

Configuration Guide — CMS Life Sciences Sample Management System

DOCUMENT	Reference
SUMMARY	Administrator reference for every configuration surface in the system: access and identity, studies, vocabularies and schema, storage, labeling and printing, data governance, integrations, notifications, reporting, and operational controls.
OWNER	CMS Life Sciences
CREATED	2026-09-10
UPDATED	2026-09-10

Configuration Guide

CMS Life Sciences Sample Management System

Document ID	CMS-CG-001
Version	1.0
Effective date	<i>(issue date)</i>
Applies to release	<i>(release)</i>
Supersedes	—

Revision history

Version	Date	Change
1.0	<i>(issue date)</i>	First issue

1. Purpose and scope

This guide is for the administrator responsible for configuring and maintaining an installed instance. It describes each configuration surface, what it governs, and how a change to it is recorded.

Configuration is held as data rather than written into code. Every setting described here is applied per instance without a software release, and every change is a governed write carrying its acting subject, time, reason and prior value.

Related documents: **CMS-VG-001 Validation Guide** for the GxP controls beneath these settings, and **CMS-UG-001 User Guide** for daily operation.

2. Access and identity

Authentication is delegated to the customer's identity provider. The system stores no passwords and issues no credentials of its own. Every session resolves to an individual subject; there is no shared operator account.

The administration console requires the configuration-administrator right. A subject without it is refused before the console renders.

Surface	What it governs
Roles	Role definitions and the rights each carries. Rights gate functions, records and individual fields
Supervisors	Which subjects hold supervisory authority for operations that require it
Delegations	Temporary transfer of authority, with its own period and record
Access requests	Requests for additional access, and their review and decision
Access review	Periodic review: current assignments, rights carried, and last authenticated session per subject
Separation of duties	Which combinations of rights may not be held by the same subject
Registration policy	How new subjects are admitted and what they receive by default
Sign-out	Session expiry and forced sign-out behavior
User activity	Activity per subject, for supervision and review

3. Studies

Surface	What it governs
Studies	Study records and their operating configuration
Study metadata	The metadata schema a study collects, field by field
Study roster	Which subjects participate in a study and in what capacity
Study documents	Documents attached to a study and their status
Study closure	The prerequisite checklist that gates closure
Study bridges	Relationships between studies where material or data crosses between them

3.1 Study configuration

A study is configured before intake begins. Its settings drive reception gates, reconciliation, retention and disposition defaults, so downstream workflows run without manual re-checking. Configured values include intake mode, study class, reconciliation point, retention posture, downstream target, manifest template, participating sites, and the accountable manager and custodian.

3.2 Study lifecycle

A study's status is a lifecycle, not a free-text field: **Active**, **Closing**, **Closed**. The transition from Closing to Closed is gated by the closure checklist. Each prerequisite reports its own state, so an administrator sees exactly what is holding closure up. Finalization captures a reason and is recorded as a governed act.

4. Vocabularies and schema

Surface	What it governs
Vocabularies	The controlled value sets used across records, so a coded value has one meaning
Schema	The record schema an instance runs, including customer-specific fields
Defect types	The defect and exception categories available, and their lifecycles
Band palette	The value bands used in reporting and on operational surfaces

5. Storage

Surface	What it governs
Storage containers	The container types in use and their properties
Storage requirements	Conditions a sample class requires, enforced at placement
Stability windows	Permitted time and condition windows for a material class

Placement into quarantine, standard, restricted, hazardous or temperature-controlled storage is enforced from sample status, type, quality-control state and the rules configured here. A placement that violates a mandatory restriction is refused, naming the rule that refused it.

6. Labeling and printing

Surface	What it governs
Label templates	Label layouts, the fields each carries, and barcode format
Printer connections	Configured printers and their destinations

Every label print event is recorded with the acting subject, the time and the template version used. A reprint is distinguishable from an original.

7. Data governance

Surface	What it governs
Retention	Retention periods per study or record class. Retention policy is itself a governed record
Archive lock	Which studies are archived and therefore read-only
Legal holds	Holds that suspend disposition and deletion regardless of retention
Deletion requests	Requests to delete, and their review, decision and record
Residency allow-list	Where data may reside
Country of concern	Destinations subject to additional control
Outbound transfers	Transfers leaving the environment, and the authorization each requires

An archived study becomes read-only, and a transition the retention standard forbids is refused with the governing rule named.

8. Integrations

Surface	What it governs
Vendor schema maps	How an external system's layout maps to the internal model
Carrier formats	Shipping and carrier document formats accepted and produced

A record failing validation on arrival is rejected with the failing field named, and is not partly applied. A corrected file re-ingests against existing records without creating duplicates, with every field change audited.

9. Notifications

Surface	What it governs
Notification delivery	Delivery channels, routing and retry behavior

Operators set their own preferences separately; see **CMS-UG-001** §13.

10. Reporting and dashboards

Surface	What it governs
Report definitions	Which reports are available and how each is scoped
Dashboard panes	Which panes appear on the operational dashboard, and for which roles

11. Operational controls

Surface	What it governs
Control gates	Where a quality gate sits in a workflow, and what it requires to pass
SOP version	The procedure version in force, recorded against the work performed under it
Integrity	Verification that the audit chain is unbroken

12. Change control

A configuration change is permissioned, recorded on the audit trail with its prior and new value, and — where it affects a validated behavior — subject to the approval routing configured for it.

Configuration is promoted between environments rather than rebuilt in each one, so the definition qualified in a lower environment is the definition that reaches production.

A change affecting a validated state is delivered as a prepared package: impact assessed against the installed configuration, affected requirements identified, regression evidence supplied. It enters the customer's own change control, and deployment into the customer environment is performed by the customer.

13. What is not configuration

Changes to the application's behavior, data model or control mechanisms are code changes, delivered through the release process, and are not made in a running instance.

14. Keeping this document current

This document describes the configuration surfaces present in the release named in its header. It is reissued with each release that adds, removes or renames one, and the revision history records what changed.

An administrator holding an earlier version should read it against the release it names rather than against the instance in front of them.