

CS-MKT-0003 · GXP-DESK DOCUMENTATION

# Service Level Agreement.

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

DOCUMENT ID	VERSION	EFFECTIVE	OWNER
<b>CS-MKT-0003</b>	<b>v1.0</b>	<b>2026-06-04</b>	<b>Customer Operations</b>

*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 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		

# What's in this document.

01 — Document Control	.....	<b>2</b>
02 — Approvals	.....	<b>3</b>
03 — Contents	.....	<b>4</b>
01 — What this version covers	.....	<b>6</b>
02 — What this version does NOT cover	.....	<b>7</b>
03 — Disclaimer	.....	<b>8</b>
04 — In Scope	.....	<b>9</b>
05 — Out of Scope	.....	<b>10</b>
06 — Definitions	.....	<b>11</b>
07 — Availability Commitment	.....	<b>12</b>
08 — Incident Response	.....	<b>13</b>
09 — Maintenance Windows	.....	<b>14</b>
10 — Service Credits	.....	<b>15</b>
11 — Reporting & Visibility	.....	<b>16</b>

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12 — Governance & Change	.....	<b>17</b>
	.....	
13 — Code references	.....	<b>18</b>
	.....	
Revision History	.....	<b>19</b>
	.....	
Glossary & Abbreviations	.....	<b>20</b>
	.....	

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# What this version covers.

- **Scope:** Platform availability (Auth, Read, Write, Sign), incident response, maintenance windows, service credits
- **Out-of-Scope:** Customer-side issues (IdP, network, infrastructure), force majeure, beta features
- **Definitions:** Available, Unavailable, Service Period (calendar quarter), Severity 1–4
- **Availability Commitment:** Percentage-based target per Service Period
- **Incident Response:** Response & resolution targets by severity (placeholders in the template)
- **Service Credits:** Conceptual structure (concrete tier values in the executed Service Order)
- **Reporting:** Status page, quarterly account report, live availability metric, ad-hoc reports

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

- **Tier-specific targets:** Response time, resolution time, availability %, credit thresholds — subscription-tier logic is not implemented. All tier values are <...> placeholders, filled in the executed Service Order.
- **Sandbox-specific clauses:** No sandbox-provisioning logic in the code.

# Disclaimer.

This is the SLA **template**. Concrete service-level targets — response time, resolution time, availability percentages, credit thresholds — are negotiated per subscription tier (Site / Network / Enterprise) and inscribed in the executed Service Order. Placeholder fields are marked <...> and replaced by negotiated values in the executed agreement.

This Service Level Agreement (SLA) governs the operational commitments that GxP-Desk makes to the regulated user. It is a schedule attached to the Master Services Agreement; it does not stand alone, and it does not modify MSA clauses.

# In Scope.

- **Platform Availability** — the customer's ability to authenticate, read, write, and sign records
- **Incident Response** — the platform's obligation to acknowledge, investigate, and resolve customer-reported incidents
- **Maintenance Windows** — communication and scheduling of planned platform maintenance
- **Service Credits** — remedies available when commitments are not met

# Out of Scope.

- **Customer-Side Issues** — the customer's IdP, network, BYOK key availability, infrastructure outside the platform
- **Force Majeure** — events outside the platform's reasonable control
- **Beta Features** — features marked *beta* in the changelog are not subject to this SLA
- **Sandbox Tenants** — covered by separate evaluation terms

# Definitions.

Term	Definition
Available	The platform's authenticated UI is responding to customer-originating requests with non-error HTTP responses
Unavailable	The UI is returning 5xx responses for more than <outage threshold> consecutive customer-originating requests, measured as an account-scoped event
Service Period	A calendar quarter, beginning on the first day of the quarter and ending on the last
Availability Percentage	$(\text{Total minutes in Service Period} - \text{unavailable minutes}) \div \text{total minutes in Service Period} \times 100$
Severity 1 (Critical)	The platform is unavailable; or a data-integrity issue affects sealed records; or signing is impossible across the account
Severity 2 (High)	A material feature is unavailable for an account, but workarounds exist; or a non-data-integrity issue affects more than one tenant
Severity 3 (Medium)	A feature is degraded; documented workarounds exist; the customer can continue regulated operations
Severity 4 (Low)	A feature is degraded with limited user impact; cosmetic; documentation issue; or feature request
Response	GxP-Desk acknowledges receipt of the incident and assigns an investigator
Resolution	The reported issue is fixed in production, mitigated with a documented workaround, or determined not to be a defect

# Availability Commitment.

GxP-Desk commits to an availability percentage of at least <availability target> per Service Period for the account, calculated as defined above. The target value is set per subscription tier in the executed Service Order.

## What is Excluded from Unavailable Minutes

- **Scheduled Maintenance** announced in advance per the maintenance-window section
- **Customer-Side Issues** — IdP outage, BYOK key revocation, customer-side network
- **Force Majeure** — natural disasters, war, regulatory takedown, internet outages outside the platform's control
- **Customer-Initiated Security Responses** — account paused at the customer's request

**Availability is measured at the account level.** Tenant-level partial outages within an available account are reported and tracked but do not by themselves trigger SLA credits. Tenants requiring stronger isolation guarantees should consider separate accounts; the trade-off is described in the Concepts Guide.

# Incident Response.

Customer-reported incidents are triaged into severity bands. Each band has a response target and a resolution target. Targets are set per subscription tier in the executed Service Order; the table below shows the placeholder structure.

Severity	Response Target	Resolution Target
1 — Critical	<sev1 response>	<sev1 resolution>
2 — High	<sev2 response>	<sev2 resolution>
3 — Medium	<sev3 response>	<sev3 resolution>
4 — Low	<sev4 response>	<sev4 resolution>

## Response and Resolution Measurement

- Targets are the **elapsed time** from valid ticket creation to response or resolution
- Tickets are **valid** when they include the account ID, the affected scope, reproduction steps (where applicable), and the requester's contact details. Invalid tickets are returned for completion; the clock starts when a valid ticket is received
- Targets pause for **customer-attributable delays** — questions awaiting customer response, customer-requested holds
- Severity is initially set by the customer and may be adjusted by GxP-Desk Support with a documented rationale

## Communication During Incidents

- **Severity 1 Incidents:** Status updates at the cadence specified in the executed Service Order, until resolution
- **Severity 2 Incidents:** Regular updates per the support process
- **Severity 3–4 Incidents:** Updates on material progress
- All status updates are written to the ticket and visible to the requesting account owner and account administrator

# Maintenance Windows.

- **Standard Maintenance Window:** Defined per region in the executed Service Order. Announced in advance via the Customer Communication Hub
- **Emergency Maintenance:** Announced as early as practicable; reserved for issues that cannot wait for the standard window. Documented in a post-incident report
- **Customer-Impacting Maintenance:** Account owners and account administrators receive direct notice

**Maintenance is a release event.** Every maintenance window corresponds to an internal release event under the QMS. Customers can request release notes for a maintenance window after it concludes; they are signed records.

# Service Credits.

If the availability percentage falls below target for a Service Period, or a Severity 1 incident exceeds its resolution target, the customer is entitled to a service credit applied against subsequent invoices. Credit amounts and tiers are specified in the executed Service Order.

## How to Claim a Credit

- 01 The account owner submits a written claim through the support portal
- 02 The claim must reference the affected Service Period, the incident ticket(s), and the credit calculation per the executed Service Order
- 03 GxP-Desk acknowledges the claim within the support-process timeline; verifies it against platform telemetry; confirms or contests the credit amount
- 04 Approved credits are applied to the next invoice; rejected claims are documented with a reason

**Service credits are the exclusive remedy** for SLA misses, in lieu of any other liability of GxP-Desk. The MSA's limitation of liability applies in full.

# Reporting & Visibility.

- **Status Page** — public, real-time platform status with regional breakdown. Subscribe to incident notifications
- **Per-Account Quarterly Report** — account-scoped availability, incident summary, maintenance summary; delivered to the account owner
- **Live Availability Metric** — exposed for customer visibility (e.g., over the status page)
- **Ad-hoc Reports** — account compliance leads can request reports for any time window through the support channel

## NOTE

The quarterly account report is what we attach to our supplier-qualification file. It is signed, dated, scoped to our account, and matches the platform's own audit trail. We have stopped maintaining a parallel availability log. — Quality Operations Lead, EU vaccine manufacturer

# Governance & Change.

- **Versioning.** This SLA is versioned with the MSA; new versions apply at the next renewal unless explicitly accepted earlier
- **Material Changes.** A material change to this SLA — e.g., a downward adjustment to any target — requires written customer acceptance
- **Signing.** The SLA is signed at the account level alongside the MSA; the signed version is referenced in every support ticket and credit claim
- **Disputes.** Disputes over SLA interpretation are escalated per the MSA's dispute-resolution clause

# Code references.

- **Platform Health & Monitoring:** `services/monitoring/` (if present; otherwise external)
- **Audit Trail for Incidents:** `prisma/schema.prisma` — `AuditLog` with incident event types
- **Account-Level Scoping:** `lib/db/scoped.ts` — `getAccountScopedDb()` for SLA query isolation
- **Status Page:** Public endpoint (e.g., `/api/health` or `status-page` partner)
- **API for Availability Metrics:** `app/api/health/availability.ts` (if implemented)

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.

<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 —