CUSTOMER CASE STUDY NHS RESEARCH · QMS

Royal Free London moves quality off paper and shared drives — to one system used by 300+ people

Across many departments, Royal Free London NHS Foundation Trust brought controlled documents, training and CAPA into **one co-developed quality system** — replacing paper and scattered shared drives, and adopted by more than 300 users.

THE CUSTOMER

NHS Royal Free London
NHS Foundation Trust

Organisation: Royal Free London NHS Foundation Trust

Setting: NHS acute & clinical research

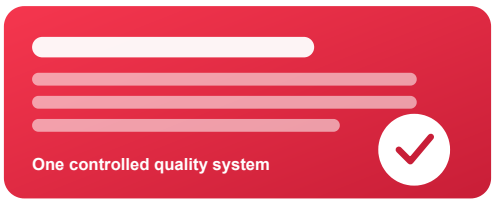
Scale: 300+ users across many departments

Modules adopted: AQ QMS (documents & training) + CAPA

BEFORE

AQ QMS

AFTER



300+
Users across the Trust working from one quality system

Many
Departments adopting AQ QMS comprehensively

1
Controlled document library, replacing paper & shared drives

CAPA
Quality events tracked end-to-end, finding to closure

More than 300 users across many departments now work from one controlled quality system, co-developed with the Trust. AQ QMS at Royal Free covers controlled documents, training and CAPA.

THE STORY IN 30 SECONDS

- ✓ **The challenge:** controlled documents, SOPs and training spread across paper and shared drives in many departments, with no single controlled system.
- ✓ **The adoption:** rolled out comprehensively across many departments, now used by more than 300 people.
- ✓ **The choice:** AQ QMS — co-developed with the Trust, proportionate for NHS, and ready for IG/IT assurance.
- ✓ **The scope:** controlled documents and training at its core, with CAPA tracking quality events end-to-end.

01 THE STARTING POINT

Quality on paper and scattered shared drives

Across many departments, the Trust's controlled documents, SOPs and training records lived on **paper and shared drives**. The approach functioned, but carried real

operational cost as research and quality activity grew across hundreds of staff.

Time lost locating the current SOP

Finding and confirming the current, approved version of a document or SOP meant searching multiple drives and folders, or retrieving paper.

No single controlled system

Documents, approvals, read-receipts and training evidence were fragmented across paper and different shared-drive locations — with no single source of truth or end-to-end audit trail.

Training hard to evidence at scale

Confirming who had read and understood the current procedure — across hundreds of staff in many departments — relied on spreadsheets and manual tracking, or was not captured at all.

Quality events managed off-system

Findings and corrective actions were captured on paper or in scattered files, making them hard to assign, action and track through to verified closure.

✕ BEFORE AQ

- ✕ Controlled documents split across shared drives and paper
- ✕ Inconsistent manual version control
- ✕ Training read-receipts in spreadsheets, or untracked
- ✕ No single audit trail across documents and training
- ✕ Quality events and findings recorded on paper
- ✕ Compliance status assembled reactively

✓ WITH AQ QMS

- ✓ **One controlled document and SOP library**
- ✓ **Version control and electronic approval workflows**
- ✓ **Assigned reading and competency tracked across 300+ users**
- ✓ **Traceable activity and a single audit history**
- ✓ **CAPA logged, actioned and closed in-system**
- ✓ **A more continuous view of quality compliance**

02

SELECTION & FIT

What Royal Free needed — and how AQ answered it

A controlled quality system was clearly required across the Trust; what mattered was the fit. Royal Free set out the requirements of an NHS research and quality operating model, then helped shape the platform to meet them.

ROYAL FREE NEEDED

One controlled source of truth

A single place for controlled documents, SOPs and quality records across many departments — not scattered drives and paper.

HOW AQ ANSWERED

One QMS document library

Controlled upload, review, approval and publication with version control — one current, approved source of truth.

ROYAL FREE NEEDED

Training visible at scale

A way to assign, evidence and report training across hundreds of staff in many departments — not spreadsheets.

HOW AQ ANSWERED

Tracked competency

Assigned reading and quizzes with certificates — completion tracked and reportable across 300+ users.

ROYAL FREE NEEDED

Quality events tracked to closure

A controlled way to log findings, assign actions and verify they are resolved — not paper logs that go stale.

HOW AQ ANSWERED

CAPA, end-to-end

Findings, owners, actions and verified closure captured in-system, with a complete audit trail.

ROYAL FREE NEEDED

NHS assurance readiness

A supplier able to support IG, IT assurance, data protection and procurement with clear documentation.

HOW AQ ANSWERED

Evidence ready for review

Certifications, validation, security, data-protection and continuity documentation prepared for assurance review.

ROYAL FREE NEEDED

A platform shaped around them

Not an off-the-shelf tool dropped in, but a system that reflects how a large NHS Trust actually runs quality.

HOW AQ ANSWERED

Co-developed with Royal Free

Reviewed and steered by the Trust through development — shaped by frontline NHS use, not assumptions.

The core of the fit

The challenge was not simply finding QMS software — it was finding a quality system that matched how a large NHS organisation works across many departments, and a partner willing to build around that reality. AQ was co-developed with Royal Free, for exactly that.

03

ROLLOUT & ENABLEMENT

Adopted comprehensively across the Trust, by more than 300 users

Rather than a single team, AQ QMS was rolled out across many departments and more than 300 users. Enablement was designed to fit busy NHS research and quality staff.

300+ **Users across many departments** now work from one controlled quality system — adopted comprehensively across the Trust, rather than in a single pilot team.

STEP 01

Train the trainer

In-house champions equipped to support their colleagues.

STEP 02

Live online sessions

Guided training for the wider research team.

STEP 03

On-demand videos

Self-paced learning and onboarding for new joiners.

STEP 04

Hypercare — month 1

Hands-on support through the early adoption window.

04

WHAT'S LIVE

One connected quality record: documents, training and CAPA

AQ QMS brings the core of day-to-day quality into one place. Three capabilities are live across the Trust today.

Controlled documents & SOPs

Upload, review, approve and publish with version control — one current, controlled source of truth, replacing paper and scattered shared drives.

Training & competency

Assigned reading and quizzes with certificates — completion tracked and reportable across 300+ users and many departments.

CAPA management

Quality events and findings logged, assigned, actioned and verified to closure, with a complete audit trail.

AQ QMS at Royal Free covers these capabilities today: controlled document management, training and CAPA.

05

RESULTS

Outcomes to date

The following outcomes are supported by the deployment to date.

- **One controlled document library** replacing paper and scattered shared drives across the Trust.
- **A single current, approved version** of each document and SOP, with controlled access.
- **Training visible at scale** — assigned reading and competency tracked across 300+ users.
- **Quality events tracked end-to-end** in CAPA, from finding to verified closure.
- **Comprehensive adoption** across many departments, on one quality system.
- **A more continuous view of compliance**, with controlled records and training evidence in one place.

300+

Users across many departments working from one controlled quality system.

1

Controlled document library, replacing paper and scattered shared drives.

CAPA

Quality events tracked end-to-end in-system, from finding to verified closure.

Figures describe adoption across the Trust. AQ QMS at Royal Free covers controlled document management, training and CAPA.

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 a Trust-wide quality system. 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

- NHS Data Security and Protection Toolkit submission
- 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 E6(R3)
- 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
- GAMP 5 principles
- ALCOA++ data-integrity principles
- ISO 27001 and ISO 22301 control principles (alignment)
- NCSC Cyber Assessment Framework principles

UK-hosted environment

AQ supports controlled electronic retention and retrieval of quality 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 QMS could fit your NHS organisation

Book a focused demonstration based on your quality documents, training and CAPA processes.

Book an NHS QMS demonstration →

ascensionQ
www.aq-trials.com

enquiries@aq-trials.com
UK-hosted environment

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