CS-LEG-0007 · GXP-DESK DOCUMENTATION

Business Case.

FIT-only redaction. Effective 2026-06-04.

DOCUMENT ID	VERSION	EFFECTIVE	OWNER
CS-LEG-0007	v1.0	2026-06-04	Legal & Compliance

Public — Documentation · Review cycle: On change

01 — DOCUMENT CONTROL

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.

DOCUMENT ID	CS-LEG-0007
TITLE	Business Case (Template)
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CLASSIFICATION	Public — Documentation
RELATED RECORDS	—
SUPERSEDES	— (initial release)

02 — APPROVALS

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 GxP-Desk 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 — WHAT THIS VERSION COVERS

What this version 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, ongoing operational
- **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

02 — WHAT THIS VERSION DOES NOT COVER

What this version does NOT cover.

- **Quantified benefits tied to specific platform features:** Statements such as "REST API for CI/CD integration" or "BYOK for compliance requirements" have been removed, as these are not FIT in the code. **Benefits are reduced to:** validation-library consolidation (Change model FIT), unified audit trail (with the caveat of append-only, no enforced hash chain), 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 <…>.

03 — HOW TO USE THIS TEMPLATE

How to Use This Template.

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

A good business case for GxP-Desk 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 GxP-Desk for the 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

04 — EXECUTIVE SUMMARY (SECTION 1)

Executive Summary (Section 1).

At most 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 GxP-Desk for the 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 GxP-Desk"* instead of *"validation throughput is limiting our ability to launch <product / market>"*, the case becomes harder to make.

05 — CURRENT-STATE PROBLEM STATEMENT (SECTION 2)

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

A brief root-cause analysis. Common patterns:

- Tool fragmentation
- Lack of audit-trail consolidation
- Ad-hoc role assignment
- Manual SoD verification
- Periodic reviews drift because there is 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 that 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

Consolidate validation library, change control, audit trail, e-signatures, and inspection exports onto a single platform. The tools eliminated 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 together manually to a unified append-only trail with a tamper-evident hash chain v2 (immutability trigger, verify report)
Inspection	From binder preparation to one-button inspection-pack exports
Periodic Review	From a calendar-driven manual workflow to platform-scheduled changes with the audit trail as reviewer input

3.3 What Stays the Same

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

Quantified Benefits (Section 4).

Each benefit area is populated with the customer's own baseline and target. GxP-Desk 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 supplied a comparable deployment's observed range, attribute it: *"based on observed deployments at peer organisations of comparable scale"*.

08 — INVESTMENT (SECTION 5)

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. Pricing scales by managed systems, not seats: Site €2,400/mo (1 tenant, ≤25 managed systems), Network €7,800/mo (multi-tenant, ≤250 managed systems), Enterprise (custom).

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

09 — RISK & MITIGATION (SECTION 6)

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 the 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 a sandbox tenant.
- **Stage 2 — Production Tenant Provisioning:** MSA / DPA / Service Order executed; account & first tenant provisioned.
- **Stage 3 — First-System Validation:** A low-risk first system validated end-to-end; learning captured.
- **Stage 4 — Migration:** Existing validation library migrated per the 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 (Site / Network / Enterprise); 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

11 — CODE REFERENCES

Code references.

- **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 sequenceNumber
- **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	2026-06-04	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 GxP-Desk, the platform-specific definition takes precedence over the generic regulatory term.

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

— End of document —