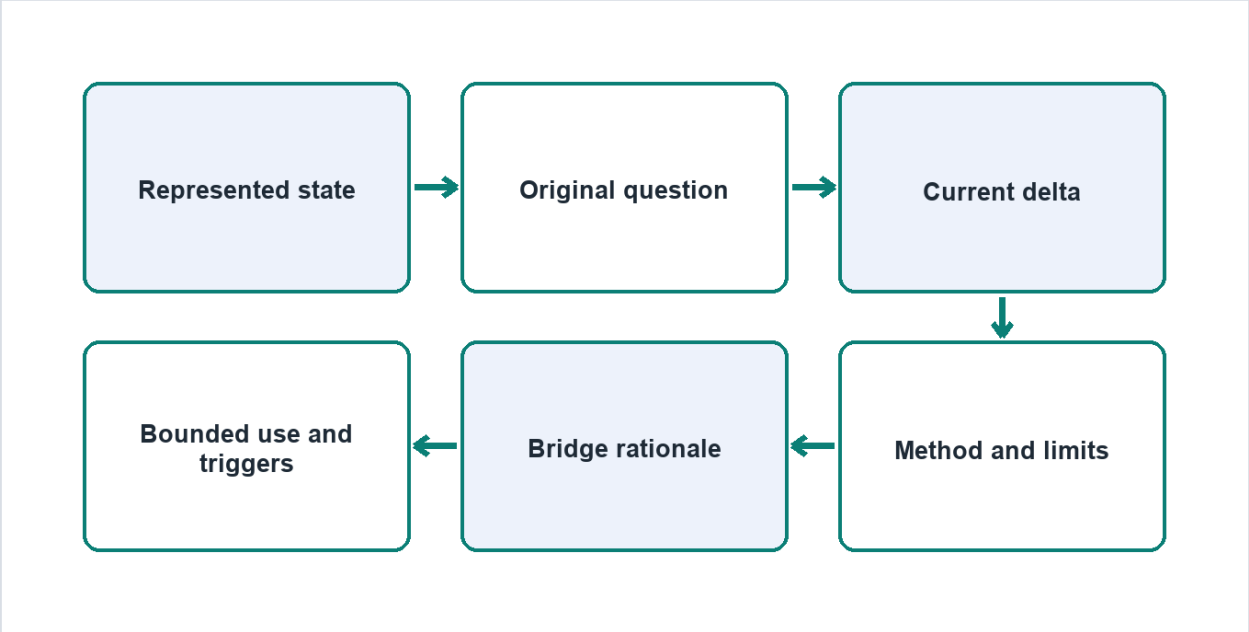

Figure 8. Evidence applicability is a bounded bridge

Start with provenance before interpretation

Provenance is the chain that allows a reviewer to know where evidence came from, what it represented and how it remained controlled. The necessary detail depends on the evidence, but a reconstructable record commonly identifies:

- document or data-set identity, version and approval state;
- author, laboratory, supplier or other originator and relevant competence;
- original purpose and question;
- test article, sample or population;

Chapter 9 — Convert Uncertainty into Answerable Decision Questions

Chapter purpose Turn missing facts, disputed assumptions and evidence limits into precise questions whose answers can change a defined decision.

Practical output A controlled question set with decision consequence, scope, owner, evidence route, dependencies, closure basis, hold and reopening condition.

“More testing required” is not an evidence plan. Neither is “obtain supplier information,” “update risk assessment” or “regulatory to confirm.” These phrases name activities or destinations. They do not state what the organization needs to know.

A decision question connects uncertainty to consequence. It explains why the answer matters, what state is covered, which evidence could answer it and who is competent and authorized to judge the result. Once the question is precise, the team may discover that existing evidence is sufficient, that a targeted analysis is needed, that new empirical evidence is appropriate, or that the proposal should be narrowed. The test menu comes later, if at all.

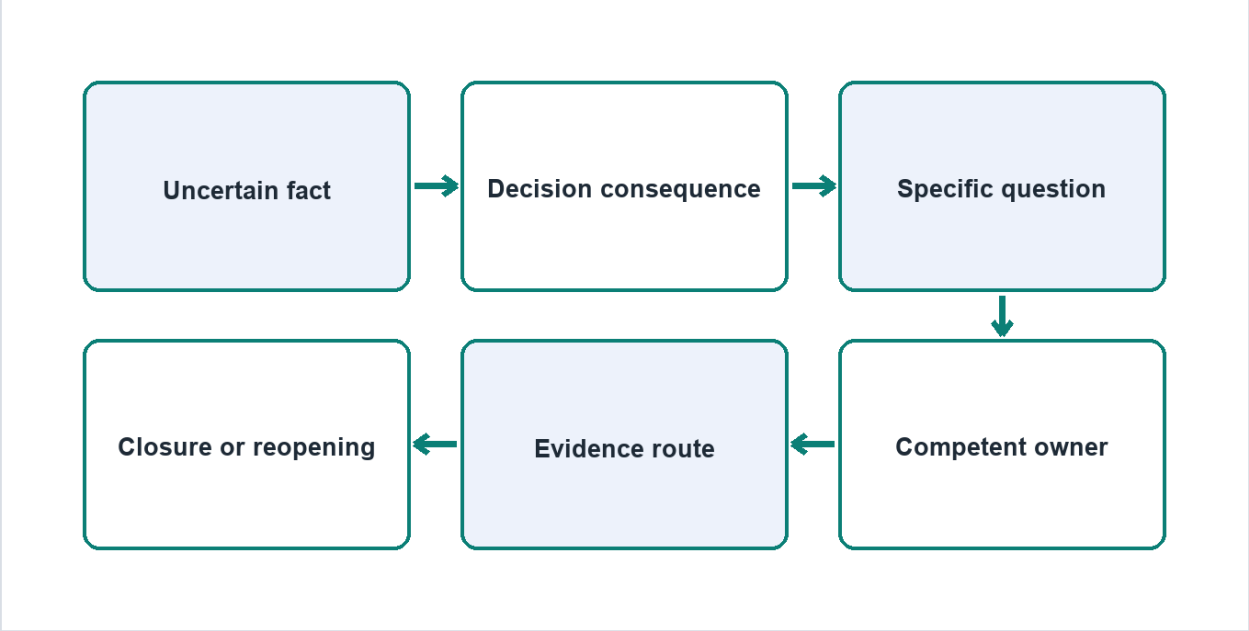

Figure 9. Convert uncertainty into an answerable decision question

Distinguish an unknown fact from decision uncertainty

An unknown fact is missing information: the sub-tier raw-material source, the software dependency version, the first lot made after a process adjustment. Decision uncertainty is the effect of incomplete or variable knowledge on a specific conclusion: whether existing evidence represents the target state, whether a control remains effective, whether a market action is required or whether the proposed scope can be authorized.

Not every unknown deserves equal effort. The change owner should ask:

- Could the answer alter an affected technical conclusion?
- Could it change evidence selection or configuration coverage?
- Could it change a jurisdiction-specific route or timing?

Chapter 11 — Build the Verification and Validation Evidence Plan

Chapter purpose Convert defined decision questions into controlled evidence activities that represent the target state, use a predeclared interpretation basis and remain connected to competent conclusions and implementation holds.

Practical output A question-led evidence plan identifying represented states, existing and new evidence, methods, acceptance basis, dependencies, deviations, reviewers, decision use and reopening conditions.

The fastest way to create an expensive but inconclusive change package is to begin with a list of tests. The laboratory completes the list, every report passes, and the decision team discovers that the articles did not contain the final material, one configuration was absent, a concurrent process change was introduced after testing, or the results answer component conformance but not the finished-device question.

An evidence plan should begin with the questions from Chapter 9 and the risk mechanisms from Chapter 10. It then determines which existing evidence can be used, what new evidence is needed, which state must be represented and how the result will enter a bounded decision.

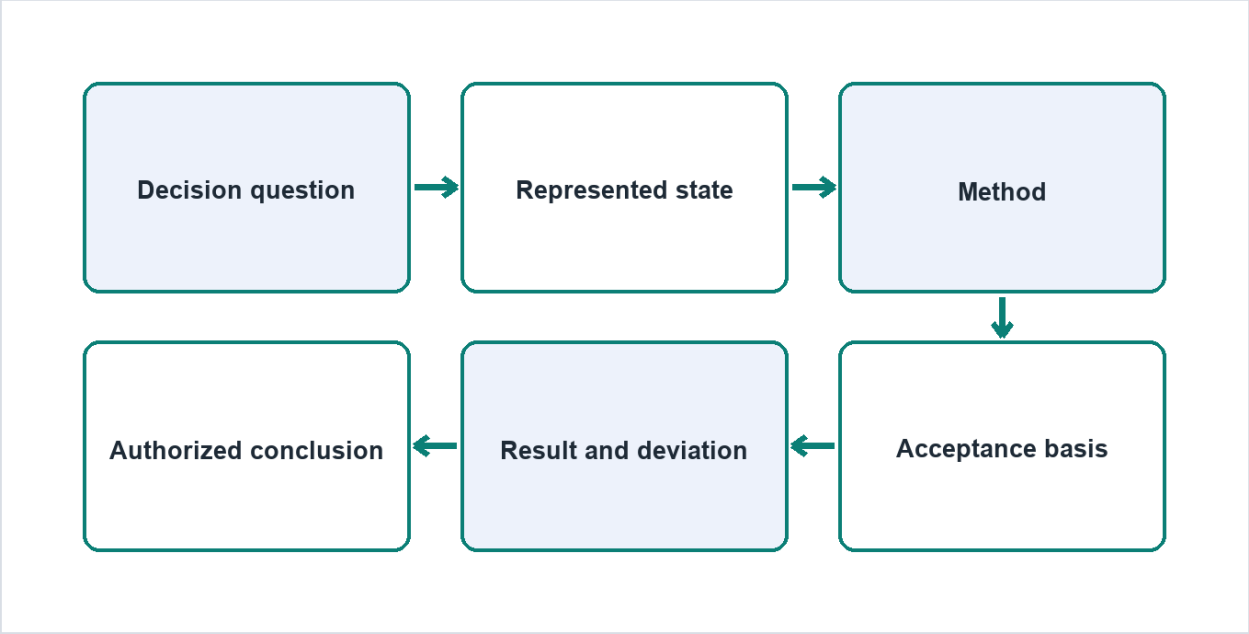

Figure 11. A verification-and-validation plan begins with the decision question

Plan an evidence chain, not a test campaign

For every material decision question, the plan should connect:

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question → represented target state → evidence route → method and interpretation basis → result and deviations → competent conclusion → affected disposition → implementation condition → monitoring or reopening
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This chain may involve document review, supplier information, engineering analysis, characterization, verification, validation, scientific assessment, historical data, post-market knowledge or new empirical work. The appropriate combination depends on the question.

Chapter 12 — Select Representative Configurations and Worst Cases

Chapter purpose Select test articles, device configurations and lifecycle states that answer a defined evidence question, without pretending that one universal “worst case” represents every performance, packaging, sterilization, biological, software or usability concern.

Practical output A purpose-specific selection rationale that links the affected population, decision question, mechanism, challenge drivers, chosen configurations, exclusions, limitations and reopening triggers.

The phrase *test the worst case* sounds conservative. It can also conceal weak reasoning. A team selects the largest model because it uses the most material, the longest tube because it has the greatest surface area, or the most complex configuration because it looks difficult. The same model is then used for performance, sterilization, packaging and biological evidence. The file calls it worst case four times but never explains worst with respect to what.

A defensible selection begins with a different question: which configuration or set of configurations creates the most informative challenge for the exact decision being made? Sometimes that is an extreme. Sometimes it is a boundary, an interaction, a representative middle, a rare variant or several deliberately different articles. The label matters less than the reasoning.

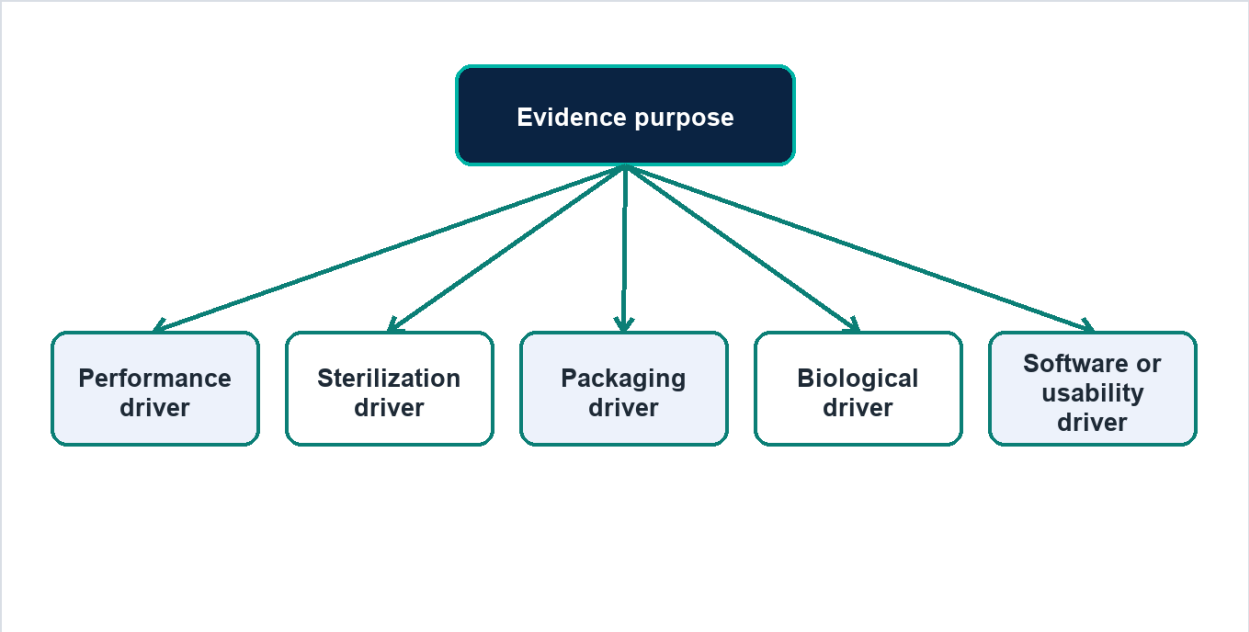

Figure 12. Representative and worst-case selections are purpose-specific

Selection is an evidence claim

Choosing a representative article makes an implicit claim about everything not directly examined. The team is saying that a result from the selected state is informative for a larger population. That claim needs the same discipline as any other evidence bridge.

A selection rationale should therefore identify:

- the population the evidence is intended to cover;
- the question and acceptance basis the activity addresses;

Chapter 15 — FDA: 510(k), PMA, IDE, Corrections/Removals, and PCCP Status

Chapter purpose Frame a U.S. change review from the device's actual FDA authorization and distribution context, while keeping 510(k), PMA, IDE, correction/removal, quality-system and predetermined-change questions distinct.

Practical output A source-dated FDA context record that identifies the device, responsible organization, authorization history, proposed and cumulative deltas, applicable pathway questions, qualified owner, supporting evidence, external dependencies, implementation hold and recheck date.

“FDA impact?” is not one question. The same physical modification can raise different issues for a 510(k)-cleared device, a PMA-approved device, an investigational device, an exempt device or a device with an authorized predetermined change control plan. If affected product is already distributed, correction and removal questions may exist alongside the prospective change.

The first task is therefore not to choose a flowchart branch. It is to establish the U.S. regulatory identity of the exact configuration and the action being considered. The analysis must then use current sources within their scope. This chapter supplies orientation rechecked on 1 September 2026. It does not make a filing, reportability, recall, safety or implementation decision for any device.

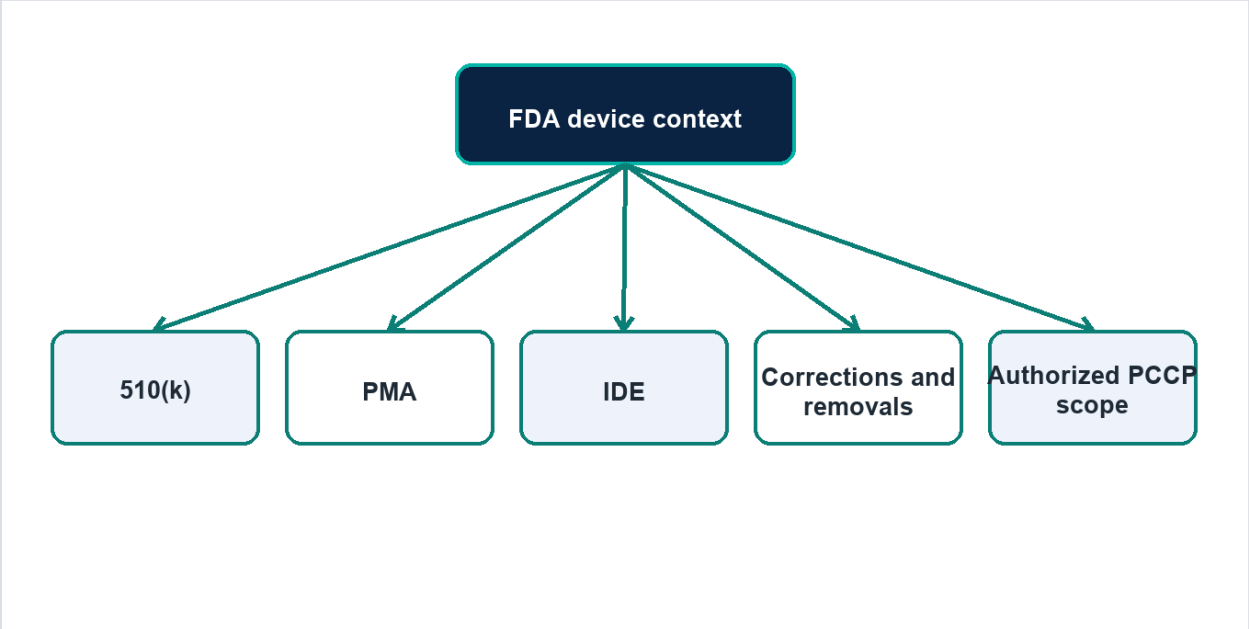

Figure 15. FDA change questions begin with authorization history

Reconstruct the U.S. authorization history before characterizing the route

A family name can hide several U.S. states. Models may have entered the market through different submissions, supplements or exemptions. A later clearance may cover only certain configurations or indications. An accessory may have a different regulatory identity from the parent device. Commitments, postapproval conditions, approved protocols or an authorized PCCP may affect the change question.

Chapter 16 — EU MDR: Current Devices, Notified-Body Change Control, and Article 120 Legacy Devices

Chapter purpose Place an EU change in its actual legal and conformity-assessment context, distinguishing an MDR-assessed device from an Article 120 legacy device and keeping notified-body arrangements, technical documentation and market action within their proper scope.

Practical output A source-dated EU device-context record that identifies the legal manufacturer, device and certificate status, conformity-assessment route, technical-documentation baseline, notified-body controls, Article 120 relevance, change evidence, qualified conclusion, implementation boundary and recheck date.

“Significant change” is often treated as the name of the entire EU review. That shortcut is particularly risky because it can import a transitional legacy-device question into a device already assessed under Regulation (EU) 2017/745. The words may appear in several practical discussions, but the controlling legal context, certificate and notified-body arrangements are not interchangeable.

The first decision is therefore contextual: what device is being changed, under which legal and conformity-assessment state, by which legal manufacturer, and under which current certificate conditions and agreements? Only then can a qualified reviewer determine which questions and external interactions apply.

This chapter is source-dated orientation rechecked on 1 September 2026. It does not decide whether a change is significant, substantial, notifiable, approvable or conforming, and it does not authorize placement on the EU market.

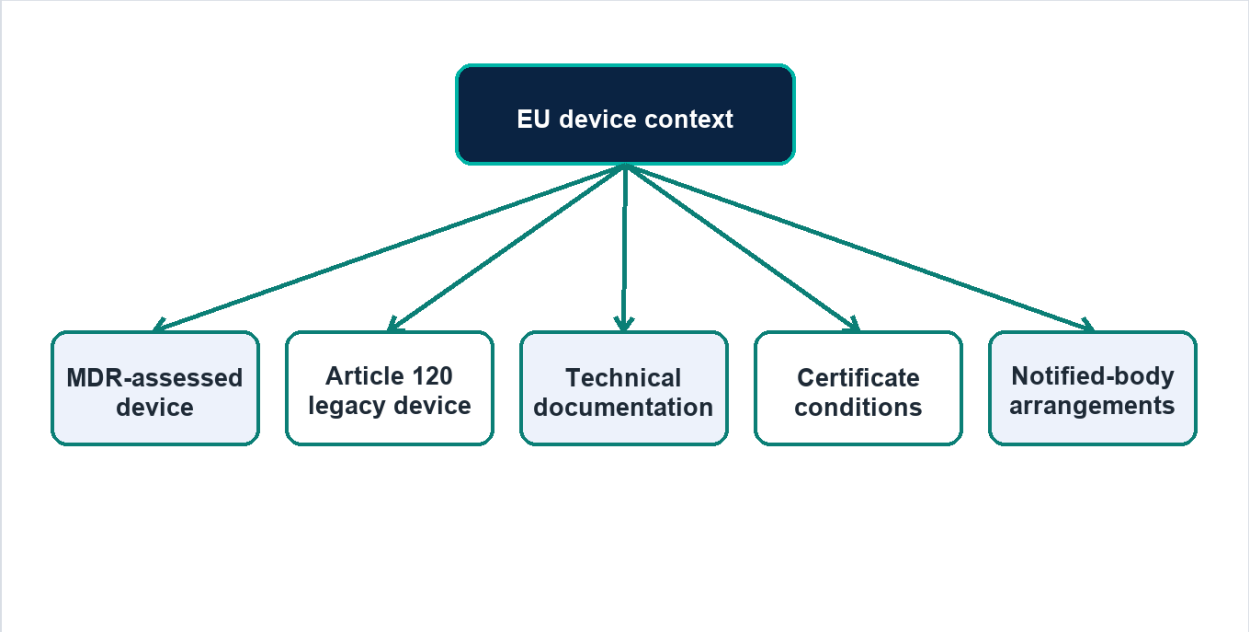

Figure 16. EU change review depends on the device's legal and conformity-assessment context

The family name does not establish one EU status

An internal product family may contain devices with different classifications, Basic UDI-DIs, intended purposes, technical-documentation files, certificates, conformity-assessment routes or transitional states. A configuration sold under an MDR certificate should not inherit the reasoning used for an

Chapter 17 — CDSCO: Major/Minor Post-Approval Changes and Current Portal Controls

Chapter purpose Frame an Indian post-approval change from the exact licence, role, device and authority context, using the Medical Devices Rules, 2017 as the legal anchor and treating current CDSCO portal materials as changeable implementation instructions rather than substitute law.

Practical output A source-dated India context record that identifies the licence and holder, domestic or import route, affected devices and sites, atomic and cumulative changes, Sixth Schedule questions, current portal/checklist evidence, qualified owner, authority dependency, implementation hold and recheck date.

International change files often arrive in India with a conclusion already written: “No new 510(k), therefore minor,” or “Not significant under EU guidance.” Neither statement classifies the change under Indian law. Technical evidence can be reused when it represents the same changed device, but the route reasoning must begin again with the Indian licence and current rules.

India's Medical Devices Rules, 2017 use a post-approval major/minor structure and identify categories in the Sixth Schedule. That apparent simplicity can invite another shortcut: match the project title to one row and let the row decide. A real project may contain several atomic changes, and terms such as *affect quality* require qualified application to the exact facts. Current CDSCO portal and checklist instructions also influence how an application or notification is presented, but those materials can change.

This chapter reports the source position rechecked on 1 September 2026. It does not classify a real change, identify the competent licensing authority for a real applicant, determine a deadline or fee at the time of use, establish approval, or authorize implementation.

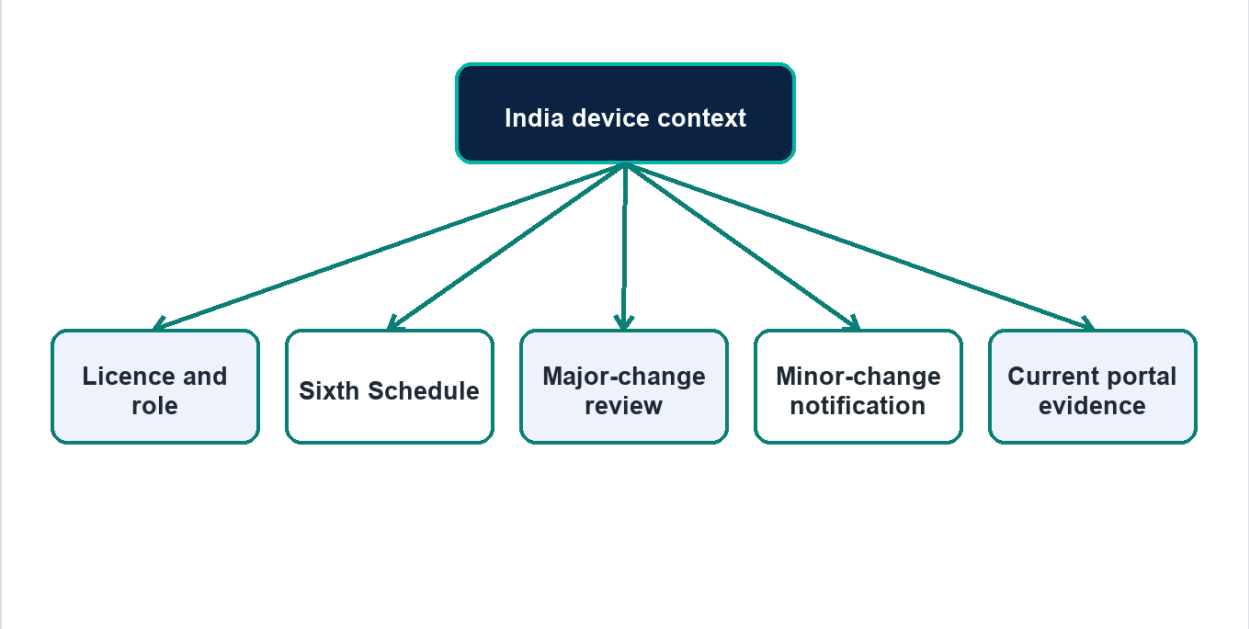

Figure 17. CDSCO post-approval review preserves licence and change-category context

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WHAT IT DOES NOT PROVIDE

- The complete handbook, an authorized standard or a customer licence
- A device-specific analytical, toxicological, quality or regulatory conclusion
- A guarantee of regulator, notified-body or market outcome

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