

Decus Biomedical, LLC

Patricia D. Olsen, CCRA

Background

Summary: 13 years Clinical Affairs and Quality/Regulatory experience, 7 years Medical Device development, 24 years of Computer Programming experience, 12 years of Project Management and Management Experience.

Experience:

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Clinical Affairs Specialist

9/2003 to
Present

Designed, initiated and ran all aspects of clinical trials for client companies such as Eastman Kodak Co./Carestream Health, Kalaco Scientific, LLC, iScience Surgical and Allux Medical. Several of the trials are being run internationally as well as in the U.S. This involves knowledge of EU regulations in addition to U.S. regulations. Responsibilities include:

- Study Management, Study Monitoring, Data Management
- Design and development of protocols, SOPs, Case Report Forms
- Development of study budgets, negotiating Research Agreements
- IRB and Ethics Committee approvals and communications

Provide Quality/Regulatory support for medical device companies to set up and execute Design Controls for their engineering development. This included such companies as Visiongate, Cornell, and Eigen Medical. Primary responsibilities included process development, requirements definition, and design and execution of V&V.

MiraMedica, Aurora, CO

Clinical Operations Manager

5/2001 to
6/2004

First employee hired in a start-up to develop a Computer-Aided Detection device for Mammography. Led a team of 2 CRAs and 2 engineers to develop, run, and project manage all aspects of a Clinical Trial from study design to site recruiting, study monitoring and data management in accordance with GCP. Managed 5 clinical trial sites in Colorado and California.

- Developed IRB protocols and managed IRB applications/renewals
- Designed, developed and managed the CRF database and image library
- Performed Training of clinical site CRAs, and doctors
- Functioned as Clinical Study Manager as well as Clinical Study Monitor
- Coordinated and ran a Reader Study with 10 doctors
- Assisted in Data Analysis of Clinical Trial results
- Assisted in development of PMA and 510K applications
- "Most Responsible Person" for FDA BIMO audit which resulted in NO deficiencies
- Instrumental in getting the company purchased by Eastman Kodak Co.
- Product received FDA approval in 11/2004.

Additionally, I managed the System Test effort for two UI software products, managed internal software tools development, developed company-wide SOPs in accordance with 21 CFR Part 820, managed validation and verification efforts for all internal and OTS tools as well as the UI products.

Fischer Imaging Corporation, Thornton, CO

Software Engineering Manager/ Software Lead

1/96 to
2/2001

Manager of all software development projects in R&D for a medical device company. This included a total of 9 direct reports. Responsibilities included management of a department budget, personnel related functions, as well as performing project management and software development functions described below. Also handled cross-functional project management

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including electrical, mechanical, physics and software as well as all aspects related to transfer to manufacturing.

Assisted in data management and clinical monitoring of Clinical Trials for Full-Field Digital Mammography at 6 clinical trial sites. Responsible for all data management activities, assisted with data analysis, wrote portions of the PMA application. This product received FDA approval in 08/2002.

Member of the National DICOM standards team for Digital Mammography (WG 15) sponsored by ACR-NEMA.

Storage Technology Corporation, Longmont, CO

**1994 to
1996**

Sr. Software Engineer

Performed product definition and requirements elicitation on a new proprietary product. Educated and lead the requirements effort using SEI software methodologies (similar to QSR). Wrote a requirements process guide and developed a method for tracking requirements. Product was to be developed using Visual C++ under Windows NT. Responsible for the software maintenance of a large robotic tape library system.

Unisys Corporation, Thornton, CO

**1986 to
1994**

Principal Software Engineer

Responsible for software development-related activities for two key Air Traffic Control projects: Mode S Surveillance and ARTS IIA ISP Air Traffic Control. This included design, documentation, software development, testing and release using the SEI software methodologies (similar to QSR).

Analysts International Corporation, Englewood, CO

**1983 to
1986**

Technical Staff/Software Engineer

Designed and developed features for the Attendant Console function on a medium-sized PBX using 'C'/UNIX on a Vax 11/780. The software was then ported to an 8086 microprocessor. The software was designed to be multi-tasking in a Realtime environment.

Systems Development Corporation, Camarillo, CA

**1981 to
1983**

Programmer Analyst

Supervised 5 programmers in the requirements analysis, design and development of the Flight Service Automation System for the FAA. Managed the Terminal Communications Subsystem, which consisted of a user interface and a printer using TAL/Guardian O/S on a Tandem Computer.

Education:

B.A. in Organizational Management, Ashford University
ACRP Certified Clinical Research Associate #FDA-A-0906-230
GCP Clinical Site Auditing (Compliance Media)
Specialized Certificate in Clinical Trials Administration (Grade = A) – University of CA at San Diego Extension

Completed 100+ semester hours toward a Computer Science B.S. degree at Cal State Northridge, Northridge, CA

In-House Training:

GMP
Clinical Trials/Clinical Trial Monitoring
SEI Software Methodologies
Object-Oriented Analysis and Design
C++, C

Software Engineering Project Management (Univ of Colorado Master's course)
Seven Habits for Highly Effective People
Excellence through Quality
Leadership in Excellence through Quality