

Professional Experience

Principal Consultant / Owner 04/2015 to Present

Driftpin Consultants
Ivyland, PA

Clients: Soterius, Vertex, RMPDS, Alkermes, Ironwood, Eversana, TRI, PRA, Techsol | **Strategic Advisor:** Dataart
Services and Technology Expertise: Product Management, Project Management, Risk-based QMS, CS Validation, Change Management, Risk Analysis, Med Info/Affairs, EDC/CDMS/CTMS, Safety/PV, Content Management

Domain Expertise: SaaS, Decentralized/Virtual Trials, RBM, Strategic Planning, Risk Analysis, Data Management, Clinical Technology, Call Center Ops, Med Imaging, 21CFR11/Annex 11/ICH, Requirements Management

- Life sciences/digital healthcare consultancy applying risk-based approach to technology initiatives: project justification, vendor selection, solution architecture, strategic road-mapping, and KPI/metrics-based operations
- Deliver advisory services across Clinical R&D and Medical Affairs/Med Info domains with a focus on client success, product road-mapping, stakeholder management, and operationalization of technology and workflows
- Lead implementations of validated systems aligning requirements, workflows/controlled documents, system integration, and user training/support, aligning solutions with client objectives and market drivers

Senior Director, Clinical Solutions 12/2009 to 03/2015

C3i, Inc.
Morristown, NJ

- Managed and grew a SaaS clinical technology practice for SMB clients, incorporating BPO services that improved the efficiency and quality of clinical trials for sponsors and site users
- Developed strategic initiatives in Risk-based Monitoring, digital health, and imaging clinical trial support; delineated services, analyzed revenue and market potential, resource planning, and external messaging
- Global Sales Lead, with services teams based in USA, Bulgaria, India, and China, responsible for operational integrity, continuous improvement, new business development, relationship management, and quality oversight
- Managed consultants in clinical development, clinical operations, clinical data management, quality management, computer system validation, and system implementation engagements

Director, eClinical Solutions 12/2008 to 09/2009

Business and Decision, Inc.
Wayne, PA

- Established a SaaS eClinical business practice for SMB clients, leveraging BPO Data Center hosting and Managed Services implementations for the Oracle Life Sciences suite
- Managed internal/external partner team delivering the Oracle Clinical – Siebel Clinical integration PIP, developed go-to-market plans to ensure project success and to realize ROI
- Created unique value propositions through alignment with Compliance and QMS practices; crafting innovative, risk-based approaches for hosted SaaS implementations

Director, Clinical Technology and Data Management 01/2006 to 11/2008

RadPharm, Inc
Princeton, NJ

- Initiated and built a Clinical Technology group, integrating it with the Clinical Data Management; managed both teams to enhance efficiencies, enhance sponsor satisfaction, reduce audit risk, and improve data quality
- Managed ClinOps business owner and IT relationship, aligned requirements, design, and solution; focus efforts to enhance KPIs; ROI and TCO analyses; change control management
- Enhanced strategic relationships with major sponsor/clients; rebuilt and improved customer confidence by driving quality improvements, focused on collaboration and communication with key sponsor personnel sponsor

**Principal Technical Writer
01/2001 to 12/2005**

**Oracle Corporation – Pharmaceutical Applications
Burlington, MA**

- Managed the development of technical documentation such as Release Notes, Installation Procedures/Requirements, Functional Design, and Technical Design specifications
- Member of the OC/RDC/TMS development team, contributed to the creation of product launch processes and go-to-market strategies
- Participated in the UI/UX development, including tests, collection and analysis of results, and formulation of design change proposals
- Negotiated with internal groups to create new interface designs that satisfy user needs, technical specifications, and resource availability

**Owner and Principal Technical Writer
1997 – 2000**

**Driftpin Consultants
LaCombe, LA**

- Delivered online help systems, procedural manuals, software development/API, safety manuals, marketing copy
- Provided complete ownership of the document cycle, from inception to production
- Incorporated usability principles to enhance end-user comprehension, retention, and satisfaction
- Client list included: S&P, Shell Offshore, McGraw-Hill, ABB, The College Board, Oceaneering

**Research Geologist/Scientific Diver
1995 – 1997**

**Naval Research Laboratory
Stennis Space Center, MS**

- Researched and wrote peer-reviewed scientific articles and in-house technical manuals
- Utilized electron microscopy to study the textures and components of clay-bearing marine aggregates and sediment
- Developed Environmental Cell procedures and instrumentation for use in hi-vacuum TEM columns
- Participated in scientific research cruises as Research Geologist and Lead Scientific Diver

**Class I Commercial Diver/Welder
1986 – 1995**

**Oceaneering International, Inc.
Morgan City, LA**

- Excelled in dynamic, hazardous projects in high-risk environments; operations that demanded team leadership, reliance, adaptability, safety, and performance under pressure
- Specialized in structural hyperbaric wet and dry weld repair and marine construction, certified to perform permanent weldments on all classes of US Naval warships
- Expert in all phases of underwater construction, salvage, inspection, and repair in challenging and environmentally sensitive offshore and inshore marine environments

Citizenship: USA and Republic of Ireland

Education

BA Geology, Lafayette College, Easton, PA

MS Geological Oceanography, University of Southern Mississippi, Hattiesburg, MS – all coursework complete

Certificate in Clinical Trials, Boston University

Certificate in Project Management, Villanova University

Professional Associations

Metrics Champion Consortium Ambassador

DIA

IEEE

American Association for the Advancement of Science

Society of Clinical Data Management

CDISC