Norton Audits, Inc.
Defining and Driving Clinical Research Excellence

2015 Capabilities Statement

Company Name:	Norton Audits, Inc.
Tagline:	Defining and Driving Clinical Research Excellence
Company Summary:	Clinical research compliance services company providing audits, consulting and training to minimize clinical research risk and streamline research processes.
Address:	100 Old Cherokee Road, Suite F, PMB 327, Lexington, SC 29072
Year of Inc.:	2001, State of South Carolina
Website:	www.nortonaudits.com
Point of Contact:	Jeff Smith, Vice President, jsmith@nortonaudits.com, 803-233-4809
DUNS:	138426684
CAGE Code:	6KKG0
Certifications:	EDWOSB; Economically-Disadvantaged Women-Owned Small Business
NAICS Codes:	541711; Research and Development in Biotechnology 541712; Research and Development in the Physical, Engineering and Life Sciences 541611; Administrative Management and General Management Consulting Services 611430; Professional and Management Development Training
GSA contracts:	Subcontract on BARDA contract HHSO100201300004C with Romark Laboratories Subcontract on BARDA contract HHSO100201100019C with Biota Pharmaceuticals
Major Clients:	Romark, ICON, Biota, Purdue Pharma, Harvard Medical, Boehringer Ingelheim
Core Capabilities:	21 Code of Regulations (CFR), Good Clinical Practices (GCP), International Conference on Harmonization (ICH) research regulation expert Clinical research qualification, in-process, end-of-study and misconduct audits Clinical research regulation, process and employment position training Quality Systems and risk management consulting
Differentiating Factors:	Key employees retain unique combination of regulatory expertise through direct U.S. Food and Drug Administration employment and extensive clinical research industry experience as monitors, clinical research coordinators, project managers, Quality Assurance managers and auditors. Significant company experience servicing both academic research institutions, such as Harvard Medical Center, and sponsor industry research on a worldwide basis. These elements position Norton Audits as an expert in assessing research compliance, minimizing risk and improving processes.

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Positive Past Performance

Example #1

Biota Pharmaceuticals; HHSO100201100019C

2011–2014

Conducted 13 total audits for Biota in support of their influenza treatment research. Audits consisted of 2 CRO's, 1 cardiac services vendor, 4 Phase I units, 2 GLP laboratories and 4 Clinical Investigators. 2 of the Clinical Investigator audits were considered for-cause audits investigating potential misconduct by the Investigator. Built successful relationships with Biota personnel, who are based in Australia, including earning a second auditing contract after completion of first contract.

Example #2

Romark Laboratories; HHSO100201300004C

2014-Present

To date, conducted 23 total audits for Romark in support of their influenza treatment research. Audits consisted of 2 CRO's, 2 GLP laboratories and 19 Clinical Investigators. Services included formal corrective action implementation oversight for each of the conducted audits, thus bringing each auditee into compliance with applicable regulations and requirements. Advised Romark on interactions and communications with U.S. governmental agencies, including Food and Drug Administration (FDA) and Biomedical Advanced Research and Development Authority (BARDA).

Example #3

Commercial and Academic Customers

Harvard Medical Center
2011-2013
Developed and implemented clinical research audit plan across five hospitals to re-start research activity after a severe noncompliance incident. Conducted nearly one hundred audits of active clinical research studies and initiated corrective action process.

ICON; Global CRO
2008-2014
Developed and implemented worldwide audit plan across multiple divisions and therapeutic areas, conducting approximately fifteen audits across twelve month period of time. Previous to this, conducted approximately ten stand-alone audits of individual processes, including mock FDA inspections.