SOLUTION STORY AQ EPSF · clinical-logistics

Extending continuous IMP accountability and cold-chain visibility upstream — across a global clinical-logistics network

Sponsors are accountable for investigational product from first shipment to final destruction. **AQ ePSF** makes that accountability continuous and sponsor-visible at the depot and kit-production layer — not just at the site.

CUSTOMER PROFILE

Global clinical-trial logistics & specimen provider

Anonymised — a representative customer profile

Sector: Clinical-trial logistics & specimen management

Operations: Kit production · biospecimen transport · cold-chain · GMP depot network

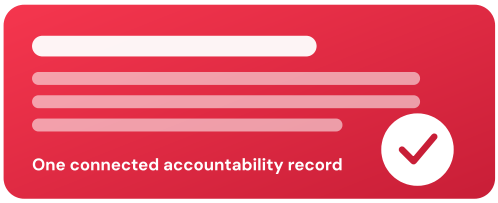
Reach: Global, multi-site

Module adopted: AQ ePSF

BEFORE

AQ ePSF

AFTER



13%
of FDA inspection deficiencies involve drug-accountability failures

95%
of sites still keep accountability on paper

1
connected accountability record across the network

~60
days to go-live

Figures are industry and AQ product context (FDA inspection data; industry data; AQ deployment) — not outcomes claimed for any individual customer.

THE STORY IN 30 SECONDS

- ✓ **The challenge:** a global logistics provider receives, stores, kits and distributes investigational product and biospecimens across many depots — but accountability and cold-chain records sit in siloed systems and paper, invisible to sponsors between handoffs.
- ✓ **The visibility:** sponsors and CRO monitors get real-time read access to accountability and temperature records across every facility, not periodic snapshots.
- ✓ **The approach:** AQ ePSF as the electronic accountability layer over the network — continuous IMP accountability, live cold-chain excursion flagging, automatic reconciliation and an ALCOA+ audit trail.
- ✓ **The scope:** ePSF sits alongside the provider's logistics and laboratory systems — it is the accountability record, not a replacement for them.

01 THE ACCOUNTABILITY GAP

The obligation is continuous. Upstream, the oversight usually isn't.

ICH-GCP E6(R3) §5.14 places investigational-product accountability with the sponsor — from receipt through storage, dispensing, returns and destruction. Much of that lifecycle happens before the site: at kit-production facilities, GMP depots and in temperature-controlled transit run by logistics partners.

Where those records live in siloed systems and on paper, sponsors can't see them between handoffs, and cold-chain excursions surface late.

Paper and silos

Accountability and chain-of-custody evidenced across separate systems and binders, per depot.

Late on excursions

Temperature excursions reconciled after the fact, not flagged when they happen.

Blind between handoffs

Sponsors and CROs can't see material status as it moves through the network.

Manual at inspection

Audit and inspection prep means assembling records by hand from many sources.

× WHAT THE SPONSOR SAW

- × Accountability seen only at the next monitoring visit
- × Cold-chain excursions surfacing weeks later, on paper
- × Records reconstructed by hand for each audit
- × Each depot keeping its own log, its own way
- × No view of material status between handoffs

→

✓ WHAT THE SPONSOR SEES NOW

- ✓ Accountability seen now, in real time
- ✓ Excursions flagged the moment they happen
- ✓ Inspection-ready records exported on demand
- ✓ One standardised record across the network
- ✓ Continuous visibility, receipt to destruction

02 SELECTION & FIT

What a logistics provider needs — and how AQ ePSF answers it

A logistics provider needs to give sponsors the accountability and cold-chain record their obligation demands — across every facility, continuously. Here is what that takes, and how AQ ePSF provides it.

THE PROVIDER NEEDS

Account for IMP across the network

Receipt, storage, distribution, returns and destruction — evidenced continuously.

→

HOW AQ ANSWERED

Continuous IMP accountability

A live accountability record across every facility, not a periodic snapshot.

THE PROVIDER NEEDS

Catch cold-chain excursions in time

Know the moment storage or transit goes out of range.

→

HOW AQ ANSWERED

Live cold-chain excursion flagging

Excursions flagged at occurrence with automated notification.

THE PROVIDER NEEDS

Keep balances reconciled

Quantities reconciled as materials move, not at month-end.

→

HOW AQ ANSWERED

Automatic reconciliation

Running balances and reconciliation status maintained continuously.

THE PROVIDER NEEDS

Give sponsors visibility

Let sponsors and CROs see accountability without a site visit.

→

HOW AQ ANSWERED

Sponsor & CRO remote access

Real-time read access to records across the network.

THE PROVIDER NEEDS

Be ready for inspection

Produce complete, auditable records on demand.

HOW AQ ANSWERED

Inspection-ready ALCOA+ export

Exportable accountability records with a full ALCOA+ audit trail.

THE PROVIDER NEEDS

Connect to the trial record

Keep accountability with the rest of the trial file.

HOW AQ ANSWERED

Connected to AQ eISF

IMP documentation travels with the site file, not a separate binder.

The core of the fit

One electronic accountability layer across the network — receipt to destruction, with cold-chain integrity and sponsor visibility built in — rather than siloed systems and paper no sponsor can see between handoffs.

REGULATORY ANCHOR

ICH-GCP E6(R3) §5.14

The sponsor is responsible for investigational-product accountability — from receipt through storage, dispensing, returns and final destruction. The obligation is continuous, not limited to monitoring visits.

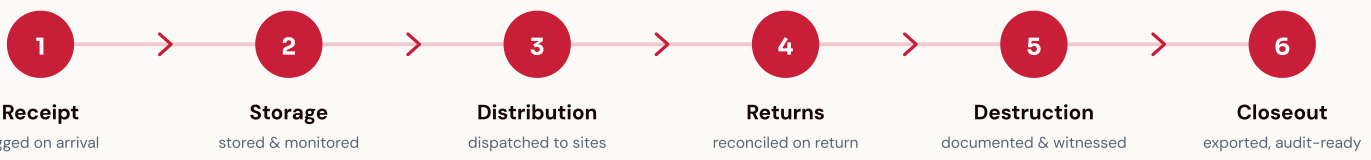
AT SCALE

03 From receipt to destruction — every stage documented and sponsor-visible, across the network

Rather than a separate log per depot, the whole material lifecycle runs through one accountability record. Each stage — receipt, storage, distribution to sites, returns and destruction — is captured as it happens, with cold-chain status and an audit trail, and is visible to the sponsor in real time.

6 **stages, one record** — receipt, storage, distribution, returns, destruction and closeout, each documented and sponsor-visible.

CONTINUOUS — ONE RECORD, RECEIPT TO CLOSEOUT



04

WHAT'S LIVE

What's live: the connected accountability record

The pieces work as one record — receipt flows into storage, storage into distribution, excursions are flagged automatically, and sponsors read across all of it.

Continuous IMP accountability

Receipt to destruction, evidenced live across every facility.

Live cold-chain visibility

Temperature excursions flagged at occurrence, with notification.

Automatic reconciliation

Running balances and reconciliation status maintained continuously.

Sponsor & CRO read access

Real-time visibility of accountability records across the network.

Inspection-ready ALCOA+ export

Complete, auditable records exportable on demand.

Connected to AQ eISF

Accountability travels with the trial file, not a separate binder.

AQ ePSF is the electronic accountability layer. It sits alongside the provider's logistics, transport-management and laboratory systems — it does not replace them.

05

RESULTS

Outcomes AQ ePSF is built to deliver

These are the outcomes AQ ePSF is built to deliver for a clinical-logistics provider and the sponsors it serves.

- **Continuous accountability** — IMP and material status visible in real time, not reconstructed at audit.
- **Cold-chain excursions caught live** — flagged at occurrence with notification, not discovered weeks later.
- **Sponsor & CRO visibility** — real-time read access across the network, not visit-dependent.
- **Inspection-ready on demand** — ALCOA+ exports without manual assembly.
- **One record across the network** — replaces siloed systems and paper logs.
- **Fast to stand up** — designed for an approximately 60-day go-live, without an enterprise build.

06

ASSURANCE & REGULATORY SUPPORT

Designed and documented to support regulated use

AQ provides documentation to support information governance, IT assurance, data protection and procurement review for continuous IMP accountability across a logistics network. Items are grouped by what AQ holds, what evidence is available, and what the platform is designed to support.

INDEPENDENT CERTIFICATIONS & REGISTRATIONS

Held by AQ

- Cyber Essentials
- ICO registration: ZB324099

ASSURANCE EVIDENCE AVAILABLE

Provided to support review

- GxP computerised-system validation documentation
- System and supplier validation documentation
- Information security documentation
- Data protection documentation (UK GDPR / DPIA)
- Business continuity and disaster recovery evidence
- Penetration-testing summary
- Hosting and data-residency information
- Supplier assurance documentation

DESIGNED TO SUPPORT

Mapped against relevant expectations — alignment, not certification

- ICH-GCP E6(R3), including §5.14 IMP accountability
- Applicable UK Clinical Trials Regulations
- UK GDPR and Data Protection Act 2018
- MHRA expectations for computerised systems
- 21 CFR Part 11 electronic record and signature requirements
- EU GMP Annex 11
- GAMP 5 principles
- ALCOA+ data-integrity principles
- GxP record-keeping principles
- ISO 27001 control principles (alignment)
- NCSC Cyber Assessment Framework principles

UK-hosted environment

AQ supports controlled electronic retention and retrieval of IMP accountability records in accordance with applicable UK requirements, including 25-year retention where required under the amended UK clinical trial regulations. Applicable retention periods depend on the type of research, regulatory route, study submission date, sponsor requirements and relevant legislation.

AQ provides a configurable platform together with supporting documentation. Achieving and maintaining regulatory compliance also depends on the organisation's own configuration, validation, procedures and oversight. ISO control principles are referenced as alignment unless formal certification is stated.

NEXT STEP

See how AQ ePSF gives sponsors continuous accountability across your network

Book a focused demonstration based on your depot and kit-production operations.

Book an ePSF demo

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UK-hosted environment

AQ supports compliant operation through configurable controls and documentation; regulatory compliance remains subject to appropriate configuration, validation and organisational procedures.