

CS-LEG-0007 · COMPLIANCESUITE DOCUMENTATION

# Business Case.

FIT-only redaction. Effective 2026-04-28.

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*Public — Documentation · Review cycle: On change*

# Control block and metadata anchor.

The control block identifies the document, its current revision, the regulated process it supports, and the people accountable for its lifecycle. Every value below is the source of truth for any downstream record, audit trail entry, or signature block.

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# Sign-off table, ready for ink or e-signature.

The signatures below confirm review and authorisation of this document. Approvals must be recorded in chronological order. If the document is signed electronically, the e-signature record on the ComplianceSuite platform supersedes any handwritten entry on this page and carries the same legal weight under 21 CFR Part 11 and EU GMP Annex 11.

Role	Name	Function	Date	Signature
Author		Validation Lead		
Reviewer		Quality Assurance		
Reviewer		Process / System Owner		
Approver		Head of Quality		
Approver		Regulatory Affairs		

03 — CONTENTS

# What's in this document.

01 — Document Control	.....	—
02 — Approvals	.....	—
03 — Contents	.....	—
01 — What this edition covers	.....	—
02 — What this edition does NOT cover	.....	—
03 — How to Use This Template	.....	—
04 — Executive Summary (Section 1)	.....	—
05 — Current-State Problem Statement (Section 2)	.....	—
06 — Target-State Operating Model (Section 3)	.....	—
07 — Quantified Benefits (Section 4)	.....	—
08 — Investment (Section 5)	.....	—
09 — Risk & Mitigation (Section 6)	.....	—
10 — Implementation & Decision (Sections 7–8)	.....	—
11 — Code Reference	.....	—

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Revision History

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Glossary & Abbreviations

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# What this edition covers.

- **Executive Summary:** One-page CFO pitch with problem, intervention, benefits, recommendation
- **Current-State Problem Statement:** Symptom, root cause, cost of inaction
- **Target-State Operating Model:** Consolidation, operating-model changes, what stays the same
- **Quantified Benefits:** Validation throughput, FTE allocation, periodic-review compliance, audit trail completeness
- **Investment:** Subscription, implementation, training, operational ongoing
- **Risk & Mitigation:** Migration disruption, internal adoption resistance, inspector unfamiliarity, vendor dependency, AI composer scrutiny, information security
- **Implementation Plan:** Stages 1–5 (sandbox, provisioning, first system, migration, steady state)
- **Decision Recommendation:** Tier, term, go-live, sponsor

# What this edition does **NOT** cover.

- **Quantified benefits with concrete platform features:** Statements like "REST API for CI/CD integration" or "BYOK for compliance requirements" are removed because these are not FIT in the code. **Benefits are limited to:** validation library consolidation (change model FIT), unified audit trail (with limitation to append-only, no hash-chain enforcement), phase-gate SoD (implemented).
- **Tier-specific targets:** Response time, resolution time, availability %, credit thresholds — subscription tier logic is not implemented. All tier values are placeholders <...>.

# How to Use This Template.

This business-case template is for the **customer's internal CFO / procurement approvals**. ComplianceSuite Customer Success can co-author specific sections with documented platform evidence; the final case is the customer's own.

A good business case for ComplianceSuite answers **four questions in order**:

- 01 What problem are we solving?** — Validation throughput / inspection readiness / tooling sprawl / supplier-qualification burden
- 02 What does the platform change about how we solve it?** — Consolidation onto ComplianceSuite for validation library & change control
- 03 What is the expected return?** — Quantified benefits (throughput, FTE, compliance, audit trail)
- 04 What are the risks and how do we manage them?** — Migration, adoption, inspector familiarity, vendor dependency, AI Act scrutiny, infosec

## Structure

- 01** Executive summary
- 02** Current-state problem statement
- 03** Target-state operating model
- 04** Quantified benefits
- 05** Investment
- 06** Risk and mitigation
- 07** Implementation plan
- 08** Decision recommendation

# Executive Summary (Section 1).

Maximum three short paragraphs for the CFO:

- **Paragraph 1:** Name the problem (validation throughput / inspection readiness / tooling sprawl / supplier-qualification burden — pick one).
- **Paragraph 2:** Name the intervention (consolidating onto ComplianceSuite for validation library and change control).
- **Paragraph 3:** Name the headline benefits and the decision recommendation.

**Lead with the problem, not the platform.** CFOs read the first paragraph and skim the rest. If the first paragraph is *"we want to buy ComplianceSuite"* instead of *"validation throughput is limiting our ability to launch <product / market>"*, the case will be harder.

# Current-State Problem Statement (Section 2).

## 2.1 Symptom

Concrete observations of the problem in the customer's own words. Example:

**NOTE**

Validation packages take a quarter to close out. The bottleneck is multi-tool coordination — URS in Word, risk in Excel, IQ/OQ/PQ in a custom database, validation report assembled by hand.

## 2.2 Root Cause

Brief root-cause analysis. Common patterns:

- Tool fragmentation
- Lack of audit-trail consolidation
- Ad-hoc role assignment
- Manual separation-of-duties verification
- Periodic reviews drift because no single owner

## 2.3 Cost of Inaction

- Operational cost — e.g., validation FTE allocation that could be redeployed to higher-value work
- Inspection cost — e.g., binder preparation effort; inspector time navigating fragmented evidence
- Risk cost — e.g., the deviation that blocked the last batch release; the warning letter a peer company received last year
- Strategic cost — e.g., validation throughput limiting product-launch cadence

# Target-State Operating Model (Section 3).

## 3.1 Consolidation

Validation library, change control, audit trail, e-signatures, and inspection exports consolidate onto a single platform. The eliminated tools are <list – typically Word/Excel fragmentation, custom database, ad-hoc SharePoint site>.

## 3.2 Operating-Model Changes

Change	Impact
Authoring	From per-tool drafting to template-driven authoring with AI assistance under explicit human review
Routing	From email-based approval trails to platform-enforced phase gates with hard-wired SoD
Audit Trail	From per-tool logs, stitched manually, to unified append-only trail (with limitations to hash-chain enforcement — see whitepaper)
Inspection	From binder preparation to one-button inspection pack exports
Periodic Review	From calendar-driven manual workflow to platform-scheduled changes with audit trail digest as reviewer input

## 3.3 What Stays the Same

QMS remains the customer's own. SOPs are unchanged in spirit; platform supports them through tenant SOP library. Roles remain in the quality function. Inspection authority remains with the inspector.

# Quantified Benefits (Section 4).

Each benefit area is filled with the customer's own baseline and target. ComplianceSuite Customer Success can provide observed ranges from comparable deployments under NDA; the customer's case uses the customer's own numbers.

Benefit Area	Baseline (Current State)	Target (With Platform)
Validation Throughput (changes closed per period)	<baseline>	<target>
FTE Allocation to validation	<baseline>	<target>
Inspection Binder Preparation (hours per cycle)	<baseline>	<target>
Periodic Review Compliance (% on schedule)	<baseline>	<target>
Tool Consolidation (number of tools eliminated)	<baseline>	<target>
Audit Trail Completeness (% of relevant events captured automatically)	<baseline>	<target>

**Use ranges, not point estimates.** Single-number targets invite scrutiny. Ranges with explicit assumptions invite agreement. Where customer success has provided a comparable deployment's observed range, attribute it: *"based on observed deployments at peer organizations of comparable scale"*.

# Investment (Section 5).

Investment is sized in the executed Service Order. The business case structures the cost discussion; concrete values come from the negotiated subscription.

Cost Line	Description
Subscription	Tier-based; per executed Service Order; multi-year terms typically available
Implementation	One-time effort; covered by customer success engagement; sized per executed Service Order
Migration	If migrating existing validation library; sized per migration plan
Training	Validation team training; platform-provided materials; effort is internal
Internal Change Management	Customer's own; typically underestimated; size deliberately
Ongoing Operational	User administration; periodic review participation; annual ComplianceSuite supplier qualification

# Risk & Mitigation (Section 6).

Risk	Likelihood	Impact	Mitigation
Migration Disruption to in-flight validation work	Medium	High	Phased migration; sandbox-first qualification; migration change pattern
Internal Adoption Resistance	Medium	Medium	Champion programme; early-adopter tenants; visible success stories; training
Inspector Unfamiliarity with the platform	Low	Medium	Inspector-friendly inspection view; compliance matrices ready; customer base across regulators
Vendor Dependency	Low	High	DPA + MSA terms cover post-termination data egress; export tooling is a button
AI Composer Scrutiny under EU AI Act / FDA AI guidance	Medium	Medium	Composer audit trail; pinning policy; disable per tenant if needed
Information-Security Incident	Low	High	ISO 27001 + SOC 2 Type II; audit log streaming (where available); configuration per tenant

# Implementation & Decision (Sections 7–8).

## 7 Implementation Plan

- **Stage 1 — Sandbox Qualification:** Complete qualification scenarios in sandbox tenant.
- **Stage 2 — Production Tenant Provisioning:** MSA / DPA / Service Order executed; account & first tenant provisioned.
- **Stage 3 — First-System Validation:** Low-risk first system validated end-to-end; learning captured.
- **Stage 4 — Migration:** Existing validation library migrated per migration plan.
- **Stage 5 — Steady State:** Ongoing operations; periodic reviews on schedule; quarterly business review with customer success.

## 8 Decision Recommendation

Specify the proposed subscription tier; term length; in-scope tenants; expected go-live; executive sponsor.

**NOTE**

Our CFO read the case once, asked one question about the migration risk, and approved. The numbers were ours; the platform supplied the structure. Six months later we ran our first FDA inspection on the consolidated validation library. — VP Operations, mid-cap CDMO

# Code Reference.

- **Change Lifecycle Model:** `prisma/schema.prisma` — Change with phase gates (URS, risk, plan, IQ, OQ, PQ, report)
- **Phase-Gate SoD:** `app/actions/change/` — phase transition guards with approver role checks
- **Audit Trail:** `prisma/schema.prisma` — AuditLog append-only with sequence number
- **Inspection Exports:** `app/actions/document/` — export-to-PDF with inspection view rendering
- **Periodic Review:** `app/actions/change/periodicReview.ts` — scheduled review change creation

REVISION HISTORY

# Every change, tracked and signed.

Add one row for every controlled revision. Minor changes (typos, formatting) increment the patch version; substantive edits trigger a fresh review cycle and a new approver round.

Version	Date	Author	Summary of Change	Approver
1.0	2026-04-28	Documentation Team	FIT-only redaction limited to codebase-verified functionality.	Head of Documentation
—	—	—	Reserved for next revision. Do not delete this row.	—

GLOSSARY

# Shared language, no ambiguity.

Definitions used throughout this document. Where a term has a specific meaning inside ComplianceSuite, the platform-specific definition takes precedence over the generic regulatory term.

<b>CSV</b>	Computerized Systems Validation
<b>GAMP 5</b>	Good Automated Manufacturing Practice, Edition 5 (2nd edition, 2022)
<b>GxP</b>	Good 'x' Practice — covers GMP, GLP, GCP, GDP, GVP
<b>IQ / OQ / PQ</b>	Installation / Operational / Performance Qualification
<b>Part 11</b>	21 CFR Part 11 — US FDA rule on electronic records and electronic signatures
<b>Annex 11</b>	EU GMP Annex 11 — EU rule on computerised systems
<b>URS</b>	User Requirements Specification
<b>FRS</b>	Functional Requirements Specification
<b>RTM</b>	Requirements Traceability Matrix
<b>SOP</b>	Standard Operating Procedure
<b>ALCOA+</b>	Attributable, Legible, Contemporaneous, Original, Accurate (+ Complete, Consistent, Enduring, Available)
<b>ICH Q9</b>	International Council for Harmonisation Quality Risk Management guideline

— End of document —