ECTU Central Office SOP QA 04:
Internal and External Audit Programme

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Authorship and Approval			
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1.0	10 Aug 2026	Initial creation

1.0 PURPOSE

The purpose of this SOP is to describe the process for planning, conducting, reporting, and following up internal audits within ECTU. Internal audits are conducted to assess compliance with applicable regulatory requirements, including UK Medicines for Human Use (Clinical Trials) Regulations, ICH Good Clinical Practice (GCP), sponsor requirements, and MHRA guidance, and to support continuous quality improvement. The SOP also details how audits with external collaborators and organisations should be handled.

2.0 SCOPE

This SOP applies to all staff within ECTU who are involved in internal processes and/or studies adopted by ECTU.

3.0 RESPONSIBILITIES

The ECTU Director and Chief Operating Officer provide senior management oversight of the internal audit programme and receive any escalations that might arise from the audit of ECTU processes.

The Chief Operating Officer (COO) is responsible for reviewing the audit schedule and sign-off of final internal audit reports.

The QA Manager/ internal auditor is responsible for the actions detailed in this SOP.

All ECTU staff as auditees are responsible for participation in the internal audits, provide access to documentation, systems, and records as necessary and implement the agreed CAPAs within defined timelines.

4.0 PROCEDURE

ECTU will operate a formal internal audit programme in line with MHRA GCP expectations.

4.1 Internal Audit Frequency and Schedule

4.1.1 Internal audits shall be conducted at a frequency of one audit every two to three months at a minimum. The frequency can be changed, for example during the staff holiday season, and will be agreed between the QA Manager and the Chief Operating Officer during preparation of the audit schedule. Any other deviation from the audit schedule will be dealt with on an ad-hoc basis as required.

4.1.2 The QA Manager will prepare an annual internal audit schedule, which may include but not limited to:

- Study/ Trial specific audits (audit of activities in a single trial)
- Performance/ Process audit (looking at the performance of specific processes within systems (for example, data query process))
- Operational/ System audit (looking at the functionality of complete systems (for example, trial management)

- Compliance/ Documentation audit (review of trial-specific or system documentation (for example, training records))

4.1.3 The schedule shall be risk-based in alignment with the risk categories approved by MHRA,

- Type A no higher than standard care
- Type B somewhat higher than standard care
- Type C markedly higher than standard care

Other criteria that could contribute to the selection process are previous inspection findings, audit outcomes, changes in regulations, regular review cycle of ECTU departments to ensure all teams are represented, studies that have been recently audited by external parties (for example, ACCORD), audit type, stage of study set up and CAPA actions following an MHRA audit (for example, partial service studies that have been audited external to ECTU).

4.1.4 The audit schedule will be stored \ECT Unit\QA\Audits\INTERNAL and will be communicated to ECTU staff by the QA Manager/auditor.

4.2 Internal Audit Planning

4.2.1 Each audit shall be planned in advance by the QA Manager, and the date of the audit will be agreed between the QA Manager and relevant staff via email.

4.2.2 At least one month prior to the audit, the QA Manager as the auditor will issue the following to the relevant staff via the ECTU QA inbox,

- An audit agenda using template QA005 ECTU Internal Audit Agenda template (Section 5)
- A documented audit plan outlining scope, objectives, criteria, timelines, and required documentation using the QA006 ECTU Audit Plan template (Section 5)

4.2.3 The audit scope shall clearly define processes, trials, systems, or departments to be audited.

4.3 Conduct of the internal audit

4.3.1 Audits shall be conducted by suitably trained personnel independent of the activities being audited.

4.3.2 Audit activities may include, but not limited to document and record review, interviews with staff, review of paper and/ or electronic systems, process walkthroughs, etc.

4.3.3 Auditors shall assess compliance with respect to:

- Relevant ECTU policies and procedures
- Relevant study protocols, sponsor SOPs or other study-specific procedures

- Medicines and Healthcare products Regulatory Agency (MHRA) guidelines
- GCP principles and guidelines.
- The Medicines for Human Use (Clinical Trials) Regulations SI 2004/1031, as amended.
- Other local policies and regulatory requirements as applicable.

4.3.4 Observations shall be documented clearly and supported by objective evidence.

4.4 Internal Audit Findings and Classification

4.4.1 Audit findings shall be classified according to their impact on participant safety, data integrity, and regulatory compliance (e.g. Critical, Major, Other). The classification approach shall be consistent with MHRA inspection and audit principles as detailed below,

Critical: Where evidence exists that significant and unjustified departure(s) from applicable requirements has occurred with evidence that:

1. the safety, well-being or confidentiality of trial subjects either have been or have significant potential to be jeopardised, and/or
2. the quality of the clinical trial data has been significantly compromised and/or
3. there are a number of Major non-compliances across areas of responsibility, indicating a systematic failure.

Major: A non-critical finding where evidence exists that:

1. a significant and unjustified departure from applicable requirements has occurred that may not have developed into a critical issue, but may have the potential to do so unless addressed, and/or
2. a number of departures from applicable requirements have occurred within a single area of responsibility, indicating a systematic failure.

Other: Where evidence exists that a departure from applicable requirements has occurred, but it is neither Critical nor Major.

4.5 Internal Audit Reporting

4.5.1 A draft internal audit report shall be prepared following completion of the audit within 10 working days using the QA007 ECTU Internal Audit Report template. (Section 5)

4.5.2 The audit report shall include, as a minimum:

- Details of the audit, including the reference number, which should match the reference in the internal audit schedule along with the dates, and the staff member/ team that the report is issued to

- Scope of the audit
- Summary of activities performed
- Audit observation grading as per the MHRA guidelines detailed in section 4.4
- Detailed findings and classifications which require a CAPA response
- Recommendations

4.5.3 The relevant team/ staff member is expected to provide a response and CAPA action for each finding within 15 working days of receiving the report from the ECTU QA inbox. If additional time is required, this can be requested by responding to the email.

4.5.4 Once the proposed CAPA actions are agreed between the QA Manager and the relevant teams, the draft is then sent to the Chief Operating Officer for review. The QA manager will feedback if there are any queries to be resolved.

4.5.5 The final audit report will be signed by the QA Manager and the Chief Operating Officer via Adobe Sign.

4.5.6 Approved internal audit reports shall be distributed to the relevant team/ staff member and retained as described in section 4.7.1.

4.6 Corrective and Preventive Actions (CAPA)

4.6.1 The CAPA responses shall address root causes and include corrective and preventive actions, responsible persons/ teams where applicable, and target completion dates.

4.6.2 The QA Manager shall track CAPA actions by adding the findings to QA008 ECTU Internal Audit Findings and CAPA tracker. The CAPA actions will be verified at the next audit (either external or internal) for the relevant department. In case of critical findings, these will be monitored to completion and verified against the date agreed with the team/ staff member.

4.6.3 CAPA status and trends shall be reviewed periodically as part of the quality management system and escalated as necessary by the QA Manager.

4.7 Records, Documentation and Escalation

4.7.1 All audit related documentation (audit plans, agendas, reports, CAPA records) shall be retained in \ECT Unit\QA\Audits\INTERNAL specified by the year and relevant team.

4.7.2 The internal audit will be discussed at the ECTU QA meeting for the awareness of ECTU management. If any urgent escalation is required, it will be raised at the weekly Operations meeting.

4.7.3 The ECTU Operations team is informed of the location of the records and shall be made available upon request if required.

4.8 External Audits

4.8.1 ECTU may be inspected by external parties, for example the MHRA GCP inspection, the QA team from the Sponsors' office etc. The documentation related to these audits and the audit certificates are retained in \ECT Unit\QA\Audits\EXTERNAL. The final versions of documents related to MHRA inspections is held in \CollegeOffice\ECT Secure\MHRA. This folder can only be accessed by the Operations teams, Line Managers and QA.

4.8.2 The Monitors' audits/ inspection of the TMF are considered separate from the above, and related documentation will be retained in the study specific folders.

5.0 RELEVANT DOCUMENTS AND REFERENCES

ECTU Website

- QA005 ECTU Internal Audit Agenda template
- QA006 ECTU Audit Plan template
- QA007 ECTU Internal Audit Report template
- QA008 ECTU Internal Audit Findings and CAPA tracker

ECTU_SOP_QA_04 Internal and External Audit Programme v1.0 and associated documents

Final Audit Report 2026-07-24

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