



STANDARD OPERATING PROCEDURES


Quality Policy

ACKNOWLEDGEMENT & APPROVAL


I hereby acknowledge that I have reviewed this document in its entirety, confirmed its accuracy, and approve its use as of the Effective Date.

Version 1.0 Effective 8-APR-2022

Original/Revision Authored by:

Role	Printed Name	Signature & Date
Compliance Manager	Lloyd Schuman	<p>DocuSigned by Lloyd Schuman</p>  <p>I am the author of this document 3/16/2022 4:32:22 PM CDT</p> <p>B5F6DEED5D964D0084A7F1C9302FCBB4</p>

Approved by:

Role	Printed Name	Signature & Date
Chief Operating Officer	Neil Schmitz	<p>DocuSigned by Neil Schmitz</p>  <p>I approve this document 3/16/2022 5:40:10 PM CDT</p> <p>104E4F8109BD4431938388FB6EA0B912</p>

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QA 804

Quality Policy

Policy

CTRG established this quality policy to implement and maintain a quality management system that meets or exceeds the requirements of ISO 9001:2015, while ensuring all work is performed within GCP and FDA regulations.

Quality Policy Statement

Quality is important to our business because we perform complex services in a highly regulated environment, with constantly changing demands from our sponsors. We strive to provide our sponsors with services that exceed their expectations.

We are committed to continuous improvement and have established a Quality Management System that provides a framework for measuring and improving our performance.

We have the following systems and procedures in place to support us in our aim of performing all our work within applicable regulations while also achieving sponsor satisfaction, while striving for continuous improvement throughout our business:

- regular gathering and monitoring of sponsor feedback
- a sponsor complaints procedure
- selection and performance monitoring of vendors against set criteria
- training and development for our employees
- audits of our internal processes
- audits of our vendors
- measurable quality objectives which reflect our business aims
- management reviews of audit results, sponsor feedback and complaints from all parties we engage with
- internal standard operating procedures are reviewed regularly and maintained within Microsoft Teams which is made available to all employees.

Although Senior Management maintains ultimate responsibility for Quality, all employees are responsible within their own areas of work to ensure Quality is embedded within each part of the company.

Quality Objectives

CTRG's quality management system objectives are to be our sponsors' first choice of CRO by:

- 1) Managing our sponsors' studies within the specified parameters (time, cost, processes, etc.), as dictated within each agreement;
- 2) Ensuring our sponsors' studies are performed within all applicable regulatory requirements and guidelines;

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- 3) Properly overseeing and correcting where necessary the site-level operations for all sites performing work on behalf of the sponsor for each protocol/project; and
- 4) Reviewing all potential vendors for critical services to ensure competency and adherence to regulatory and industry requirements.

DOCUMENT CHANGE RECORD:

Author	Issued Date	Effective Date	Change(s)	Version
Lloyd Schuman	16-MAR-22	8-APR-22	New Document	1.0

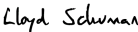
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Neil Schmitz nschmitz@ctrgresearch.com Chief Operating Officer CTRG, LLC Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 104E4F81-09BD-4431-9383-88FB6EA0B912 Using IP Address: 63.239.169.186 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 3/16/2022 4:31:47 PM Viewed: 3/16/2022 5:39:51 PM Signed: 3/16/2022 5:40:22 PM
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