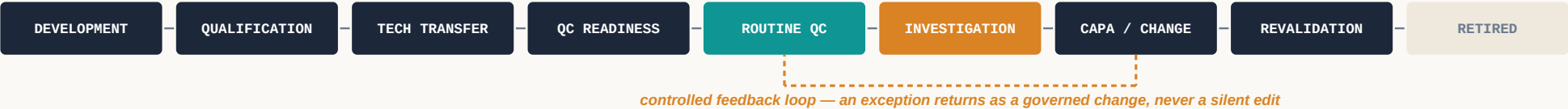


Analytical Method Data Lineage

Development to QC and continuous improvement · entities, lineage, state transitions, relationship rules

LIFECYCLE STATE one entity moving through defined transitions — state governs what may happen to the record



SYSTEM RECORDS where each attribute is governed, and which system is source of truth

DEFINITION	CONFIGURATION	EXECUTION	EXCEPTION + CHANGE
- Method master record - SOP / document control - Validation protocol + report - Specification record	- Instrument configuration - LIMS method configuration - Data-processing rule set - Training / qualification record	- Raw instrument data - Analytical result record - Run / batch context - Analyst and timestamp	- Deviation / OOS record - Investigation / CAPA record - Change-control record - Retained archive

ATTRIBUTE GOVERNANCE one owner and one source of truth per attribute — the rest of the estate reads, never writes

ATTRIBUTE	SOURCE OF TRUTH	GOVERNING RULE
Method ID / version	Method master record	Immutable once active
Intended use + specification	Specification record	Change-controlled
Instrument + software config	Instrument configuration	Verified at readiness gate
Analyst qualification	Training record	Blocks execution if absent
Result + run context	Analytical result record	Write-once, audit-trailed

RELATIONSHIP RULES the constraints that keep the graph valid while records change state

1:1 Every QC run maps to exactly one approved method version.	1:1 Every method version maps to a valid specification and a defined intended use.
N:1 Every deviation references method, version, instrument, sample or product, analyst, and run context.	GATE A revised version cannot go active until training, documentation, system configuration, and acceptance are complete.
STATE A retired method stays historically traceable but cannot be selected for a new routine run.	TRIGGER A post-transfer trend signal opens a reviewable case linked to the method version and every affected record.

THE SAME SHAPE IN A CONTENT CATALOG

A method record carries identity, versions, attributes, relationships, state transitions, owners, dependent systems, and exceptions. A title record carries the same structure across seasons, episodes, assets, language versions, rights, releases, and formats. Both break the same way: an entity changes state and the rules governing that transition were never written down. The governing problem is identical — keep every entity valid, interpretable, connected, and controlled through change.