Pharmaceuticals, Biotechnology & Medical Device Intelligence: Client Evidence Preparation Guide

ILLUSTRATIVE DIVISION CLIENT GUIDE | PUBLIC-SOURCE AND SERVICE METHODOLOGY

No completed client matter is represented. This document demonstrates questions, evidence requirements, limitations and possible deliverables. It contains no verified findings about a named buyer or company. A matter, source access, fixed fee and timing require separate written acceptance.

Why a buyer commissions this work

What is the authoritative product, trial and regulatory-record status?

Typical instruction: FDA communication, study update, device recall or partner review. Buyer groups include Life-science investors, device manufacturers, counsel and procurement.

Documents and identifiers to assemble

- Exact company, counterparty, project or asset identity, aliases and known registration numbers.
- Current decision owner, written decision, jurisdiction and relevant deadline.
- Main client-supplied statement together with previous iterations or terms, where lawful.
- Original `FDA device database`, `ClinicalTrials.gov` and `product manufacturer registration`, or a list of unavailable originals.
- One account or public record likely to contradict the client's preferred explanation.

The five questions a buyer should resolve first

- What is the authoritative product, trial and regulatory-record status?
- Is the `FDA device database` properly dated and matched to the exact legal subject?
- Does the `ClinicalTrials.gov` have an independent issuer, or is it repeating a press statement?
- Might `trial not approval` or `device name mismatch` cause reliance to be misplaced?
- What precise record would resolve `recall absent due to search limitation`?

Choose the smallest justified purchase

Immediate buyer problem; Evidence product; Starting point

Entry decision; Medical Device Regulatory Evidence Brief; /specialist-divisions/pharmaceuticals-biotechnology-medical-device-intelligence/offers/evidence-first-look/

Identity decision; Identity & Source Map; /specialist-divisions/pharmaceuticals-biotechnology-medical-device-intelligence/offers/identity-source-map/

Claim decision; Material Claims Verification; /specialist-divisions/pharmaceuticals-biotechnology-medical-device-intelligence/offers/claim-verification/

Timing decision; Independent Chronology Reconstruction; /specialist-divisions/pharmaceuticals-biotechnology-medical-device-intelligence/offers/chronology-reconstruction/

Counterparty decision; Counterparty & Relationship Check; /specialist-divisions/pharmaceuticals-biotechnology-medical-device-intelligence/offers/counterparty-network-check/

Decision-pack review; Decision-Ready Evidence Dossier; /specialist-divisions/pharmaceuticals-biotechnology-medical-device-intelligence/offers/decision-dossier/

Repeat-work pilot; Repeat-File Evidence Desk; /specialist-divisions/pharmaceuticals-biotechnology-medical-device-intelligence/offers/repeat-file-desk/

Monitoring pilot; Clinical & Device Public Record Watch; /specialist-divisions/pharmaceuticals-biotechnology-medical-device-intelligence/offers/material-change-watch/

Outputs and reliance

The outcome should contain `regulated product state brief`, `trial-source crosswalk` and `manufacturer evidence map` as appropriate to the agreed scope, together with a dated source index, contrary evidence, remaining uncertainty and human review status.

Source candidates and critical caveats

Ref; Primary source / comparator; Link; Evidence limitation and status

FDA-DEVICE; U.S. FDA: openFDA device recall API; https://open.fda.gov/apis/device/recall/how-to-use-the-endpoint/; WEB CHECKED 2026-10-12. Database refresh and product name ambiguity require original FDA reconciliation

FTC-ADS; U.S. FTC: Advertising substantiation standards FAQ; https://www.ftc.gov/business-guidance/resources/advertising-faqs-guide-small-business; WEB CHECKED 2026-10-12. US advertising context; scientific/health claims may require specialised testing not performed by Aperture

S16; U.S. FDA open data for devices; https://open.fda.gov/apis/device/; REGISTER STARTING POINT; NOT NEWLY RECHECKED. Source candidate; subject relevance, date and access must be verified case-by-case.

Do not confuse source availability with proof of the individual case. Data may be stale, incomplete or access-controlled. Initial portal research is not a mandate, accreditation or certification.

Legal and professional boundary

No medical advice, efficacy certification or approval determination.

Next step

Request a written, defined scope and commercially approved fee before instructing, paying or sharing confidential records.

- Confirm the appointing client, exact research question, relevant location, decision date, conflicts, privacy, sanctions and licensing.
- Check original source identity, authority, issue date, effective date, retrieval timestamp, version and lawful access.
- Reproduce important calculations and compare at least one plausible contrary explanation.

- Keep allegations, regulatory findings, historical claims and unresolved matches distinct.
- Mark each proposed finding supported, partially supported, contradicted, unresolved or outside mandate; include missing-source requests.
- Confirm that illustrations do not imply a real engagement, completed investigation, certified outcome or affiliation with named comparators.
- Obtain final human sign-off on accuracy, legal boundaries, confidentiality, claims and publication version before release.

Professional boundaries: Independent research support only. No legal, tax, investment, audit, valuation, brokerage, investigation requiring a specific professional licence or regulated opinion is implied. No confidential material should be sent before instructions.