MEDDEV ADVISORY

SAMPLE PREVIEW

FDA Additional Information (AI) & EU Notified Body Biocompatibility Response Pack

Deficiency decomposition, evidence traceability, response drafting, clock control, and qualified-review handoff

An honest view of the response-control workflow, real workbook, source transparency, and professional-judgment boundary

MDA-TLK-RESP-BIO-REG-01 • v3.0 • PUBLIC PRODUCT PREVIEW

PRE-PURCHASE TOUR — COMPLETE PAID FILES NOT INCLUDED

Help medical-device teams convert FDA and EU notified-body biocompatibility questions into controlled, evidence-linked response records without conflating review routes, clocks, or decision authority.

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

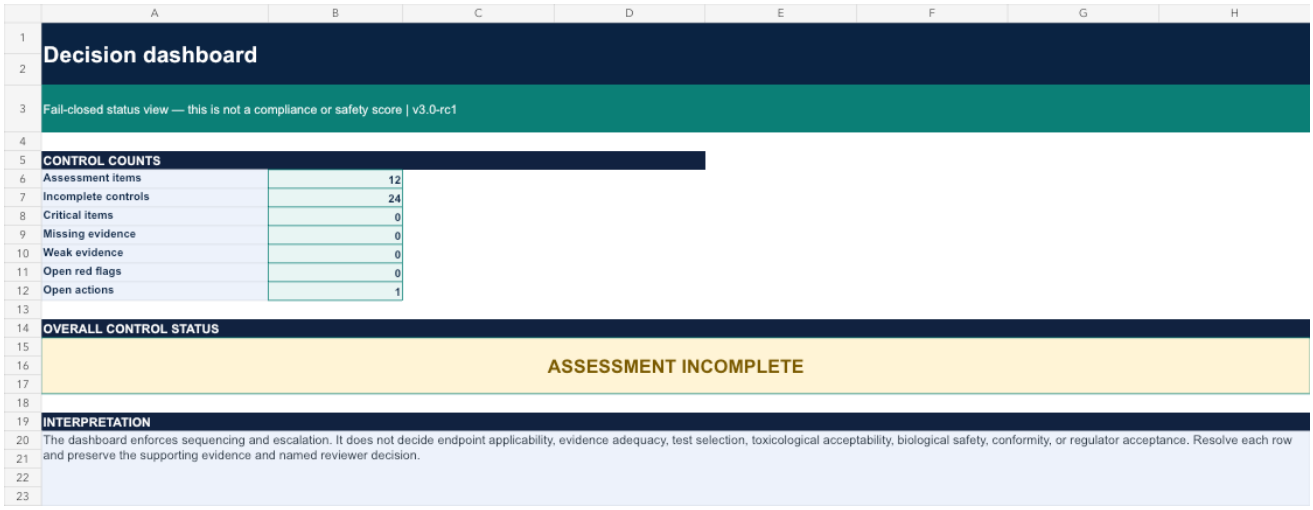
What this resource helps a team produce

- A controlled case record that preserves the exact communication, route, submission or certificate identity, device version, dates, and accountable owners.
- A verbatim deficiency register with stable response IDs, requested outputs, rationale, route, dependencies, and explicit ambiguity flags.
- A response architecture that separates facts, evidence, analysis, commitments, proposed wording, and qualified decisions for each question.
- An evidence and locator map linking every response statement to controlled reports, pages, tables, figures, versions, and applicability limits.
- A distinct FDA response record that preserves Additional Information, Technical Screening, and Interactive Review differences and the original eSTAR lineage.
- A distinct EU notified-body response record linked to the applicable MDR requirement, technical-documentation location, change record, and the notified body's own classification and due date.
- A clock, commitment, action, and cross-file consistency system that keeps deadlines and promised follow-up visible without inventing universal rules.
- A reviewer-ready handoff showing what changed, what remains unresolved, who reviewed each conclusion, and which files comprise the controlled response candidate.

SCOPE This resource structures response work. It does not interpret a specific agency or notified-body communication, select tests, establish biological safety or toxicological acceptability, determine conformity or substantial equivalence, negotiate a deadline, or predict acceptance. The exact communication, contract, submission record, live source, and qualified technical and regulatory decisions control every response.

The working sequence

Step	Action	Output
1	Capture the exact incoming communication and freeze the case identity before drafting.	Controlled case record
2	Classify each item using the route stated in the communication, without converting FDA and EU processes into one generic deficiency workflow.	Route and clock record
3	Transcribe every question verbatim, assign a stable ID, and decompose it into requested facts, evidence, analysis, and decisions.	Deficiency register
4	Freeze the device, claims, intended use, final finished state, evidence cut-off, and submission or technical-document versions addressed by the response.	Response scope baseline
5	Map each proposed statement to controlled evidence and verify the report, test article, method, result, limitation, and current-device applicability.	Evidence and applicability map
6	Draft route-specific responses using a direct answer, supporting evidence, analysis, limitation, commitment, and exact attachment or technical-file location.	FDA or EU response matrix
7	Run cross-file identity, claim, number, version, locator, confidentiality, and change-propagation checks.	Controlled response candidate
8	Obtain named biological-safety, toxicology, laboratory, regulatory, quality, and authorized sign-off as applicable, then hand off through the verified channel.	Qualified-review handoff



Decision dashboard

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

CONTROL COUNTS

Assessment items	12
Incomplete controls	24
Critical items	0
Missing evidence	0
Weak evidence	0
Open red flags	0
Open actions	1

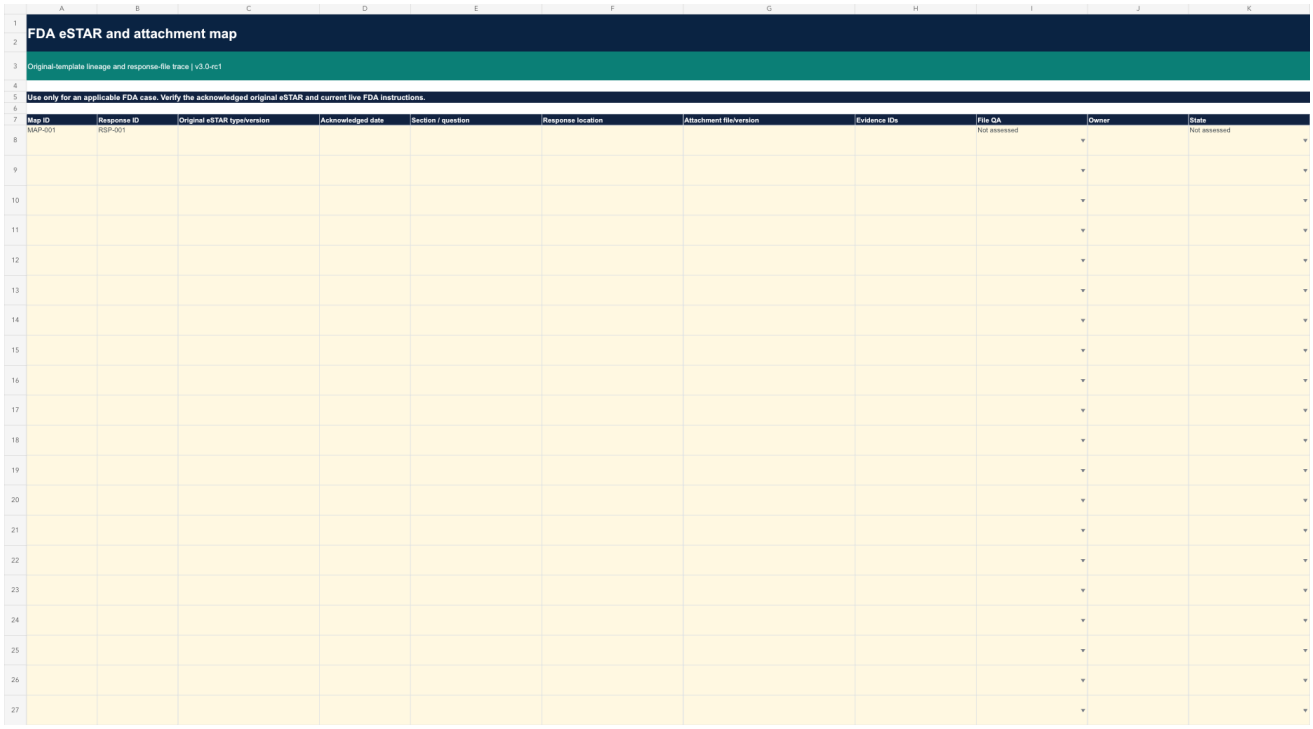
OVERALL CONTROL STATUS

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.

Decision dashboard — fail-closed view before the response controls are completed



FDA eSTAR and attachment map

Original-template lineage and response-file trace | v3.0-rc1

Use only for an applicable FDA case. Verify the acknowledged original eSTAR and current live FDA instructions.

Map ID	Response ID	Original eSTAR type/version	Acknowledged date	Section / question	Response location	Attachment file/version	Evidence IDs	File QA	Owner	State
MAP-001	RSP-001							Not assessed		Not assessed

FDA eSTAR and attachment map — original-template lineage and file trace

WHAT THE PREVIEW DEMONSTRATES The product controls case identity, questions, evidence, route, response drafting, attachments, commitments, changes, QC, and approvals. It does not provide prewritten answers or decide scientific or regulatory adequacy.

Exactly what is included

File	Use it for	Complete when
Quick Start PDF	Set up the case, separate the review route, and identify immediate stop conditions.	The team knows the exact case, current clock, file set, owners, and first controlled action.
Implementation Guide PDF	Apply a disciplined response method for FDA and EU notified-body biocompatibility questions.	The route, evidence logic, response anatomy, limitations, and review boundary can be explained clearly.
Editable Working Templates DOCX	Draft intake, deficiency, evidence, response, commitment, QC, and approval records.	All example and blank fields are replaced by controlled case-specific content.
Operational Workbook XLSX	Control questions, evidence, route, drafting, attachments, actions, review, and status.	Every seeded assessment and red flag has a complete companion record and no unresolved stop condition is hidden.
Source Status and Release Notes PDF	Verify source dates, regulatory distinctions, recognition limits, and recheck triggers.	The source register matches the exact rules and public authorities used for the response method.
README, responsible-use terms, manifest, and checksums	Orient the recipient, preserve package integrity, and control authorized use.	Product identity, version, inventory, hashes, support route, and use boundary agree.

What is deliberately not promised

- No interpretation of a specific FDA or notified-body communication, contract, route, clock, or deadline.
- No automated test selection, endpoint applicability, toxicological acceptability, biological-safety, substantial-equivalence, conformity, or acceptance determination.
- No universal response language and no guarantee that a prior answer or evidence set applies to a changed device or different reviewer question.
- No reproduction of ISO standards or replacement for lawfully obtained standards, current regulator instructions, and the exact submission or certification record.
- This preview does not provide legal, privacy, refund, tax, processor, regulatory, scientific, or individualized commercial advice; the applicable order and terms control.

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