

Illustrative Quality Intelligence Pack

NovaCura Manufacturing - fictional illustrative organization

A synthetic example of quality-process scope, governed metrics, recurrence candidates, CAPA aging, human review, controlled AI assistance, testing, and a 90-day roadmap.

Pragy Business Process Consulting Services

Creating Value, Delivering Excellence

No client information, regulated records, inspection claims, compliance claims, or measured client outcomes are included.

2. Scope and governance

This fictional pack focuses on one site-level deviation and CAPA review system. Accountable quality decisions remain with authorized NovaCura personnel.

Boundary

Element	Illustrative definition
Trigger	A quality event or CAPA status changes
Owner	Site Quality Systems Lead
Outcome	Verified signal, assigned action, evidence and authorized decision
Sources	Synthetic deviation, CAPA and audit-action extracts
Exclusions	Batch release, disposition, regulatory interpretation and formal CSV

Decision rights

Classification drafts, trends and recurrence candidates support review. Root cause, CAPA effectiveness, record closure, product disposition and regulatory conclusions remain authorized client decisions.

One bounded quality system - not an eQMS replacement.

3. Current-state quality workflow

The current state illustrates fragmented reporting, inconsistent categories, repeated spreadsheet preparation, and unclear escalation.

Observed flow

Event record -> local categorization -> spreadsheet extract -> manual reconciliation -> slide preparation -> meeting follow-up -> separate action tracking.

Failure modes

Condition	Operating effect	Control need
Category variants	Trends are not comparable	Controlled taxonomy
Missing status history	Aging is disputed	Source reconciliation
Separate action log	Follow-through is unclear	Linked ownership
Unrecorded decisions	Rationale is hard to trace	Decision register

Illustrative operating conditions only - not measured client findings.

4. Quality taxonomy

A controlled taxonomy makes trends reviewable and preserves the distinction between source facts, classifications, candidate signals and approved conclusions.

Illustrative categories

Field	Controlled example	Reviewer
Event type	Deviation / nonconformance	Quality systems
Process area	Material handling	Process owner
Impact	Potential / confirmed	Authorized quality reviewer
Recurrence	Candidate / rejected / confirmed	Investigator and quality approver

Rule

A recurrence candidate is a review signal, not a proven recurrence or root cause.

Controlled definitions require owner approval and change control.

5. Data readiness

The sample checks unique identifiers, dates, status history, categories, ownership, due dates, approvals, action links and transformation logic.

Readiness status

Data element	Illustrative status	Required action
Unique event ID	Complete	Retain source key
Status history	Partial	Reconcile 6 synthetic records
CAPA action link	Available	Verify relationship
Effectiveness evidence	Inconsistent	Define evidence field
Owner and due date	Available	Confirm accountability

Traceability

Every displayed metric should identify its source, transformation, refresh point, owner, quality status and limitation.

A dashboard cannot repair missing ownership or unreliable source data by itself.

6. Quality scorecard

Synthetic values show how status, owner, threshold, response and data quality can appear together.

Scorecard

Measure	Value	Threshold	Owner	Response
Open quality events	42	>40 review	Quality systems	Review aging
CAPA >60 days	9	>5 escalate	CAPA owners	Escalation review
Data completeness	94%	<98% reconcile	Data steward	Correct exceptions
Effectiveness due	7	Any overdue	Quality approver	Schedule review

Synthetic values are not benchmarks, targets, or client outcomes.

7. Trend and recurrence-candidate view

A rising similarity signal may justify accountable review, but it does not establish recurrence or root cause.

Candidate review

Signal	Context	Evidence needed	Decision
Category A increase	8-week window	Source records and classification quality	Quality review required
Similar description	Draft text match	Investigation evidence	Candidate only
Repeat equipment	Same asset context	Maintenance and event history	Escalate for review

Required label

Candidate signal - quality review required.

False positives, incomplete records and taxonomy changes must be recorded.

8. CAPA aging and escalation

Aging bands connect time, accountable ownership, escalation and evidence without automatically closing or judging effectiveness.

Illustrative escalation

Age	Open	Expected response	Decision owner
0-30 days	18	Owner follow-through	Action owner
31-60 days	11	Manager review	Process owner
61-90 days	6	Quality escalation	Quality systems
>90 days	3	Executive attention	Authorized governance forum

Effectiveness requires evidence and authorized assessment.

9. Quality event-to-action workflow

The future-state flow brings data-quality checks, controlled classification, review, action, escalation, evidence and authorized closure into one traceable sequence.

Controlled sequence

Quality event -> completeness check -> controlled classification -> quality review -> investigation or action -> CAPA follow-up -> aging and escalation -> effectiveness evidence -> authorized closure -> trend review.

Human control

Classification may be assisted but requires review. Root cause requires evidence. Closure remains a client decision.

No autonomous record approval or closure.

10. AI-assisted quality controls

Optional AI assistance can draft a classification, summary or recurrence signal only inside an approved environment with defined verification and fallback.

Controlled flow

Approved source records -> AI-assisted draft or signal -> source verification -> quality review -> edit / reject / escalate -> authorized approval -> controlled use.

Prohibited independent decisions

AI may assist	AI must not independently
Draft classification	Determine final root cause
Controlled summarization	Approve or close a deviation or CAPA
Similar-record retrieval	Determine effectiveness
Narrative draft	Release a batch or product

AI-assisted draft - authorized quality review required.

11. Management-review pack

The review pack supports a disciplined conversation about data quality, signals, aging, decisions, actions and sustainment.

Illustrative agenda

Minutes	Topic	Output
0-10	Data-quality exceptions	Reconciliation decisions
10-25	Events and recurrence candidates	Review or investigation route
25-40	CAPA aging and effectiveness	Escalations and owners
40-55	Actions and decisions	Named commitments
55-60	Close	Recorded decisions and next review

The review does not replace the client quality unit or approved quality procedures.

12. Test and reconciliation plan

Ordinary implementation testing verifies the configured pilot. The client determines whether formal validation applies.

Test set

Scenario	Expected result	Evidence	Owner
Missing event date	Data-quality exception	Test record	Data steward
CAPA crosses threshold	Escalation alert	Rule evidence	Quality systems
AI draft lacks source	Reject and fallback	Review log	Authorized reviewer
Closure attempted	Client approval required	Access test	Quality owner

Boundary

Client validation decision and approved testing pathway.

Ordinary testing is not formal validation unless performed under the client's approved system.

13. 90-day roadmap

The sequence is illustrative and must be adjusted to approved scope, quality oversight, security, data and validation decisions.

Roadmap

Period	Priority	Evidence
Days 1-30	Confirm scope, owners, taxonomy and sources	Approved definitions and data inventory
Days 31-60	Configure views, rules and review controls	Pilot, reconciliation and issue log
Days 61-90	Test, train, hand over and review	Acceptance, SOP, ownership and sustainment plan

Scale, stabilize, pause or stop based on evidence and authorized decisions.

14. Disclaimer and next steps

This sample illustrates a possible engagement structure for a fictional organization using synthetic information.

What it does not provide

It does not provide legal or regulatory advice, compliance certification, inspection readiness, formal computer-system validation, a product-release decision, a root-cause conclusion, a CAPA-effectiveness conclusion, or guaranteed results.

Possible next step

Request a Quality Intelligence Blueprint, a bounded CAPA & Quality Workflow Accelerator, a Quality Intelligence Operating System, or a custom regulated and validated scope review.

Contact

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Actual scope, tools, measures, controls, timeline and deliverables depend on the approved statement of work and client environment.