Wessam Sonbol

Wessam can be reached through
cdginc@clinicaldevice.com

Executive Summary

Experienced health care professional with over 11 years of experience in Clinical Data Management. Passionate about quality, customer satisfaction and process improvement. Record of improving efficiency, productivity and profitability through automation and process improvement.

Objective

To work in a professional environment providing Data Management solutions and help improving company processes and system design.

Clinical Experience

- Knowledge of Good Clinical Practice and CFR Part 11.
- Development of Clinical Processes and SOPs
- Development, design and architecture of Clinical Data Management Systems (EDC).
- Good knowledge of Clinical Trial Management Systems.
- eClinical Solutions, Oracle Clinical, Clindex development and understanding of Oracle Life Sciences data HUB.

Professional Experience

Clinical Systems Consultants Inc. Minneapolis, MN 4/2009 – Present

Clinical System Consultant

Serving as a technical subject matter expert with different Data Management System tools such as Clindex and Oracle Clinical as well as project lead.

- Implement Clinical Systems, CTMS and Data Management tools.
- Gather user requirement and manage implementation process.
- Serve as a technical subject matter expert with Clindex related questions.
- Develop Oracle Clinical add-on modules.
- Develop projects related to the Corporate teams.
- Responsiuble for meeting project timelines and making sure the team is on schedule.
- Develop clinical studies from start to finish including query process and analysis plan.
- Assist international groups in making sure they have good understanding of project timelines, process and how to use different tools within the department.
- Train employees on corporate trial management system.
- Develop study related edit checks and reports.
- Lead the a corporate team in designing site information and study log forms.
- Work with the coporate team to help establish the process knowledge within Clindex.
- Help with Database related questions.
- Develop Oracle procedures and database system architecture.
- Assist and write SOPs.
- Working with clinical operations and data management teams to develop monitoring forms and reports.
- Assist with Data Management related questions and processes within Clindex.
- Work with IT on Clindex related issues.
- Develop customized tools with Oracle Clinical.
- Manage projects with multiple medical organizations.

Sorin Group – Ela Medical Plymouth, MN 3/2007 – Present

CRM Global Clinical Data Manager Lead

Responsible for the Sorin Group Data and Technology Management processes.

- Managed cross-functional teams between the US and EU.
- Developed Data Management Plan and all associated processes.
- Conducted study analysis and reports for FDA submissions and abstracts.
- Developed strategies, department processes and work instructions for international use.
- Managed all database related activities.
- Acted as study analyst to gather data required for study design.
- Responsible for database testing and validation.
- Developed study related reports and help with FDA audit
- Developed tools to manage study payment, monitoring and help automate CRF development
- Managed development of Clinical Studies in Clindex (US) and Oracle Clinical (Europe).

Project Management Skills

Responsible for the life cycle of all Data Management projects and International Trial Management Systems.

- Lead and develop an internal CTMS for Sorin Group Trial Management world wide.
- Provided mentorship to project team.
- Managed CRO's and external data used for internal studies.
- Worked with project managers to deliver project status of study design.
- Coordinated between US and European clinical teams to build a robust Global CTMS.
- Developed project plans and assume responsibility for project profit and loss.
- Communicated with the European team to assure completeness of the projects.
- Managed all phases of study development, including testing and validation.
- Lead a team in developing test cases and UAT.
- Directed the coordination of all implementation tasks.
- Worked with hospital coordinators to better manage Reports and data being distributed to them.
- Worked with Clinical team to gather study requirement to be developed in the database.

Medtronic Shoreview, MN 5/2008 – 10/2008

Responsible for working with the Clinical Staff, gather requirements and development of an online CTMS system

I3Innovus – United Health Eden Prairie, MN 11/2006 – 5/2007

Sr. Product Consultant

Responsible for managing a product launch timeline, documenting the project and meeting with clients to present the product and help with the sale.

- Worked with clients to demo the product and engage in the product sale.
- Increased company growth by consulting engagements and bringing more data resources to the product.
- Assisted with client engagement services and solution implementation.
- Responsible for management of multiple phases within the project.
- Developed strategies to assist with product sale.
- Worked with the product development team to deploy the project and work on client issues.
- Assisted in improving communication with all the different business units of the project.
- Produced project status reports with emphasis on SDLC.
- Helped in product testing and validation.

American Medical Systems Minnetonka, Minnesota 01/2005 – 11/2006

Sr. Database Programmer Analyst

Responsible for developing the Clinical Data Management Process for the Clinical Department.

- Integrated a new Patient Management Record system.
- Developed training material and Train client on new processes and procedures.
- Developed system requirements documents.
- Conducted study analysis for FDA submissions and abstracts.
- Introduced the use of Microsoft project in-order to track and manage project milestones.
- Managed all clinical trial development and validation.
- Assisted in writing new SOPs for creating/developing clinical trials.
- Assisted client in Case Report Form Design.
- Provided mentoring and training to physicians and AMS users with using the clinical database.

- Developed a payment system to interact with eRT and JDE with respect to the HL7.
- Integrated the CRF requirement documents into the hosted Oracle DB using XML, XSL, C# and NANT.
- Created reports, macros and validation for clinical trials.
- Introduced new ways to develop and effectively manage and produce clinical trials.
- Created migration scripts to move all studies from Microsoft Access database to Microsoft SQL Server using DTS (Data Transformation Service).
- Created migration scripts to automatically transfer data entered into the AMS Microsoft SQL Server through Teleforms (OCR system) to an offsite Oracle Database using DTS.

Project Management Skills

Developed a full project cycle to coordinate between the client and sponsor.

- Implemented the use of MS Project within the Clinical Project Cycle.
- Used UML user diagrams to better define the development process.
- Worked closely with testers in validation the study development.

Eminent Research/PPD Medical New Hope, Minnesota 06/1999 – 12/2004

Manager of Software Development 10/2003 – 12/2004

Managed a group of four programmers in developing enhancements to the tctmd.com website as well as developing new clinical EDC projects using the Clinsights clinical eRegistry project.

- Worked closely with our International clients on product development and system design.
- Responsible for the full cycle of the Electronic Data Capture system developments.
- Fostered customer loyalty by ensuring that our customers fully utilize the value of our solutions and services.
- Developed project workflow and web services within Weblogic using EAI technology.
- Created project design, and project workflow using UML.
- Created database design using Visio.
- Responsible for maintaining an FDA Electronic Capture System used for clinical database, which is fully capable of creating audit trails and capturing query processes.
- Helped develop test cases and user acceptance testing documents.

Sr. Software Engineer 06/1999 – 10/2003

Developed and designed the largest Stent eRegistry (J&J Cypher Stent).

Developed, launched and maintained the premier online Interventional Cardiology and Vascular Medicine community web site (http://www.tctmd.com), which is a dynamic web-based community for interventional cardiologists, endovascular physicians, and allied clinical professionals.

- Worked closely with Doctors from Europe and US to gather Global Database requirements.
- Developed a client GUI interface to migrate data from Hospital Patient Medical Record to Global Database.
- Met professional services revenue and profit quotas.
- Architected and designed the database for TCTMD.com and eRegistry system.
- Knowledge of HL7 and implementing voice XML to a Clinical Trial System.
- Developed the Clinsights/PPD global view registry services for the purpose of capturing remote data over a secure connection on the World Wide Web.
- Worked closely with the QA staff to test our internal developed products.

Project Management Skills

Responsible for managing multiple European/US projects phases, timelines and analysis.

- Traveled between Europe and US to gather requirements for the Patient Global Database development as well as for the development of the Global View EDC system.
- Worked closely with some of the top cardiology physicians in the world to coordinate the project timeline.
- Worked with Integration of Hospital systems with the Patient Global Database.
- Developed well organized connections with our international sources.
- Developed UML diagrams for the project visual specification.

Digital River Eden Prairie, Minnesota 06/96 – 06/99

Internet Help Desk Specialist

Digital River is the first Commerce Service Provider to offer a multi-channel e-commerce suite that can be outsourced in a hosted environment or purchased as a packaged application.

- Provided clients help desk and on-line support regarding their purchased software.
- Assisted customers in using the purchased software.
- Worked on developing the company's first FAQ website, as well as helping debug the download site.

Technical Skills

- Proficient in database architecture and design
- Oracle8i database and Oracle9i are the default databases used for all projects, which helped develop strong knowledge in using Oracle programming as well as database architecture.
- *Programming Languages:* .Net, *J2EE*, JSP, Visual basic, PHP, XML, XSL, TCL/TK, HTML, Java, and JS.
- *Applications:* Eclipse, Apache, Crystal Reports, Adobe Photoshop, Microsoft Visual C++, Microsoft Visual C#, BEA Weblogic.
- *Database Skills:* Oracle, MS Access, MS SQL Server, SQL, and PL/SQL.
- *Operating Systems:* Mac, Windows95/98/2000/NT, Unix, Linux.
- *Reporting Applications:* Crystal Reports, Brio, Oracle Raptor, Toad
- *Microsoft Applications:* Project, Word, Excel, Publisher, Power Point and Microsoft Outlook.
- *OCR System:* Teleform
- *Training:* Introduction to Java, Complete Server-Side Java, Use of computers in clinical research required by FDA.
- *Languages:* English, French and Arabic.

Education

University Of Minnesota, Minneapolis Minnesota
Bachelor's of science in Computer Science / Business Management