ComplianceQuest Inc.
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Can This Change Safely Go Effective?

Pharmaceutical Change Readiness Assessment

An approved change does not guarantee implementation.

Before a process, equipment, supplier, specification, document, or procedural change becomes effective, pharmaceutical organizations must ensure that all affected documents, personnel, risks, and operational controls have been updated and verified.

Use this assessment to evaluate whether your change is truly ready for implementation.

Impact Assessment

#	Assessment Question	Yes	No	N/A
1.	Have all affected departments and stakeholders been identified?	☐	☐	☐
2.	Have impacted SOPs, work instructions, specifications, forms, and templates been identified?	☐	☐	☐
3.	Have affected products, processes, equipment, systems, suppliers, and sites been evaluated?	☐	☐	☐
4.	Has a documented quality risk assessment been completed?	☐	☐	☐
5.	Have regulatory and compliance impacts been assessed?	☐	☐	☐
6.	Have validation, qualification, or verification requirements been identified?	☐	☐	☐

Document & Procedure Readiness

#	Assessment Question	Yes	No	N/A
7.	Have all affected SOPs and controlled documents been revised and approved?	☐	☐	☐
8.	Have related specifications, records, and supporting documents been updated?	☐	☐	☐
9.	Have obsolete document versions been retired or removed from use?	☐	☐	☐
10.	Are current approved versions accessible to all affected personnel?	☐	☐	☐
11.	Are document effective dates aligned with the planned implementation date?	☐	☐	☐

Training & Personnel Readiness

#	Assessment Question	Yes	No	N/A
12.	Have all affected roles and employee groups been identified?	☐	☐	☐
13.	Has training been assigned to all impacted personnel?	☐	☐	☐
14.	Has required training been completed prior to implementation?	☐	☐	☐

15.	Can completion records be readily demonstrated during an inspection?	☐	☐	☐
16.	Have contractor, temporary, and third-party personnel been included where applicable?	☐	☐	☐
17.	Have competency or qualification requirements been verified where required?	☐	☐	☐

Reality Check

The SOP was updated.

But:

- Was every affected employee trained?
- Were obsolete versions removed?
- Were suppliers and external partners notified?
- Can you prove implementation during an inspection?

If the answer to any of these questions is “No,” your change may be approved, but it may not be ready.

Operational Implementation

#	Assessment Question	Yes	No	N/A
18.	Have all implementation actions been assigned and tracked?	☐	☐	☐
19.	Have affected suppliers, contract manufacturers, or external partners been notified?	☐	☐	☐
20.	Have equipment, process, system, or workflow updates been fully deployed?	☐	☐	☐
21.	Have all required approvals been completed before go-live?	☐	☐	☐
22.	Is there documented evidence that implementation activities were completed as planned?	☐	☐	☐

Change Effectiveness & Verification

#	Assessment Question	Yes	No	N/A
23.	Has implementation been verified following go-live?	☐	☐	☐
24.	Have effectiveness criteria been clearly defined?	☐	☐	☐
25.	Have effectiveness checks been scheduled and assigned?	☐	☐	☐

26.	Is there objective evidence the change achieved its intended outcome?	☐	☐	☐
27.	Has residual risk been reviewed after implementation?	☐	☐	☐
28.	Have related deviations, investigations, CAPAs, complaints, or quality events been evaluated following implementation?	☐	☐	☐

Scoring Your Results

Total "Yes" Responses: _____ / 28

24–28 Yes Responses

Change Ready

Your organization appears prepared to implement the change and demonstrate implementation effectiveness.

18–23 Yes Responses

Implementation Risk

Some elements of change readiness may be incomplete. Review gaps before allowing the change to take effect.

Fewer Than 18 Yes Responses

Approval Does Not Equal Readiness

Significant readiness gaps may exist between change approval and operational adoption. Additional actions should be completed before implementation.

Key Insight

Approval Is a Decision.

Readiness Is the Proof.

A pharmaceutical change is not complete when the change record is approved.

It is complete when affected documents are current, employees are trained, risks are assessed, implementation is verified, and the organization can demonstrate that the change achieved its intended outcome.

Is Your Change Process Connected From Approval Through Effectiveness?

ComplianceQuest Change Management Module connects change control with document management, training, risk assessments, CAPA, and implementation activities, giving quality teams visibility into readiness, execution status, and post-change effectiveness across the organization.

Learn more about ComplianceQuest Change Management here.

About ComplianceQuest

ComplianceQuest is the #1 AI-powered Quality, Risk, and Compliance (QRC) system that connects Product, Quality, Manufacturing, People, Suppliers and Customers in a single system. Built on Salesforce, the system delivers end-to-end visibility, AI-driven intelligence, and enterprise-scale execution, enabling organizations to manage risk, ensure regulatory compliance, and turn quality into a driver of growth.

ComplianceQuest is pre-validated and easy to implement, use, and maintain, allowing for streamlined communication and collaboration across the product value chain.

For more information, or to request a demo with a ComplianceQuest Expert, contact us today:

- Visit **www.compliancequest.com**
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