MEDDEV ADVISORY

SAMPLE PREVIEW

Device Family & Worst-Case Representative Device Justification Pack

Variant boundaries, question-specific challenge dimensions, representative-device decisions, evidence applicability, and lifecycle change control

An honest buyer view of the fail-closed dashboard, family boundary, question matrix, and candidate comparison

MDA-TLK-FAMILY-WORSTCASE-10993-01 • v3.0 • PUBLIC PRODUCT PREVIEW

PRE-PURCHASE TOUR — COMPLETE PAID FILES NOT INCLUDED

Help medical-device teams define a defensible device-family working boundary and document which final-finished device or devices represent each biological-evaluation question, with traceable facts, evidence, limitations, named review, and change triggers.

A structured working aid. It does not determine biological safety, compliance, or regulatory acceptance.

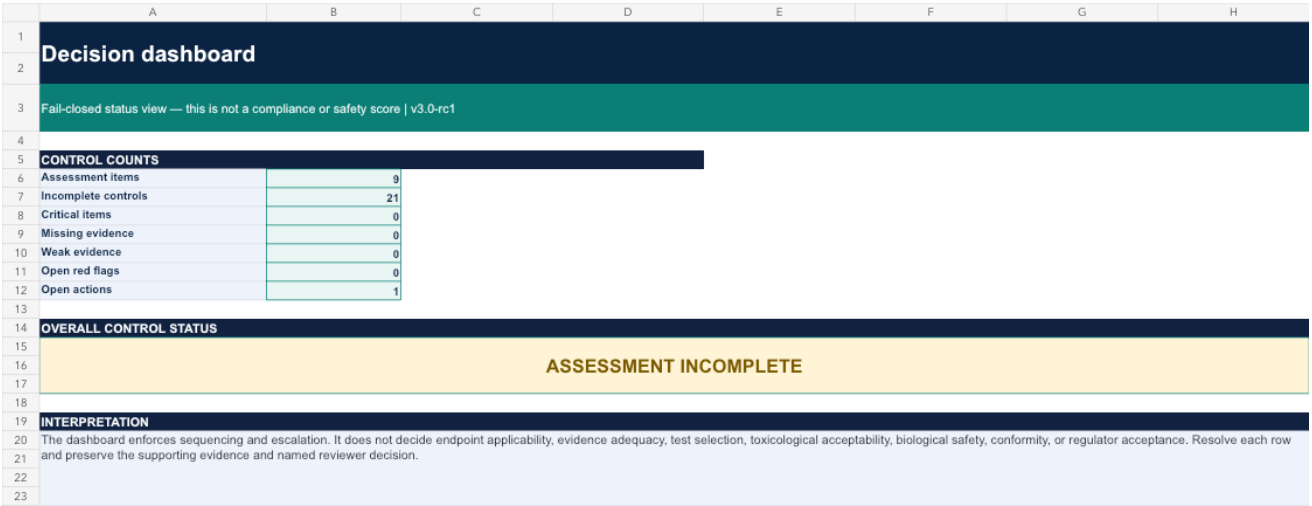
What this resource helps a team produce

- A controlled variant inventory tied to final-finished configurations, intended use, contact route, cumulative duration, population, manufacturing state, sterilization, packaging, and shelf-life state.
- A family-boundary hypothesis that records shared characteristics, meaningful differences, exclusions, evidence, uncertainty, and the precise decision for which grouping is proposed.
- Question-specific challenge dimensions instead of a single ranking score or a universal worst-case device.
- A candidate comparison that can select one device, multiple devices, pooled articles, or no adequate representative, with explicit coverage and limitations.
- An evidence bridge comparing the tested subject and current variants across formulation, supplier, process, surface, geometry, sterilization, packaging, age, use, and exposure.
- A representative-device plan and article trace record that preserves configuration, revision, lot, processing, sterilization, packaging, age, handling, exclusions, and linked protocol or report.
- A risk, PMS, jurisdiction, and change-control bridge that reopens affected decisions when device or external requirements change.
- A fail-closed review package in which unresolved questions, red flags, actions, sources, limitations, and named decisions remain visible.

SCOPE This working aid structures device facts, comparisons, evidence, uncertainty, and decision records. It does not create a legally recognized device family, select one universal worst case, authorize a test article, choose tests or waivers, establish evidence equivalence, determine toxicological acceptability or biological safety, declare conformity or submission readiness, or predict regulator acceptance. Each family boundary and representative-device conclusion is question-specific and must be approved by appropriately qualified biological-safety, toxicology, laboratory, regulatory, risk, and quality reviewers for the exact device and market use.

The working sequence

Step	Action	Output
1	Freeze the exact decision question, device line, market context, and review roles.	Decision charter
2	Build the variant inventory and preserve meaningful differences rather than normalizing them away.	Controlled variant inventory
3	Map contact, exposure, material, process, surface, geometry, and final-state characteristics.	Comparability fact base
4	State a family-boundary hypothesis for one defined purpose and identify exclusions.	Family-boundary record
5	Define the biological question and its relevant challenge dimensions.	Question matrix
6	Compare candidate final-finished devices and select one, several, a pooled set, or no adequate representative.	Representative-device plan
7	Bridge prior evidence and trace the exact proposed article to the controlled device configuration.	Evidence and article trace
8	Reconcile red flags, risk, PMS, jurisdictions, changes, actions, sources, limitations, and approvals.	Qualified-review package



Decision dashboard

Fail-closed status view — this is not a compliance or safety score | v3.0-rc1

CONTROL COUNTS

Assessment items	9
Incomplete controls	21
Critical items	0
Missing evidence	0
Weak evidence	0
Open red flags	0
Open actions	1

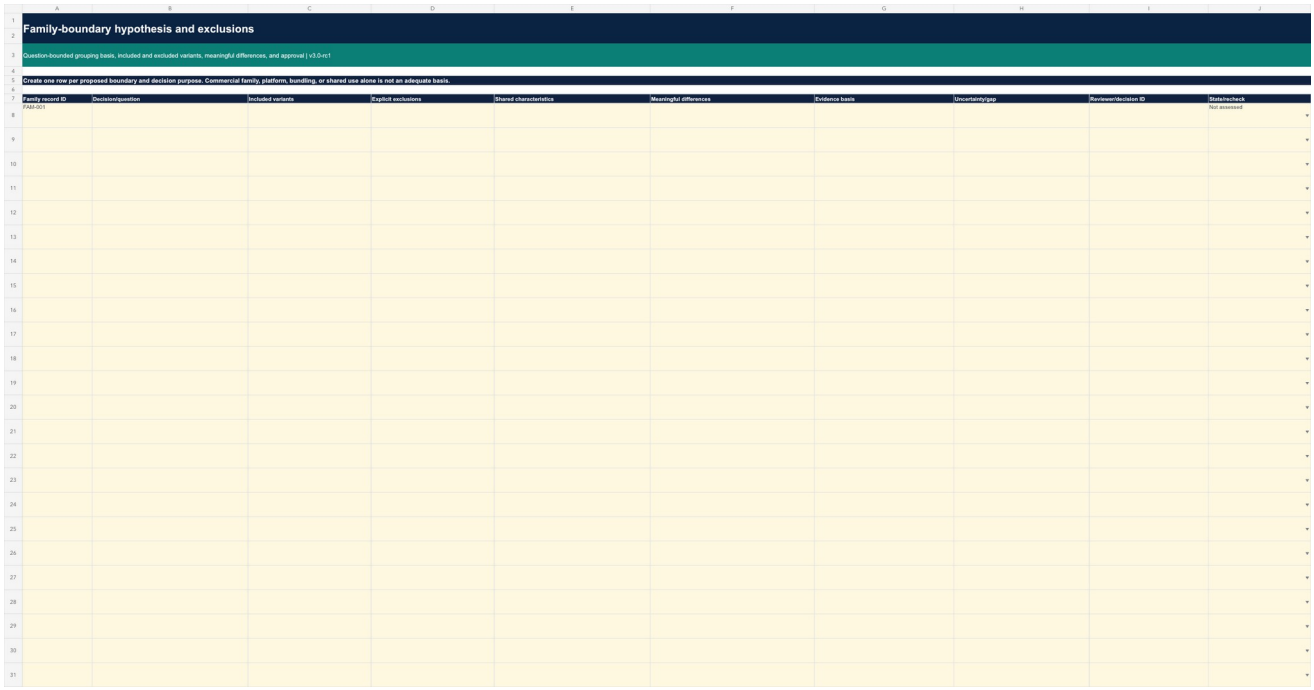
OVERALL CONTROL STATUS

ASSESSMENT INCOMPLETE

INTERPRETATION

The dashboard enforces sequencing and escalation. It does not decide endpoint applicability, evidence adequacy, test selection, toxicological acceptability, biological safety, conformity, or regulator acceptance. Resolve each row and preserve the supporting evidence and named reviewer decision.

Fail-closed decision dashboard from the actual candidate workbook — workflow control, not a safety or readiness score



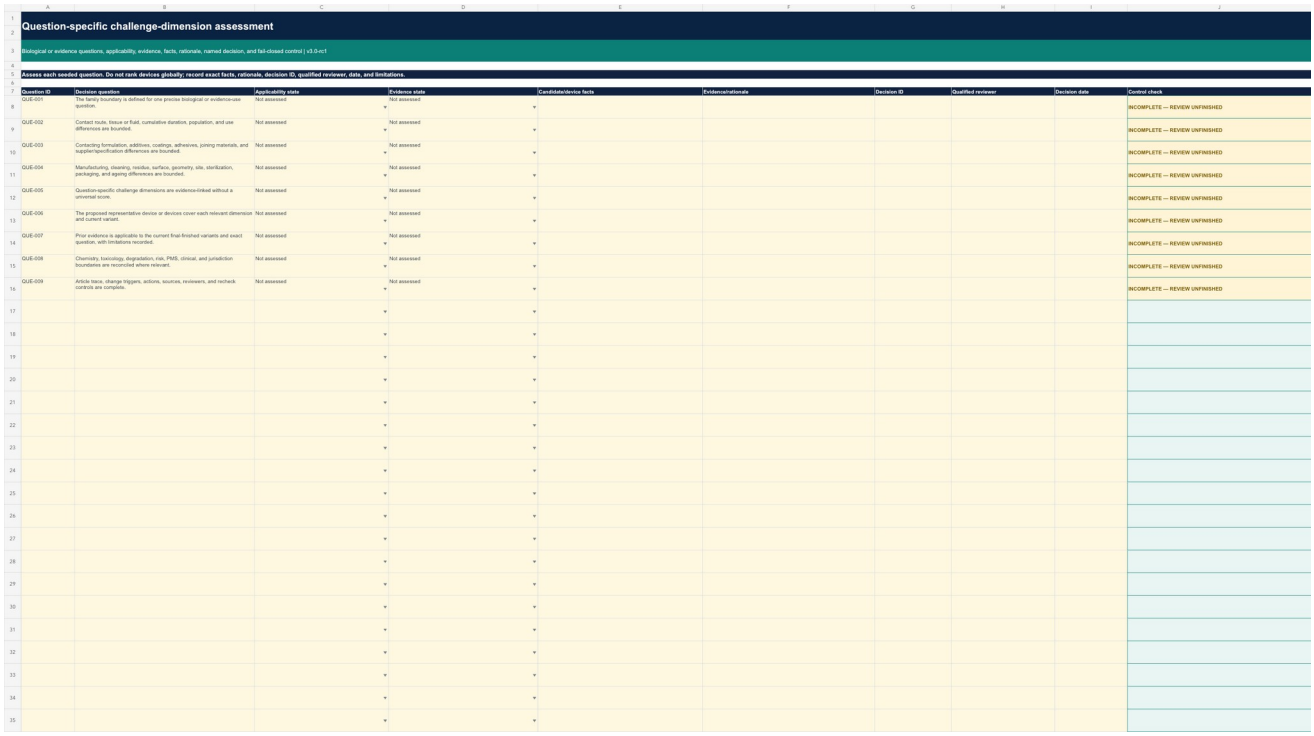
Family-boundary hypothesis and exclusions

Question-bounded grouping basis, included and excluded variants, meaningful differences, and approval | v3.0-rc1

Create one row per proposed boundary and decision purpose. Commercial family, platform, bundling, or shared use alone is not an adequate basis.

Family record ID	Decision/question	Included variants	Explicit exclusions	Shared characteristics	Meaningful differences	Evidence basis	Uncertainty/gap	Reviewer/decision ID	State/recheck
FAM-001									Not assessed

Family-boundary record from the actual workbook — question, inclusions, exclusions, differences, evidence, and uncertainty



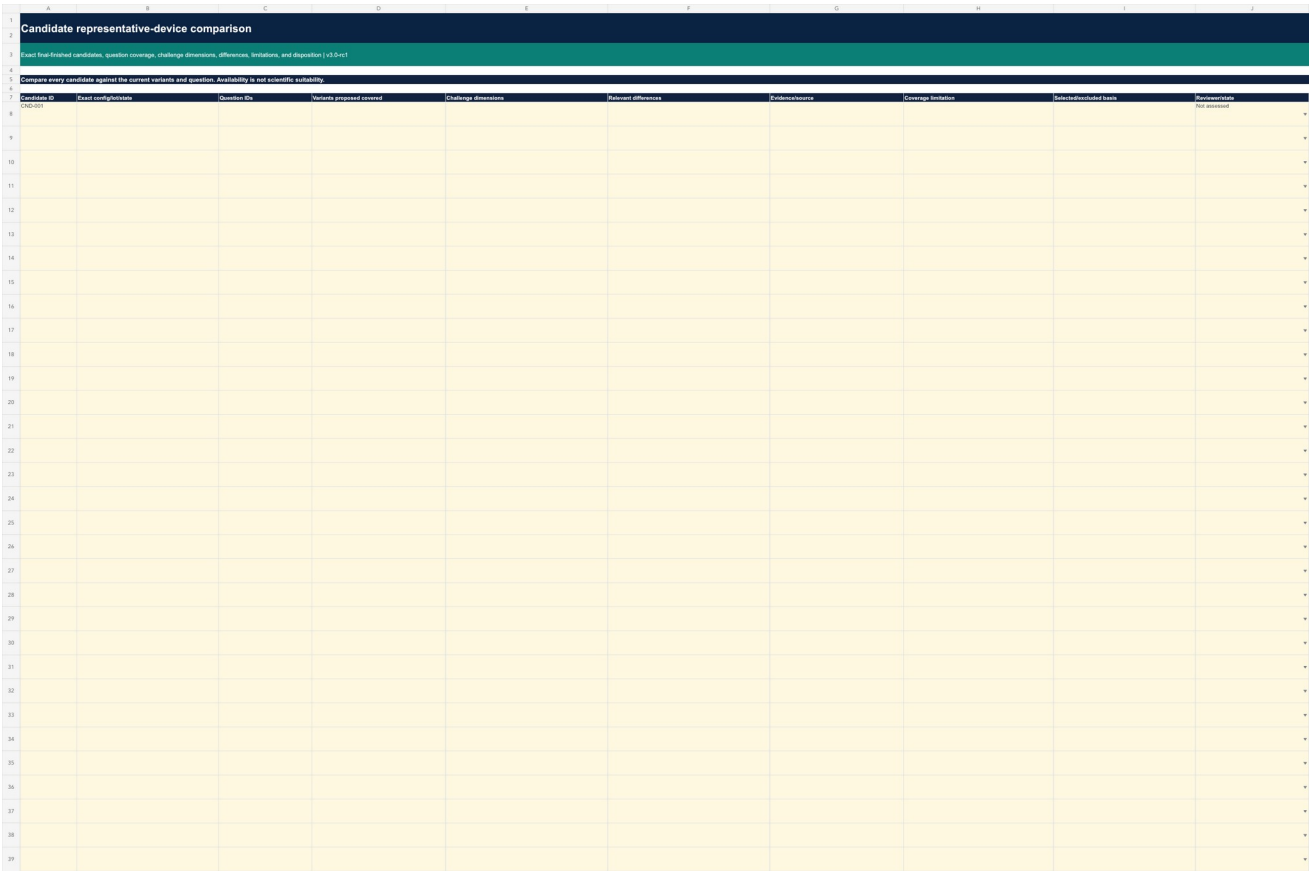
Question-specific challenge-dimension assessment

Biological or evidence questions, applicability, evidence, facts, rationale, named decision, and fail-closed control | v3.0-rc1

Assess each seeded question. Do not rank devices globally; record exact facts, rationale, decision ID, qualified reviewer, date, and limitations.

Question ID	Decision question	Applicability state	Evidence state	Candidate/device facts	Evidence/rationale	Decision ID	Qualified reviewer	Decision date	Control check
QUE-001	The family boundary is defined for one precise biological or evidence-use question.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
QUE-002	Contact route, tissue or fluid, cumulative duration, population, and use differences are bounded.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
QUE-003	Contacting formulation, additives, coatings, adhesives, joining materials, and supplier/specification differences are bounded.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
QUE-004	Manufacturing, cleaning, residue, surface, geometry, site, sterilization, packaging, and ageing differences are bounded.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
QUE-005	Question-specific challenge dimensions are evidence-linked without a universal score.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
QUE-006	The proposed representative device or devices cover each relevant dimension and current variant.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
QUE-007	Prior evidence is applicable to the current final-finished variants and exact question, with limitations recorded.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
QUE-008	Chemistry, toxicology, degradation, risk, PMS, clinical, and jurisdiction boundaries are reconciled where relevant.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED
QUE-009	Article trace, change triggers, actions, sources, reviewers, and recheck controls are complete.	Not assessed	Not assessed						INCOMPLETE — REVIEW UNFINISHED

Question-specific control matrix from the actual workbook — facts, evidence, rationale, named decision, and fail-closed status



Candidate representative-device comparison

Exact final-finished candidates, question coverage, challenge dimensions, differences, limitations, and disposition | v3.0-rc1

Compare every candidate against the current variants and question. Availability is not scientific suitability.

Candidate ID	Exact config/list/state	Question IDs	Variants proposed covered	Challenge dimensions	Relevant differences	Evidence/source	Coverage limitation	Selected/excluded basis	Reviewer/state
<CND-001									Not assessed

Representative-device candidate comparison from the actual workbook — no universal ranking

WHAT THE PREVIEW DEMONSTRATES The product links controlled variants, family boundaries, contact and material differences, question-specific challenge dimensions, candidate coverage, evidence, article trace, risk, jurisdictions, change, sources, actions, and named review. It does not provide a prewritten equivalence or biological-safety conclusion.

Exactly what is included

File	Use it for	Complete when
Quick Start PDF	Set the decision question, stop conditions, and eight-step working sequence.	The team knows what grouping and representative decision is being considered, which reviewers are required, and what the pack cannot conclude.
Implementation Guide PDF	Apply the full variant, boundary, challenge-dimension, candidate, evidence, article, jurisdiction, and lifecycle method.	A reviewer can reconstruct the facts, question, selected representative or representatives, exclusions, limitations, and change triggers.
Editable Working Templates DOCX	Draft ten controlled narratives and approval records.	All blank and fictional fields are replaced with device-specific controlled information.
Operational Workbook XLSX	Control variants, boundaries, contact, material/process, questions, candidates, evidence, articles, risks, changes, red flags, actions, and sources.	Every seeded control is assessed, open actions remain visible, and named scientific decisions are recorded outside the formulas.
Source Status and Release Notes PDF	Verify current ISO, FDA, EU, MDCG, and India source status used by the candidate.	Edition, recognition extent, transition, draft status, legal text date, jurisdiction, and recheck trigger match the intended use.
README, responsible-use terms, source register, manifest, and checksums	Orient the buyer and preserve package identity and integrity.	Product ID, version, inventory, hashes, use boundary, and support route agree across the controlled delivery.

What is deliberately not promised

- No legally recognized family designation, universal worst-case ranking, automatic representative-device choice, or test-article authorization.
- No automatic endpoint, test, waiver, method, extraction, sample-size, toxicological-acceptability, biological-safety, evidence-equivalence, conformity, submission-readiness, or regulator-acceptance conclusion.
- No assumption that the largest device, longest contact, maximum surface area, common intended use, shared material name, platform, trade name, or submission bundling controls every biological question.
- No reproduction of ISO standards or replacement for lawfully obtained controlled standards, device-specific requirements, laboratory procedures, and current regulator instructions.
- No assumption that legacy evidence remains applicable after a material, supplier, process, sterilization, packaging, shelf-life, geometry, use, population, clinical, PMS, or regulatory change.
- No personalized consulting, legal advice, or final commercial terms are included in this public preview.

AVAILABILITY Current customer edition — available by request. Online checkout, payment collection, public buyer-file download, and automatic delivery are not enabled.