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# Quality Assurance Auditor for Clinical Trials

## Purpose

Due to additional regulatory requirements for clinical trial compliance, special Quality Assurance considerations are required. This document describes the role of the Independent Quality Assurance (QA) Auditor, an integral part of the Clinical Trials Quality Plan.

## Policy

The Independent Quality Assurance (QA) Auditor (known henceforth as “the QA Auditor”) will report directly to Corporate Counsel and be independent of the Clinical Trials Department.

The QA Auditor will conduct periodic, pre-announced audits of operational and study-specific processes of the Clinical Trials Department, and of selected Laboratory and Information Technology functions that support clinical trials activities.

The QA Auditor will also serve as the primary host for external audits of the Clinical Trials Department by sponsors or other regulatory agencies

# External Audits

## PURPOSE

The purpose of this document is to define appropriate procedures for the Independent Quality Assurance (QA) Auditor in accommodating external audits or inspections of the Clinical Trials Department conducted by a sponsor or regulatory agency.

## PROCEDURES

### Audit Notification and Preparation

#### The VP of Clinical Research will notify the Independent QA Auditor of any audits requested by an external sponsor or regulatory agency.

#### The QA Auditor is responsible for scheduling the audit, and obtaining a list of agenda items from sponsors with notice as determined by contractual agreement with the sponsor.

#### The QA Auditor is responsible for notifying upper management of all RCA Laboratories departments that will be involved, and for coordinating audit preparation efforts.

#### The QA Auditor is responsible for ensuring that appropriate documentation specifically requested by or reasonably expected to be relevant to the auditor be available during the audit (e.g. Laboratory certifications, training records, SOPs, etc.) and that appropriate personnel are available to help as needed. A list of all documentation provided, will be maintained by the QA Auditor.

### Conduct during the Audit

#### The QA Auditor will serve as the host during the audit, greeting the delegation upon their arrival and providing requested materials as appropriate.

#### It is the responsibility of the QA Auditor to ensure that any outside visitors coming to RCA Laboratories under the auspices of an audit have signed a current RCA Laboratories Confidentiality Disclosure Agreement and/or a RCA Laboratories Business Associate HIPAA Privacy Agreement.

## ATTACHMENTS

### Quality Manual Attachment 9 Confidentiality and Disclosure Agreement

### Quality Manual Attachment 9 Business Associate HIPAA Privacy Agreement

# Internal Audits

## PURPOSE

This document describes the role of the Independent Quality Assurance (QA) Auditor with regards to the Clinical Trials Quality Assurance Internal Audit Program. Guidelines by which the QA Auditor will conduct and report audits of the Clinical Trials Department (CTD) and supporting laboratory functions to assess compliance with GCP, GLP Best Practices, 21 CFR Part 11, HIPAA, internal SOPs, protocols, contractual obligations, and other applicable regulatory requirements are outlined.

## PROCEDURES

### Audit scheduling

The Independent QA Auditor will schedule regular, periodic audits of clinical trials and supporting operations and study-specific processes. The VP of Clinical Research and upper management of other affected RCA Laboratories departments will be notified in writing at least 1 week prior to the audit.

### Audit Conduct

Guidelines for the scope and conduct of audits of clinical trial activities are described in the Clinical Trials Internal Audit Program Guide (ATTACHMENT I).

### Areas subject to auditing include, but are not limited to:

#### Registration and accessioning of Clinical Trial cases

#### CTD Organizational structure, personnel requirements, qualifications, training records

#### Project management / Study-specific documentation

#### SOP development, implementation, and review

#### Histology and other laboratory processing, training, and documentation

#### Accuracy and completeness of final reports

#### Medical Records

#### Shipping procedures and documentation

#### Site query process and documentation

#### 21 CFR Part 11 compliance

### Specifics of the Clinical Trials Internal Audit Program are developed by the Independent QA Auditor in collaboration with the CTD and the upper management of other departments of RCA Labs that support clinical trial activities. Ongoing development of this program will not necessarily require revision of this SOP, inquiries regarding the most current version of the program guide should be directed to the Independent QA Auditor.

## Reporting / CAPAs

### Internal Audit Reports summarizing the main findings of specific audits will be presented to the VP of Clinical Research and upper management of other affected GX departments within 2 weeks following completion of the audit. (See Attachment II for audit report cover page).

### Specific instances of any errors, omissions, or other violations of SOPs or relevant regulatory requirements and recommendations for dealing with them will be documented with the issuance of Corrective and Preventable Actions (CAPAs), using the form provided in ATTACHMENT III

### The audit report and or CAPAs are issued to the VP of Clinical Research, and the Clinical Trial Quality Management Team designee who will co-ordinate resolution of the issue. A response and or resolution is expected to occur within 30 days of issuance of the CAPA.

### The audit report and or CAPAs relating to inter-departmental issues will be forwarded to the VP of Clinical Research and the appropriate upper management in the affected department. A response and or resolution is expected to occur within 30 days of issuance of the CAPA.

### Internal Audit Reports and CAPAs are for internal use only, and will not be shared with external entities without written permission from the VP of Clinical Research. If requested by the FDA, written certification that these audits have been implemented, performed, and documented and that any required corrective action has been taken will be provided, as outlined in the FDA’s guidance document on FDA access to Results of Quality Assurance Program Audits and Inspections (CPG 7151.02).

### Documentation of all audit activities, reports, CAPAs, and audit closure will be maintained by the Independent QA Auditor.

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| Revision Number | Reason for Revision | Effective Date |
| 0 | Change company name and SOP number, reformat Quality System, Add CEO signature Line, clarification of record retention policy | Upon Signatures |

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