

Decus Biomedical, LLC

Terry Passarotti, MBA CBA

Professional Experience

2007 - present

Operations Manager Decus Biomedical, LLC, Berkeley, CA

Operations Responsibilities:

- Manage organization operations by directing and coordinating activities consistent with established goals, objectives, and policies.
- Follow direction set by the CEO and implement plans to ensure attainment of business plan for growth and profit.
- Manage projects and company resources in the areas of Quality System development, Clinical Data Management, Clinical Database Requirements Specification, and Software Verification.
- Manage accounting, client billing, and payroll systems.

Client Responsibilities:

Clinical Studies:

- Design and manage clinical databases
- Design and implement data management processes
- Train and manage data entry clerks
- Discrepancy resolution
- Perform and document data analysis and data verification activities
- Create standing and custom reports for interim analysis
- Design Case Report Form based on clinical protocols
- Clinical monitoring at investigational clinical sites per Good Clinical Practice (GCP) guidelines.

Design Control:

- Draft customer and system level requirements for medical devices comprising hardware and/or software subsystems.
- Manage and/or perform Design Verification and Validation activities for medical devices for compliance with 21CFR820, ISO 13485, ISO 14971 and IEC 62304 including writing master plans, test plans, requirements traceability and summary reports as well as training, scheduling and supervising testers and performing quality checks on test result documentation.

Quality Systems:

- Certified Biomedical Auditor
- Design, implement and train staff on document control systems in electronic or paper environments.
- Perform gap analysis on 21 QSR 820, ISO 13485, ISO 14971 and IEC 62304 quality system environments and draft procedures and templates to fill gaps.

Decus Biomedical, LLC

- Quality System mapping: process maps, input – output maps, custom maps for client needs.
- Computerized System Validation design, training and implementation.

2004 -2007

Project Analyst / Business Planning Decus Biomedical, LLC, San Carlos, CA

Relevant Responsibilities:

- Support client projects in their planning, monthly reporting and forecasts, monthly analysis and tracking of resources and expenditures. Help set up the reporting infrastructure and perform ad hoc reports and analysis as requested by internal customers. Assist Decus managers with cost analysis and reporting.
- Manage Decus accounting systems and data entry including month end reconciliations and reporting, the monitoring of employee time, contractors requests and hours; reconciliation of various expenses against ledger; trending of project expenditures; assist in the development of the project resource plan including monthly updates.
- Preparation of reports to the Project Manager on various measurement metrics on projects being supported. Assist in the annual budgeting and quarterly planning process and perform ad hoc reports and analysis as needed. Provide assistance in resolving financial and administrative problems.
- Perform verification procedures for validation of Decus data management systems.

2003 - 2004

Management Consultant Plan Resonate, LLC, San Francisco, CA

Relevant Client Responsibilities:

- Integrated web-based collaboration applications with existing business systems for reduction in email volume, enhanced communication, and decentralization of decision making and information sharing.
- Designed integrated inventory / accounting systems: increased employee productivity and improved managerial decision-making capacity.
- Created database systems for project grant, constituent and budget management: 10-25% improvement in productivity and data quality.
- Analyzed and documented processes and procedures: 10% reduction in employee training time

Education and Certifications

2008 C.B.A. Certified Biomedical Auditor, American Society for Quality

2005 M.B.A. Sustainable Management, Presidio School of Management, San Francisco, CA

1990 B.A. Chemistry, Wells College, Aurora, NY