

MEDDEV ADVISORY

PUBLIC PRODUCT PREVIEW

# ISO 10993-18 Chemical Characterization Evidence & ISO 10993-17 TRA Handoff Toolkit

Traceable study-fitness, constituent, exposure-basis, source, and qualified-review controls

A transparent pre-purchase tour of the released v3.0 workflow, files, live blank-state controls, and professional limits

MDA-TLK-CHEM-TRA-10993-01 • v3.0 • PUBLIC PRODUCT PREVIEW

PUBLIC PRODUCT PREVIEW — FULL WORKING FILES NOT INCLUDED

**Help medical-device teams turn chemical-characterization outputs into a traceable evidence intake, exposure-basis record, and qualified-toxicologist handoff without automating toxicological judgment.**

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

## What this resource helps a team produce

- A controlled characterization-study fitness record tied to the final finished device, study purpose, extraction design, analytical coverage, and unresolved limitations.
- A traceable constituent and unknowns register that preserves identity confidence, reported amount, units, method, source location, concern screening, and action ownership.
- A controlled exposure-basis package showing transparent device-count, release-fraction, route, duration, population, and source assumptions without choosing a toxicological threshold.
- A qualified TRA handoff record that separates chemistry facts, exposure assumptions, toxicology-source decisions, reviewer qualifications, uncertainty, and open questions.
- A fail-closed assessment, red-flag, action, and approval trail that cannot display a reassuring status while required review is unfinished.
- A BEP/BER and risk-management bridge that records what chemistry and qualified toxicology do and do not support for each biological decision area.
- Dated FDA, ISO, EU, and India source controls with draft, final, partial-recognition, amendment, transition, and recheck boundaries.
- A conspicuously fictional worked case that demonstrates mechanical exposure arithmetic and stops when unknown-substance and qualified-review evidence remain unresolved.

**SCOPE** This resource organizes chemical-characterization evidence for qualified toxicological and biological-safety review. It does not select toxicological values or uncertainty factors; establish biological safety, toxicological acceptability, conformity, or regulator acceptance; or replace a laboratory report or TRA. Device-specific conclusions require qualified reviewers in toxicology, biological safety, laboratory science, risk management, clinical practice, and each market.

The working sequence

| Step | Action                                                                     | Output                                      |
|------|----------------------------------------------------------------------------|---------------------------------------------|
| 1    | Define the controlled device, use, roles, and live-source baseline.        | Approved scope and source register          |
| 2    | Define the chemistry question and verify article representativeness.       | Study-purpose and article-fitness record    |
| 3    | Review extraction, controls, methods, AET, LOD/LOQ, and reporting.         | Method-fitness review                       |
| 4    | Load constituents and unknowns with report-level traceability.             | Constituent register                        |
| 5    | Build each time-segment and use-scenario mechanical exposure basis.        | Auditable exposure-basis record             |
| 6    | Prepare the factual constituent handoff for qualified toxicology.          | TRA handoff package                         |
| 7    | Link approved toxicology decisions to BEP/BER, risk, and markets.          | Evidence bridge                             |
| 8    | Close red flags; record qualified decisions, limits, dates, and approvals. | Controlled draft ready for qualified review |

Real workbook views

|    |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |
|----|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-------------------------------------------------------------|---------------|-------------------|-----------------|-------------------|--------------------|---------------|-------|
| 1  | A                                                                                                                                              | B                             | C                                                           | D             | E                 | F               | G                 | H                  | I             | J     |
| 2  | Characterization study fitness                                                                                                                 |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 3  | Study purpose, article representativeness, extraction, controls, report integrity, limitations, and disposition (v3.0-01)                      |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 4  | Assess every seeded control against the actual protocol and signed report. A seeded report is not automatically fit for the intended decision. |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 5  | Process ID                                                                                                                                     | Control area                  | Expected record                                             | Current state | Photo/signed test | Source location | Limitation/impact | Action/decision ID | Review/revise | Notes |
| 6  | FIT-001                                                                                                                                        | Characterization question     | Primary question and decisions informed/assessed            | Not assessed  | ▼                 |                 |                   |                    |               |       |
| 7  |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 8  | FIT-002                                                                                                                                        | Final finished article        | Configuration, process, storage/packaged state              | Not assessed  | ▼                 |                 |                   |                    |               |       |
| 9  |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 10 | FIT-003                                                                                                                                        | Worst-case rationale          | Question-specific comparison and countervailing factors     | Not assessed  | ▼                 |                 |                   |                    |               |       |
| 11 |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 12 | FIT-004                                                                                                                                        | Extraction design             | Solvents, ratio/volume, time, temperature, agitation        | Not assessed  | ▼                 |                 |                   |                    |               |       |
| 13 |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 14 | FIT-005                                                                                                                                        | Replicates/blanks/controls    | Actual design, variability, contamination disposition       | Not assessed  | ▼                 |                 |                   |                    |               |       |
| 15 |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 16 | FIT-006                                                                                                                                        | Analytical coverage           | Methods, analyte classes, blind spots                       | Not assessed  | ▼                 |                 |                   |                    |               |       |
| 17 |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 18 | FIT-007                                                                                                                                        | Threshold/variability         | AET, LOD/LOQ, UF, units, method exceptions                  | Not assessed  | ▼                 |                 |                   |                    |               |       |
| 19 |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 20 | FIT-008                                                                                                                                        | Identification/quantification | Confidence, calibration/response, result basis              | Not assessed  | ▼                 |                 |                   |                    |               |       |
| 21 |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 22 | FIT-009                                                                                                                                        | Deviation/report integrity    | Signal version, corrections, deviations, raw-data trace     | Not assessed  | ▼                 |                 |                   |                    |               |       |
| 23 |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 24 | FIT-010                                                                                                                                        | Use/exposure linkage          | Relationship between extraction model and intended exposure | Not assessed  | ▼                 |                 |                   |                    |               |       |
| 25 |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 26 |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 27 |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 28 |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 29 |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 30 |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |
| 31 |                                                                                                                                                |                               |                                                             |               |                   |                 |                   |                    |               |       |

Study-fitness sheet with seeded review questions, controlled states, and no prefilled conclusion.

|    |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|---------------------------|-------------|------------------------|-----------------------------|-----------------------------|----------------------|-------------------|----------------|-------------------------------------|
| 1  | Mechanical exposure basis                                                                                                                                       |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 2  | Transparent article count and release fraction arithmetic for qualified toxicologist review; no toxicological threshold or margin (v3.0rc1)                     |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 3  | Enter mass in micrograms/article, article/day, and release fraction 0 to 1. Document route, duration/time segment, population, source, and reviewer assignment. |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 4  | Exposure ID                                                                                                                                                     | Constituent ID | Mass/article (micrograms) | Article/day | Release fraction (0-1) | Daily mass (micrograms/day) | Route/duration/time segment | Population/body mass | Source/assumption | Reviewer state | Control state                       |
| 5  | 439-001                                                                                                                                                         |                |                           |             |                        | INCOMPLETE                  |                             |                      |                   | No assignment  | INCOMPLETE - REQUIRED BASIS MISSING |
| 6  |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 7  |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 8  |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 9  |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 10 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 11 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 12 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 13 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 14 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 15 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 16 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 17 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 18 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 19 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 20 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 21 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 22 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 23 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 24 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 25 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 26 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 27 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 28 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 29 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 30 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 31 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 32 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 33 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 34 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 35 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 36 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |
| 37 |                                                                                                                                                                 |                |                           |             |                        |                             |                             |                      |                   |                |                                     |

Exposure-basis sheet showing transparent mechanical arithmetic and a qualified-review control state.

|    |                                                                                                                                                                            |                                                        |               |            |             |                  |                                            |                                   |                               |                               |                                  |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|---------------|------------|-------------|------------------|--------------------------------------------|-----------------------------------|-------------------------------|-------------------------------|----------------------------------|
| 1  | Fictional training example - do not submit                                                                                                                                 |                                                        |               |            |             |                  |                                            |                                   |                               |                               |                                  |
| 2  | Complete workflow demonstration excluded from all live formulas (v3.0rc1)                                                                                                  |                                                        |               |            |             |                  |                                            |                                   |                               |                               |                                  |
| 3  | Northstar Devices, NS-HYDRO-100, FIC-CHR-001, all values, and all decisions are invented. Delete this sheet from a project copy if it could be mistaken for live evidence. |                                                        |               |            |             |                  |                                            |                                   |                               |                               |                                  |
| 4  | Step                                                                                                                                                                       | Procedural record                                      | Linked ID     | Manuscript | Article/day | Release fraction | Daily mass                                 | Evidence/rationale                | State                         | Next action                   | Answer key                       |
| 5  | Scope                                                                                                                                                                      | NS-HYDRO-100, sterile aged hydrogel-contact device     | FIC-SCOPE-001 |            |             |                  |                                            | Invented device/use profile       | Recorded                      | Review article                | Training data only               |
| 6  | Study                                                                                                                                                                      | Final article/fictional report FIC-CHR-001             | FIC-FIT-001   |            |             |                  |                                            | Article and method trace complete | Bounded use                   | Load results                  | Not a real report                |
| 7  | Constituent                                                                                                                                                                | FIC-C01 identified                                     | FIC-C01       | 25         | 2           | 1                | 50 FIC-CHR-001 Table 7: 25 x 2 x 1         | Mechanical basis ready            | Qualified toxicology review   | Qualified toxicology review   | No toxicity value selected       |
| 8  | Unknown                                                                                                                                                                    | FIC-U01 below reporting threshold, identity unresolved | FIC-U01       |            |             |                  | FIC-CHR-001 Figure 4                       | OPEN - QUALIFIED REVIEW           | Identity/Coc investigation    | Identity/Coc investigation    | Below threshold is not closure   |
| 9  | TRA handoff                                                                                                                                                                | Device, chemistry, and exposure inputs assembled       | FIC-H01       |            |             |                  | No qualified toxicology source or decision | INCOMPLETE                        | Assign qualified toxicologist | Assign qualified toxicologist | Administrative completeness only |
| 10 | Outcome                                                                                                                                                                    | Open unknown and no qualified conclusion               | FIC-RP-001    |            |             |                  | Unresolved scientific and review controls  | STOP - QUALIFIED REVIEW REQUIRED  | Resolve and re-review         | Resolve and re-review         | Correct fail-closed outcome      |
| 11 |                                                                                                                                                                            |                                                        |               |            |             |                  |                                            |                                   |                               |                               |                                  |
| 12 |                                                                                                                                                                            |                                                        |               |            |             |                  |                                            |                                   |                               |                               |                                  |
| 13 |                                                                                                                                                                            |                                                        |               |            |             |                  |                                            |                                   |                               |                               |                                  |
| 14 |                                                                                                                                                                            |                                                        |               |            |             |                  |                                            |                                   |                               |                               |                                  |
| 15 |                                                                                                                                                                            |                                                        |               |            |             |                  |                                            |                                   |                               |                               |                                  |
| 16 |                                                                                                                                                                            |                                                        |               |            |             |                  |                                            |                                   |                               |                               |                                  |
| 17 |                                                                                                                                                                            |                                                        |               |            |             |                  |                                            |                                   |                               |                               |                                  |
| 18 |                                                                                                                                                                            |                                                        |               |            |             |                  |                                            |                                   |                               |                               |                                  |
| 19 |                                                                                                                                                                            |                                                        |               |            |             |                  |                                            |                                   |                               |                               |                                  |

Isolated fictional example ending in a stop state because the unknown and qualified toxicology decisions remain unresolved.

WHAT YOU WILL NEED Bring a controlled device/use profile, final chemistry protocol and report, report locations and units, extraction and method details, an exposure-use basis, applicable official sources, and named qualified reviewers.

## What the current v3.0 edition contains

| File                                                   | Use it for                                                                                                 | Complete when                                                                                   |
|--------------------------------------------------------|------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| Quick Start PDF                                        | Use the eight-step route and stop conditions before entering project data.                                 | The team understands required inputs, source controls, and escalation.                          |
| Implementation Guide PDF                               | Apply the study-fitness, data-quality, exposure, TRA-handoff, integration, and jurisdiction modules.       | Each applicable module records its output, evidence, limits, owner, and reviewer.               |
| Editable Working Templates DOCX                        | Create controlled memos, clarification requests, handoffs, evidence indexes, and approvals.                | Instruction fields are completed, sources cited, examples removed, and named reviewers approve. |
| Operational Workbook XLSX                              | Maintain source, study, constituent, unknown, exposure, assessment, red-flag, action, and example records. | The dashboard stays fail-closed until each control has a traceable disposition.                 |
| Source Status PDF and CSV                              | Verify official status, recognition extent, exclusions, draft/final state, transitions, and rechecks.      | Each decision cites the live source and lawfully consulted edition.                             |
| README, Responsible-Use Terms, Manifest, and Checksums | Orient users, control permitted use, confirm package identity, and verify integrity.                       | Inventory and hashes match, and organizational handling rules are applied.                      |

## What is deliberately not promised

- The toolkit is not a chemical-characterization laboratory protocol and does not replace laboratory method development, validation, raw-data review, or report correction.
- The workbook does not choose TTC, TI, TSL, PDE, DNEL, a point of departure, uncertainty factor, or toxicological source and does not calculate an acceptable margin.
- Completing the templates does not establish biological safety, endpoint closure, conformity, FDA acceptance, CE marking, CDSCO acceptance, or a no-new-testing conclusion.
- The September 2024 FDA chemical-analysis document is draft and Not for Implementation; it is not presented as final FDA policy.
- The source register is dated, not permanent. Recognition, guidance, law, standards, amendments, submission formats, and regulator expectations must be rechecked at material use.
- The fictional example is training content, not device evidence, and is excluded from live workbook formulas and customer project inputs.

**AVAILABILITY** Current v3.0 customer edition. Online checkout, payment, customer download, and automatic delivery are not currently enabled. Request current availability to receive any controlled offer, including the exact version, licence, price, update entitlement, policies, and delivery method before payment.

Product page and current availability: [meddevadvisory.com/chemical-characterization-tra-integration-toolkit](https://meddevadvisory.com/chemical-characterization-tra-integration-toolkit)