CONTROLLED DOCUMENT

User Guide — CMS Life Sciences Sample Management System

DOCUMENT	Reference
SUMMARY	Operator reference: the dashboard, reception and accessioning, tracking, storage, distribution and return, reconciliation, exceptions, disposition, archive, privacy operations, and the full report set.
OWNER	CMS Life Sciences
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User Guide

CMS Life Sciences Sample Management System

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Version	Date	Change
1.0	*(issue date)*	First issue

1. Purpose and scope

This guide is for the people who work in the system daily — sample managers, operators, custodians, and the quality staff who review their work.

Every stage described here is gated, attributed and recorded. No step happens off-system, and nothing is written up afterward. Where a step asks for a reason, the reason becomes part of the record.

Related documents: **CMS-CG-001 Configuration Guide** for administrator settings, and **CMS-VG-001 Validation Guide** for the controls beneath the workflow.

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2. The dashboard

The dashboard opens on the day's work and the state of the system. Clean items progress on their own, so attention goes to exceptions rather than to reviewing everything by hand. Which panes appear depends on the rights your role carries.

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3. Reception

Reception runs as a sequence of gates. Each must pass before the next opens.

Stage	What happens
Receive	The inbound shipment is opened against its manifest
Consent	Consent covering the material is confirmed and linked
Metadata	Required metadata is captured or inherited from the study
Validation	Required fields, counts and conditions are checked before acceptance

Condition on arrival, date and time, discrepancies and temperature evidence are recorded as part of receipt. Material arriving without a manifest is accessioned directly from the physical shipment as a stub record — complete enough to be in custody, and marked as awaiting its remaining data.

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4. Accessioning

Scanning timestamps every sample to a named operator from the first touch, and matches each against the expected manifest. Anything unexpected, missing, duplicated or mismatched is raised as an exception with an owner.

Bulk accessioning handles high-volume intake, with spot-check validation rather than individual verification of every item.

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5. Tracking

Samples are searchable and filterable across lifecycle status and the storage hierarchy. Location, custody, condition and consent travel on the sample itself, so the state of any sample is available without asking anyone.

6. Storage

Storage is a hierarchy from site down to position. Capacity is reportable with utilization and projected growth. Relocation moves material in bulk with physical-scan confirmation, and placement rules are enforced at the point of placement.

7. Distribution, use and return

Surface	What it covers
Transfer	Movements between freezers, sites and studies, through approval chains with deadlines and a recorded custody hand-off
In use	Material currently issued out, and to whom
Returns	Material coming back, and its condition on return

Custody is continuous across a boundary rather than resuming at the destination.

8. Reconciliation

Expected-against-actual counts and field mismatches surface for guided resolution. Each correction captures a reason for change and retains the prior value. Over- and under-delivery both route through the exception path rather than being absorbed silently.

9. Exceptions

Anything that does not proceed cleanly becomes a recorded exception with an owner and a next step.

Excursions — a temperature or condition excursion attaches to the material it affected and the interval it covers, so *what was exposed, and for how long* has an answer rather than an estimate. Raising one notifies the assigned custodian as its own recorded event.

Defects — follow a controlled lifecycle. Each transition is a recorded event with its actor and time; resolution and waiver require a comment, and a waiver on a clinical study requires second-person approval by someone other than the person seeking it.

10. Disposition

End-of-study destroy, retain or deplete decisions are made with custodian sign-off, second-person authorization where the configuration requires it, a tracked deadline per sample, and linked evidence.

A disposition record stands independently of the sample record it terminates, and remains readable against the consent and retention schedule that governed it.

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11. Archive and privacy operations

Archive — archived studies are read-only. Archive verification confirms that what was archived is intact and retrievable.

Consents — consent instruments in force, the samples they govern, and re-use decisions taken against them.

Data subject requests — requests from subjects, and the actions taken.

Re-identification — permitted only under the recorded approval the configuration requires.

Breach cases — incidents, their assessment and the notification record.

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12. Reports

All reports compose from the same underlying records rather than from a separate export pipeline. Exports carry the exporting subject and the time of generation.

Compliance and evidence

Audit trail · Data integrity pack · Inspection readiness (and summary) · Data dictionary · Data flow

Custody and inventory

Chain of custody · Sample inventory · Sample lineage · Unlabeled samples

Consent and privacy

Consent status · Ethics approval · Breach notification · Residency status

Quality and exceptions

Defect analysis · Non-conformance · Temperature excursion log

Retention and disposition

Retention checks · Destruction catalogue · Archive

Operations

Effort and capacity · Storage maintenance · Ad-hoc export

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13. Notification preferences

Each operator sets which events they are notified about and how. Delivery routing itself is configured centrally; see **CMS-CG-001** §9.

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14. Roles

What you see depends on the rights your role carries. Every screen is gated, so each role reaches exactly the surfaces and actions it is authorized for. A refusal names the right that was required. The full role-to-rights mapping for an installed instance is in **CMS-CG-001** §2.

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15. Keeping this document current

This document describes the operator 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.