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OBJECTIVE

Seeking a challenging opportunity within clinical research management that involves innovative or disruptive medical therapies.

SUMMARY OF QUALIFICATIONS

Very unique and capable clinical research professional with over 10 years of experience directly managing and/or supporting all aspects of medical device and pharmaceutical clinical studies across various roles, phases and therapeutic areas including vascular disease, electrophysiology, oncology, cardiovascular, neuroscience, endocrinology and gastroenterology. Experience with supporting FDA BIMO and MHRA inspections.

Prior clinical experience in the field directly supporting implants and follow up of active Class 3 medical devices in commercial and investigational setting. Analytically minded and academically trained as Biomedical Engineer. Experience working with companies ranging from startup to large corporations. **Core Problem Solver.**

KEY ACHIEVEMENTS

- Successful Internal QA audit by Medtronic (2015)
- PMA Approval of VenaSeal Closure System (2015)
- Successful FDA BIMO Inspections (Sponsor and Site) with no major findings (2014)
- Successful MHRA Inspection with no major findings (2012)
- SOCRA (Society of Clinical Research Associates) Certified (2011)
- Recipient of the Novella Clinical President's Award for Achievement (2010)
- IBHRE (International Board of Heart Rhythm Examiners) Certified (2007)

RELEVANT EXPERIENCE

Boston Scientific (Aug 2015 – Present), Cardiac Rhythm Management Division

Company Profile

Boston Scientifics' Cardiac Rhythm Management (CRM) Group is a leading developer of implantable devices (pacemakers and defibrillators) and disposables (Diagnostic and Ablation Catheters) used to treat cardiac arrhythmias, sudden cardiac arrest, and heart failure.

Clinical Trial Manager – Cardiac Electrophysiology

- Reporting to Director of Clinical, responsible for management of clinical operations for global Clinical Trials involving cardiac electrophysiology products and high resolution 3-D cardiac electrophysiology mapping software and associated hardware.
- Development and finalization of key clinical documents, including but not limited to Protocol, Informed Consent, Training documents and Clinical Site Agreements.
- Engaged KOLs, Steering Committee members and Site investigators. Supported design and delivery of training to key integrated teams.
- Work directly with various teams to track key performance indicators, drive enrollment and resolve questions and issues.

Medtronic (Feb 2013 – Aug 2015) – *Formerly Covidien, Formerly Sapheon*

Company Profile

Sapheon is a medical device company whose mission is to develop new approaches and disruptive technologies for the treatment of vascular disease. Sapheon was acquired by Covidien in AUG 2014. Covidien was acquired by Medtronic in JAN 2015.

Clinical Program Manager / Clinical Project Manager – Vascular Disease

- Reporting to the VP of Clinical, Responsible for project management, metrics and quality associated with startup medical device company's first US IDE Pivotal study and other ongoing global clinical studies under minimal supervision.
- Contributed clinical outcomes to regulatory documents supporting PMA submission.
- Created and established internal clinical environment, processes and standards for supporting company's first US IDE clinical study.
- Development and publishing of key study documents including protocols, case report forms, informed consents and clinical study reports.
- Procured, inventoried, shipped and managed 180+ units of investigational medical device and other study supplies including 300+ study binders and ongoing management of content.
- Supported enrollment completion within 6 months of study initiation.
- Systematically managed and triaged 23,000+ ultrasound images for processing by core lab.
- Directly responsible for creating, filing and managing electronic and paper Trial Master File (TMF).
- Review and approve all CRA monitoring trip reports, clinical study agreements and study invoices.
- PMA Approval of VenaSeal device (20FEB2015)
- FDA BIMO inspection of pivotal IDE study returned with no findings or observations (DEC2014).
- Successful Internal QA audit by Medtronic with no major findings or observations (MAR2015).

Novella Clinical (Dec 2008 – Feb 2013)

Company Profile

Novella Clinical is the first fully electronic Contract Research Organization (CRO) capable of integrating clinical and technological expertise to completely manage both pharmacological and medical device clinical trials.

Clinical Project Manager / Associate Clinical Project Manager – Various Therapeutic Areas

- Reporting to various Directors and VPs of Clinical, assured thorough planning and effective implementation of over 14 clinical trials based on contracted scope of work, project timelines, and milestones.
- Reestablished relationship with high-profile client leading to contracts exceeding $15M+.
- Experience managing 8+ EDC system builds.
- Successfully developed and applied new technical solutions to support internal activities.
    - Site Payment Manager: Reduced timeline from 40 hours to 20 minutes.
    - Action Item Extractor: Reduced timeline from 40 hours to 20 minutes.
- Recipient of the 2010 Novella Clinical President's Award for Achievement.
- Several projects selected for audits by MHRA, Sponsors and Internal QA – No major findings

MetaCure (June 2007 – June 2008)

Company Profile

Metacure is the developer of TANTALUS, an intelligent medical device that helps diabetic patients control their eating habits, lowering their blood glucose and body weight.

Field Clinical Engineer (field-based Clinical Research Support) - Diabetes

- Reporting to the Director of Clinical, working in tandem with CRA team, act as primary point of contact and provide medical device technical expertise to investigational clinical sites.
- Responsible for attending all device implants and surgeries to ensure compliance with protocol.
- Support pre-implant activities such as site initiation, technical training, IRB management, patient recruitment, study document version control, etc.
- Support post-implant activities such as site management, treatment assignment, device interrogation, adverse event reporting, query resolution, etc.
- Assisted in the development of Standard Operating Procedures (SOPs) and Working Practices (WPs) for Field Clinical Engineering (FCE) team.

Boston Scientific (Oct 2005 – April 2007, June 2008 – Dec 2008) – *Formerly Guidant*

Company Profile

See above.

Field Clinical Representative – Cardiac Rhythm Management

- Reporting to regional Sales Manager, served as a primary resource to cardiologists and electrophysiologists
- Supported surgical coverage, troubleshooting, programming and patient follow-up of implantable pacemakers and defibrillators.
- Promoted sales through demos / presentations to potential customers on product merits and clinical usage.
- Contributing team member in a region that consistently exceeded quarterly sales plan.
- Managed inventories valued at > $1,000,000.
- Improved device-clinic worksheets leading to better informed physicians and patient care.
- Finished in Top 3 of class for the Heart Rhythm/Device training program.
- Awarded 1st Place case study presentation and recognized by expert trainers for development and demonstration of Arrhythmia Detection Simulator.
- Acquired IBHRE (NASPE) certification within 18 months of hire date.
- Completed company NASPE certification equivalency (GAMExam) within 6 months of hire date.

EP MedSystems (Apr 2005 – Oct 2005)

Company Profile

EP MedSystems develops, manufactures and markets a line of products for use in the cardiac rhythm management or electrophysiology market which are used for visualization, diagnosis and treatment of cardiac rhythm disorders.

Field Clinical Engineer – Cardiac Electrophysiology

- Direct interaction with Physicians and Clinicians, to provide on-site clinical, technical and training support of various cardiac electrophysiology (EP) related medical equipment (Recording systems, Pulse Generators, RF Generators, etc) during hospital procedures.
- Demonstrated technical mastery of company products within one month of employment.
- Revised technical documentation to improve ease of use for customers and field technicians.
- Assisted with development of training program for clients and in-house personnel.

EDUCATION AND ACCREDITATION

Education

- Masters of Science, Biomedical Engineering — Duke University — 2003
- Bachelors of Science, Biomedical Engineering — North Carolina State University — 2001
- Bachelors of Science, Biological Engineering — North Carolina State University — 2001

Certifications

- SOCRA Certified (Society of Clinical Research Associates) — 2011
- NASPE Testamur, aka IBHRE (International Board of Heart Rhythm Examiners) — 2007
- NCBEES Engineering Intern (Fundamental Engineering Exam Certified) — 2001

Technical Skills:

- Electronic Data Capture (EDC): Oracle INFORM, Medidata Rave, DataFax
- MS Office (Excel, Word, PowerPoint, Outlook)
- General Programming: VBA, PHP, PERL, HTML, JavaScript and SQL
- Operating systems: Windows (all versions), Unix, Mac OS

CLINICAL TRIALS EXPERIENCE

Medical Device and Diagnostics:

	Study Details					Operational Phases				
Contributing Role	**Therapeutic Area**	**Study Phase**	**Sites**	**Subjects**	**Global**	**S**	**E**	**A**	**C**	**B**
Clinical Trial Manager	Cardiovascular (EP)	Post Market	40	500	Y	X	X	X		
Program Manager	Vascular Disease	Pivotal (IDE)	12	244	N	X	X	X	X	X
Program Manager	Vascular Disease	Post Market	7	70	Y			X	X	X
Program Manager	Vascular Disease	Feasibility	1	38	Y			X	X	X
CRO PM (Primary)	Cardiovascular (EP)	Post Market	50	500	N	X	X	X		
CRO PM (Primary)	Cardiovascular (EP)	Post Market	50	500	N	X	X	X		
CRO PM (Primary)	Laboratory Diagnostics	Feasibility	8	200	N	X				
CRO PM (Supporting)	Cardiovascular (IC)	Post Market	200	2000	N	X	X	X		
CRO PM (Supporting)	Cardiovascular (IC)	Pivotal (IDE)	95	1770	N		X	X		
Field Clinical Engineer	Diabetes	Pivotal (IDE)	30	300	N	X	X	X		
Field Clinical Engineer	Diabetes	Feasibility	30	100	N		X	X		
Field Clinical Support	Cardiovascular (EP)	Post Market	100	2000	N		X			

Pharmaceutical:

	Study Details					Operational Phases				
Contributing Role	**Therapeutic Area**	**Study Phase**	**Sites**	**Subjects**	**Global**	**S**	**E**	**A**	**C**	**B**
CRO PM (Primary)	Gastroenterology	Phase 3	250	800	N	X	X			
CRO PM (Primary)	Gastroenterology	Phase 3	20	200	N	X	X	X		
CRO PM (Primary)	Gastroenterology	Phase 3	150	600	N	X	X	X		
CRO PM (Primary)	Gastroenterology	Phase 2	20	90	N	X	X	X	X	
CRO PM (Primary)	Alzheimer's Disease	Phase 3	70	600	Y	X	X	X	X	X
CRO PM (Primary)	Prostate Cancer	Phase 3	150	1200	Y	X	X	X		X
CRO PM (Primary)	Gastroenterology	Phase 3	150	300	Y		X	X		
CRO PM (Primary)	Gastroenterology	Phase 3	150	300	Y		X	X		
CRO PM (Supporting)	Prostate Cancer	Phase 3	175	1200	Y		X			

S – Startup E – Enrollment A – Active/Treatment C – Closeout and Database Lock B – Bios/Analysis