SR. CLINICAL STUDIES SCIENTIST- PROJECT COORDINATOR

Skills

- Administration and management of Clinical GCP studies for Specimen Procurement for Beckman Coulter Development
- Administration and management of Clinical Vendors (Supplier Quality Management)
- Budget development and implementation for Clinical studies including payment of Clinical sites and suppliers via purchase orders/check requests
- Laboratory Manager with experience managing small to intermediate internal Clinical IVD Studies for Quest Diagnostics
- Completed Regulatory Affairs Certificate Program (RAPS) for Medical Devices
- Knowledge of Good Clinical Practices, IRB requirements, CAP, CLIA, FDA
- Write Study Protocols for IRB submission
- Prepare Case Report Forms (CRF's)
- Worked closely with Legal and Compliance to execute Clinical study contracts (CSA/MTA) and non disclosure agreements (NDA)
- Manage cross functional teams from start-up through completion of Clinical Projects
- Coordinate specimen and data management for Clinical Projects
- Capable at problem resolution and compliance resolution
- Create and deliver presentations and reports
- MS Project Management
- Licensed CA CLS, ASCPCM
- MBA Pepperdine
- Microsoft Excel, Word, Outlook, PowerPoint
- Master Control Super User (Document Control Software)
- Knowledge of basic statistical methods using SYSTAT and Analyze-It

Accomplishments

- Validated Commercial Software for Specimen Management Clinical Study Protocols.
- Created and submitted IRB approved Study Protocols.
- Work with Scientific and Medical Directors to prepare Study Protocols as needed Clinical Research Management.
- Experience with Clinical Studies.
- Oversight of internal and site management of Clinical Studies.
- Laboratory assay management for Clinical Studies.
- Assay validation both FDA approved kits and in-house preparation.
- Validated ~70 body fluid studies complete with stability and reference range reports.
- Developed Case Report Form (CRF) templates.

Experience

02/2013 to Current

Sr. Clinical Studies Scientist- Project Coordinator Iec Electronics Corp

- Coordinate and manage multiple projects including research studies and other assigned duties.
- Created and implemented new SOP's for vendor management and to establish specimen tracking, standard specimen management, basic data handling processes.
- Meetings with stake holders as needed for Projects.
- Invite and conduct monthly meetings for Research.
- Project and Budget tracking of Clinical Studies Staff and Corporate Development.
- Managed employees in laboratory and processing positions, including training, supervising, and conducting performance reviews.
- Evaluated potential candidates for Laboratory and Research and Development Regulatory Knowledge.
- Knowledge of GCP Guidelines, HIPAA and 21 CFR, CAP, CLIA.

08/1987 to 01/2013

Manager of Clinical Correlations *Manager of Human Specimen Biobank Us Oncology, Inc. ï¼ Rochester , TX

- Upgraded and automated statistical analysis programs for optimum efficiency.
- Collaborative project management including banking of specimens; worked closely with legal and compliance creating legal agreements for collaborative projects.
- Managed multiple ongoing collaborative laboratory projects.
- Advanced IRB Training July 2010.
- Internal Auditor for CAP and CLIA internal inspection.
- Responsible for HIPPA and Compliance within Clinical Correlations.
- Introduced new Freezerworks Software for Bio-banking and increased banking of specimens.
- Instituted new Clinical Correlations Web site for posting of reference ranges, specimen comparisons and method comparisons.

Supervisor Thyroids Endocrinology Department

- Oversaw 14 employees and 30 different tests, responsible for quality control and monitoring of assays Worked with Clinical Trials group, prepared written reports for Clinical Trials.

- Member of ISO 9001 Laboratory Team for successful certification of ISO 9001 Performed assay validations with complete validation reports.

Medical Technologist Thyroids Department

- Prepared reagents and performed in-house proprietary assays Performed testing on automated equipment, responsible for quality control of assays Eisenhower Medical Center Rancho Mirage, CA Training School of Medical Technology and Employment Primary activities: STAT LAB and Chemistry Department.

Education and Training
Masters : Business Administration University of Pepperdine ï¼ City , State Business Administration
MBA Eisenhower Medical Center Rancho Mirage, CA School of Medical Technology, CLS and ASCP licensed
B.S. Microbiology and B.S : Agriculture California State University ï¼ City , State Agriculture
Activities and Honors
San Diego Regulatory Affairs Network (SDRAN) American Society of Clinical Pathologists (ASCP) Regulatory Affairs Professional Society (RAPS) 3 Scheele 2017
Skills
banking, basic, Budget development, Budget, Business Systems, CLS, Chemistry, Clinical Research, Clinical study, Clinical Trials, CA, contracts, data management, Economics, Forms, functional, GCP, inspection, Internal Auditor, ISO 9001, legal, Legal and Compliance, managing, MBA, Medical Technology, Meetings, Microsoft Excel, Outlook, PowerPoint, MS Project, SharePoint, Word, PSP, performance reviews, presentations, problem resolution, Problem Solving, processes, Procurement, project management, Protocols, Quality Management, quality control, Quest, Regulatory Affairs, Research, SOP, statistical analysis, supervising, Validation, vendor management, Web site, written