Federal Supply Service
Authorized Federal Supply Schedule Price List

On-line access to contract ordering information, terms and conditions, up-to-date pricing, and the option to create an electronic delivery order are available through GSA Advantage!, a menu-driven database system. The INTERNET address for GSA Advantage! is: http://www.gsaadvantage.gov

00CORP – Professional Services Schedule

SIN 874-1 Integrated Consulting Services
SIN 874-4 Training Services
SIN 874-9 Off-The-Shelf Training Devices and Training Materials

Contract Number: GS-02F-092BA

For more information on ordering form Federal Supply Schedules, click on the FSS Schedules button at www.fss.gsa.gov.

Contract Period: March 18, 2014 – March 17, 2019

S. Pyper Research Group, dba Solar Biomedical
10 GlenLake Parkway, Suite 130, Atlanta, GA 30328
www.solarbiomedical.com

Contact for Contract Administration: Avis Williams
info@solarbiomedical.com
877-433-9583

Business size: Woman Owned Small Business

(ii) CUSTOMER INFORMATION:

1a. Table of awarded special item number(s) with appropriate cross reference to item descriptions and awarded prices(s): SIN 874-1; 874-4; 874-9

1b. Identification of the lowest priced model number and lowest unit price for that model for each special item number awarded in the contract: See Price List

1c. A description of all class description is shown in our Price List.

2. Maximum order: SIN 874-1 $1,000,000; 874-4 $1,000,000; 874-9 $1,000,000

3. Minimum order: $100

4. Geographic Coverage (delivery area): CONUS

5. Point(s) of production: Atlanta, GA

6. Discount from list prices or statement of net price: Prices shown are net with a basic discount of 15% on Services, 20% on Training Classes and 2% on Training Materials

7. Quantity discounts: 4% on orders for Services over $100,000

8. Prompt payment terms: Net 30

9a. Government purchase cards are accepted at or below the micro-purchase threshold.

9b. Government purchase cards are accepted above the micro-purchase threshold.

10. Foreign items: N/A

11a. Time of delivery: To be negotiated between the contractor and ordering agency.

11b. Expedited Delivery: To be negotiated between the contractor and ordering agency.

12. F.O.B. point: Destination

13a. Ordering address: Solar Biomedical, 10 GlenLake Parkway, Suite 130, Atlanta, GA 30328

13b. Ordering procedures: For supplies and service, the ordering procedures, information on Blanket Purchase Agreements (BPA's) are found in Federal Acquisition Regulation (FAR) 8.405-3.

14. Payment address: Solar Biomedical, PO Box 42246, Atlanta, GA 30311

15. Warranty provision: SCW

16. Export packing charges, if applicable: N/A

17. Terms and conditions of Government purchase card acceptance (any thresholds above the micro -purchase level): Accepted at all levels.

18. Terms and conditions of rental, maintenance and repair (if applicable): N/A

19.Term and conditions of repair parts indicating date of parts price lists and any discounts from lists prices (if applicable): N/A

20. Terms and conditions for any other services (if applicable): N/A

21. List of service and distributions points (if applicable): Kent, WA.

22. List of participating dealers (if applicable): N/A

23. Preventive maintenance (if applicable): N/A

24a. Special attributes such as environmental attributes (e.g., recycled content, energy efficiency, and/or reduced pollutants): N/A

24b. Section 508 compliance: N/A

25. Data Universal Number System (DUNS) number: 800943206

26. Notification regarding registration in System for Award (SAM) database: CAGE Code 4Y0Y1

Solar Biomedical was founded in 2002 to provide both clinical research monitoring as well as regulatory process consultation to assure clinical research process consistency and increase efficacy. We are able to offer our services to investigator sites who are interested in achieving or maintaining the highest level of quality in their research studies. Our knowledge base includes review and direction regarding policy and clinical process, clinical research training module designs and clinical research coordinator training.

Solar Biomedical is a Woman Owned Small business. Our clients have enjoyed the expertise provided by our firm due to the fact that we come from a clinical research background so we know the regulatory requirements necessary to assure accuracy in the clinical research process. Our services have been provided for the Department of Veteran's Affairs as well as the Department of Health and Human Services. In any research project, accuracy and consistency are vital to assure the resultant outcome is a viable result. Solar Biomedical has become an industry leader in the field of clinical research monitoring and auditing.

Being an environmental conscience clinical research consulting group, Solar Biomedical is able to provide site support to medical research centers, practices, and hospitals. Our highly experienced staff can offer services to investigator sites who are interested in achieving or maintaining the highest level of quality in their research studies. Our staff have come from the fields and up through the ranks of statisticians, data managers, clinical trial monitors, and clinical trial auditors. With our Clinical Research Training Courses, health science professionals, specialists, and graduates, now have a fast and affordable way to seek entrance into a field, where they can use their skills and knowledge to work as Clinical Research Coordinators or Clinical Research Associates.

PRICING

SIN	Labor Category	GSA Price
874 1	Senior Project Manager	$ 149.87
874 1	Lead Clinical Resarch Monitor	$ 128.46
874-1	Clinical Research Monitor	$ 107.05
874-1	Lead Clinical Quality Assurance Auditor	$ 128.46
874-1	Clinical Quality Assurance Auditor	$ 107.05

SIN	Course Title	Course Length	Minimum Participants	Maximum Participants	Contractor or Customer Site	GSA Price
874 4	Clinical Research A Training	10.5 hours	3	15	Contractor Site	$ 644.84
874 4	Clinical Research B Training	10.5 hours	3	15	Contractor Site	$ 644.84

SIN	Support Product	Brand Name	GSA Price
874 9	All About Clinical Research: Word Search and Flash Cards	SPRG	$ 15.75

SOLAR BIOMEDICAL LABOR CATEGORY DESCRIPTIONS

Senior Project Manager

- Plans and tracks clinical trial milestones
- Participates in the selection of study sites and the negotiation of budgets/contracts
- Plans investigator meetings; may present as needed
- Develops monitoring strategy and provides oversight to its implementation
- Coordinates the data review and query resolution aspects of the study, through the CRO
- Prepares monthly reports regarding study progress, budget issues, etc.; participates in the preparation of the final study report
- Oversees tracking of study grants; oversees the tracking of clinical supply packaging and shipment to investigate sites through the CRO
- Interacts with Legal, Regulatory, Logistics, Quality and other departments as needed for oversight or input into project critical issues (e.g., contracts, regulatory submissions, drug supply).
- Maintains a high level of professional expertise by enhancing working knowledge of Federal regulations and keeping abreast of current developments and advancements in relevant therapeutic areas

Requirements

- B.A./B.S., preferably in Health Care discipline, from a four-year college or university
- An advanced degree (M.S. or PharmD, nursing degree) desirable.
- Seven or more years related pharmaceutical industry experience in clinical research/operations including 4 years experience in managing clinical trials
- Demonstrated organizational and management skills and able to create/track a budget
- Experience with management of clinical trials in different development phases helpful
- Experience as clinical trial manager or clinical trial monitor at a CRO helpful

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Lead Clinical Research Monitor

Perform site monitoring visits in accordance with the study Monitoring Plan to ensure compliance with the Investigational Plan, Monitoring Plan, applicable regulatory, IRB/EC, and Medtronic standards, guidelines and policies

- Communicate visit findings with site personnel and complete a written letter for distribution to the Principal Investigator and appropriate site personnel for follow-up
- Prepare site visit reports and correspondence for all visits conducted in accordance with the study

Monitoring Plan

• Identify site needs, provide solutions to facilitate the clinical trial process
• Act as a primary point of contact for study sites as requested
• Provide input into the development and improvement of investigator and site management systems (e.g., CTMS)
• Assist in initial and ongoing site personnel training as required
• Identification and escalation of protocol deviations, discrepancies in data, and non-compliance to study protocols, applicable regulations, Good Clinical Practices and Standard Operating Procedures
• Propose solutions and collaborate with monitoring management and study team personnel towards securing Investigator compliance.
• Understand the study protocol and accompanying background information (e.g., Investigator Brochure, Report of Prior Investigations etc.)
• Possess a working knowledge of disease state and investigational product
• Possess understanding of regulatory requirements
• Mentor and/or train junior personnel
• Assist sites/study teams with audit preparation
• Adhere to all applicable Medtronic policies and procedures
• Attend Investigator and/or Coordinator meetings
• Prepare meeting presentations and/or deliver training during meetings (Investigator/Coordinator meetings, study/monitoring team meetings, etc.)
• Provide input into final study site selection
• Be involved in site management activities
• Be assigned lead monitor responsibilities which include but are not limited to:
o Providing input on study protocol, CRFs and other study documents
o Authoring Monitoring Plans, monitoring section of Data Management Plans, and source document worksheets
o Assisting in the creation of corrective and preventive action plans and trending reports
o Managing site assignments in collaboration with manager
o Facilitating communication and information flow between assigned project teams and assigned monitors on project
o Ensuring monitors are trained, current with project requirements and understand study milestones
o Overseeing action item tracking and resolution status
o Performing co-monitoring visits as needed
o Ensuring Monitoring Plan requirements are being met and escalates risks
o Attending Core/Study team meetings

Basic Requirements

• Bachelor's Degree in life sciences, nursing or other health related disciplines

• Four (4) years clinical research experience with at least two (2) years of clinical monitoring experience or Master's degree with 2 years clinical research experience

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Clinical Research Monitors

-Conducts clinical site initiation visits, routine monitoring visits, and site close-out visits

-Ensure adherence to FDA and ICH-GCP regulations

-Ensure adherence to local regulations

-Ensuring the completion of regulatory documents

-Evaluate and report site performance and protocol compliance

-Performing data verification of source documents

-Performing case report form (CRFs) collection if applicable

-Performs product accountability and supply tracking

-Ensures completion and collection of serious adverse events (SAEs)

-Assists with data validation and resolution of queries

Basic Requirements

- Bachelor's degree from an accredited institution of higher education or RN certificate required. Degree in Life Sciences preferred
- At least 1 year of experience as a field monitor or in related clinical research field such as study coordination, in–house CRA, data management, or regulatory activities
- Ability to travel as needed (approximately 65% to 70%)
- Where applicable, fluency in English and local language
- Availibility of a valid driver's license

Lead Clinical Quality Assurance Auditor

Overseeing the auditing activities carried out by the auditors at the clinical research sites, including assigning auditors and tracking audit assignments, developing and maintaining audit schedules, resolving scheduling conflicts, ensuring completion of appropriate pre-audit activities and correspondence, and assisting in the assessment of auditor performance and the quality of auditing activities performed

Required Experience:

- Bachelor's Degree in life sciences, nursing or other health related disciplines
- :Proven GCP knowledge (4 years experience) of working within a GCP Audit function
- Proven understanding of Clinical processes and systems.

621- 099 Clinical Auditors

Plan, schedule, and conduct client QA audits of clinical trials research studies including:
o Protocol & CRF Audits
o TMF Audits
o Investigator Site Audits
o Database Audits
o Clinical Study Report Audits
o System Audits (Quality Management Systems, SOP compliance)
o Vendors of critical services - Capability or performance audits; Central Readers, IVRS, e-CRF and remote data entry systems, CROs, and clinical and bio-analytical labs
- Conduct internal client audits (internal systems, trial master file, investigator sites, clinical service providers, inspection readiness) to assess the accuracy and quality of scientific data collected, and to determine the level of compliance with applicable regulations
- Provide inspection readiness training for both internal client staff, site personnel, and potentially external vendors
- Evaluate the impact of the audit findings and identifies corrective or preventive actions
- Collaborate effectively with business partners and clients to ensure resolution of audits and ensure expected work products and output are aligned with regulatory guidelines, ICH-GCP and applicable regulatory requirements
- Identify quality system improvements

Required Experience
- Bachelor's Degree in life sciences, nursing or other health related disciplines
- Four (4) years clinical research experience with at least two (2) years of clinical monitoring experience or Master's degree with 2 years clinical research experience

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Solar
Solar Biomedical
Embrace the Solar System

TRAINING COURSES

All About Clinical Research Part A

Description of Course

This training is an excellent comprehensive introduction to clinical research for individuals and/or professionals seeking a new career or career change, but do not know which job track within clinical research to pursue. This training is appropriate for anyone considering a career as a Clinical Research Associate, Clinical Research Coordinator/Nurse, or Data Manager. It is designed to increase understanding of the laws, practices, and careers of clinical research in order to promote better compliance and patient safety, and to stimulate interest in clinical research careers. This training presents topics and hands-on interactive activities relevant to monitoring, coordinating, and managing clinical research and device trials.

Who Should Attend

- RNs, APRNs, OCNs, LPNs
- PhD, Masters, BS
- Aspiring and novice Clinical Research Coordinators/Nurses
- Aspiring and novice Clinical Research Associates
- Aspiring and novice Clinical Data Managers

You will learn about the following topics:

- The history of clinical research
- Definitions and terminology in clinical research
- Code of Federal Regulations (CFRs)
- ICH/GCP Guidelines
- Clinical Trials
- Device Trials
- The Clinical Team: Roles and Responsibilities of the Clinical Research Associate , Clinical Research Coordinator/Nurse, and Clinical Research Data Manager , and the principal investigator
- Study Visits
- Preparing for a job in clinical research

This continuing nursing education activity was approved for 10.58 contact hours by the Georgia Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

All About Clinical Research Part B

Description of Course

This training is designed to provide the participant with an excellent introduction to clinical research and the roles and responsibilities of Clinical Research Associates, Clinical Research Coordinators, and Data Managers. It will explore topics and hands-on knowledge relevant to those considering a career as an entry-level monitor, site coordinator, or data manager. Additionally, this course is appropriate for individuals seeking a new career or career change, but do not know which job track within clinical research to pursue.

Who Should Attend

- RNs, APRNs, OCNs, LPNs
- PhD, Masters, BS
- Aspiring Clinical Research Coordinators
- Aspiring Clinical Research Associates – In-house or Field-based
- Aspiring Clinical Data Managers
- Nurses

You will learn to

- Discuss Clinical Research Overview
- Discuss the Protocol and its importance in Clinical Research
- Discuss in detail the different study Phases and Monitoring Visits and the activities involved in each visit
- Discuss and Review the Regulatory Binder and Essential Documents
- Discuss and Participate in Case Report Forms, Drug Accountability and Other Important Forms Reviews
- Discuss Quality Assurance GCP/ICH & Fraud
- Discuss Site Education