

Material Changes: Build a Traceable Comparison

RUIKANG Li (Neo)

Hongkong Kannry Industrial Co., Ltd. | www.kannrybio.com

Abstract. A material can remain within its COA limits after a supplier, process or analytical change while its behavior in the customer process shifts. This guide sets out a proposed change-comparison record that connects the changed attribute, affected lots and evidence needed for disposition.

Keywords: material change; supplier notification; lot traceability; comparison; risk

1. Describe the delta, not just the grade

Record the old and new supplier, site, route, raw-material source, equipment, milling or thermal step, packaging or analytical method as applicable. Identify what changed, what did not, the reason and the planned effective date.

List affected grades, specifications and customer uses. A shared trade name or a passing COA is not an adequate description of equivalence. Avoid combining several unrelated changes in one unexplained comparison.

2. Link the change to a failure pathway

Write an explicit hypothesis: for example, a milling-media change may introduce a different impurity pathway, while a milling-energy change may affect dispersion or surface area. These are assessment prompts, not claims that a particular supplier has such problems.

Select tests that can detect the hypothesized difference. Preserve the method, sample preparation and units. Add a customer-process response when an incoming material attribute alone cannot resolve the risk.

FDA device-change guidance recognizes that supplier or manufacturing changes can need assessment even where specifications remain unchanged [1]. Its regulatory decision framework is not a raw-powder approval certificate.

5. Proposed change-comparison packet

This is a practical buyer-supplier record, not a standard-mandated form. Set acceptance criteria before reviewing results and separate the decision on raw-material supply from the device manufacturer's regulatory assessment.

3. Design a fair bridge

Compare retained pre-change material and post-change material using the same justified methods where possible. Document storage age and condition so that aging is not mistaken for a manufacturing effect.

Choose representative independent lots and replicates based on the uncertainty and intended decision. Repeated measurements from one sample do not demonstrate consistency across manufacturing lots. State the sample-size rationale rather than selecting a universal count.

If the analytical method also changes, separate method comparability from material comparability. A paired reference measured by both methods can help identify a measurement shift; it does not remove all sampling uncertainty.

4. Keep the lot boundary visible

Record the last identified pre-change lot, first post-change lot and any mixed or reworked inventory. Link production, packaging and shipped lot identifiers where they differ. Record who received the affected material.

Keep the original results, deviations and investigation outcome. Preserve an explicit disposition of accept for the defined use, investigate further, or do not use under the current approval. Avoid replacing an unresolved result with a later passing value.

Record	Evidence to retain	Decision supported
Change identity	Unique change ID; old/new revisions; scope and reason.	A specific, reviewable difference.
Risk hypothesis	Potentially affected chemistry, physical attributes and customer process.	Tests tied to the change mechanism.
Comparison design	Pre/post lots, retained controls, methods and sample-size rationale.	A comparison not confounded by method or age.
Results	Raw data, variability, deviations and out-of-criterion findings.	A traceable basis for disposition.
Supply boundary	Effective date; first changed lot; inventory and shipment mapping.	Prevent accidental mixing of approval states.
Closure	Responsible reviewer, approved scope, unresolved items and communication record.	No implied approval beyond the defined use.

6. Document what the bridge does not prove

A comparable BET area does not establish comparable trace impurities; a matching phase result does not establish unchanged processing residues. Identify untested attributes explicitly. The customer may need evidence on its final processed article where raw-material comparisons cannot resolve a relevant change [2].

Relation to the existing series

KB-TG-023 concerns routine lot consistency and KB-TG-027 concerns sample-to-pilot evaluation. This guide addresses an identified change after a baseline exists. It does not decide whether a regulatory submission is required or claim that Kannrybio operates a certified change-control system.

References and evidence boundaries

[1] FDA. Deciding When to Submit a 510(k) for a Change to an Existing Device. 25 October 2017. Section C, materials changes. Official guidance PDF. The retrieved document carries a QMSR update notice; device-specific regulatory requirements must be assessed separately.

[2] FDA. Component and Device Documentation Examples for Test Articles or Previously Marketed Devices. Official resource. Based on Attachment F of the September 2023 biocompatibility guidance; supports justified comparison to the final finished article.

Sources checked 30 October 2026. Research planning guidance only; no Kannrybio lot-performance, clinical or regulatory-approval claim.

Prepared by: RUIKANG Li (Neo)



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