

SERI R. GOMBERG

44 Estates Drive • Orinda CA 94563 • gomalool@yahoo.com • 415.425.7797

Qualifications

Dynamic, detail-oriented professional with 15+ years' experience in business management, clinical trials and computer programming. Focuses on implementing efficient and effective processes in a productive atmosphere. Analytical, flexible, creative. Extremely computer literate, capable of learning new systems quickly. Successfully communicates with people from many disciplines. Understands the big picture without losing sight of critical details.

Core Competencies include:

- Clinical trials manager
- Computer programmer
- Team builder
- Solution strategist
- Organizational development
- Vendor manager

Professional Experience

Independent Business Consultant

Self-Employed

Orinda, CA

2003-present

Provide fresh, creative analysis of business operations for clients in a variety of business endeavors. Support clients to make them more efficient and effective.

- Collected and analyzed data for entrepreneurial ventures.
- Hired and trained Administrative Assistant for Landscaper, managed job description writing to operations.
- Screened assistants for organizational consultant.
- Tracked three construction projects to completion, performed accounts payable, purchasing, and more.
- Wrote and edited protocols for biotech & medical device companies.

Manager, Field Operations and Office Administration

University of California, Berkeley

Berkeley, CA

2001-2003

- Managed daily operations of survey research program. Responsibility expanded progressively from 5 to 14 employees.
- Planned and implemented restructuring to improve quality, productivity and cost-effectiveness, resulting in a 50% reduction in expenses.
- Negotiated and managed outsourcing relationships, including specialized expertise in the project.

Clinical Informatics Analyst

iKnowMed

Berkeley, CA

2000-2001

- Managed implementation of screening for over 100 oncology clinical trials in Electronic Medical Record (EMR)
- Wrote one of first CDISC file to export records from database; wrote data collection program.
- Programmed clinical trial screening to review EMR and alert physician when a patient qualified for a study.
- Programmed detailed eligibility criteria to provide automated definitive determination of eligibility.
- Programmed capture of CRF data within patient chart and maintained program written by others.

Manager, Clinical Operations

Karmel Medical Acoustic Technologies

Yokneam Illit, Israel

1999-2000

- Managed six device operators; built team and coached them to achieve company goals; created GCP-compliant protocols for existing studies and monitor studies.
- Wrote SOPs and revised User's Manual.
- Represented users of innovative medical device in complaint review and design review meetings.
- Monitored incoming data for three studies, managed daily operations on two studies.

Consultant/Clinical Program Manager**BRM Capital****Jerusalem, Israel****1998**

- Provided 3-day needs analysis; subsequently hired to provide clinical trial expertise to identify Principal Investigator, develop study protocol, prepared IRB paperwork, identify sites, and participate in all business meetings and decisions for what was then BRM Technologies, Ltd., VC, now BRM Capital.
- Planned logistics in different types of sites (hospital, site management organization).
- Negotiated with vendors and participated in all business meetings.

Grant Administrator, Breast Care Center**Cancer Center, University of California****San Francisco****1994-1998**

- As a senior administrative analyst, managed activities for federal SPORE grant (\$2.5 million/year).
- Designed, planned and coordinated projects involving 13 Principal Investigators and their support staff.
- Managed annual budget, and prepared financial and scientific reports.
- Assisted patient advocacy core develop and implement research projects.

Manager, Breast Care Center Clinical Research Unit**Cancer Center, University of California****San Francisco****1997-1998**

- Coordinated and tracked all pre-study activities: completed questionnaires, represented the Unit during pre-study visits, established a logistical plan to perform complicated studies, and assured prompt completion of internal review, Institutional Review Board approval and contract negotiations.
- Identified and solicited new studies; initiated and maintained relationships with sponsors.
- Coordinated work load of the clinical research staff.

Computer Skills

Computer proficiencies include the following, as well as several proprietary applications:

Power User

- MS-Word
- MS-Excel
- Eudora
- HTML
- QuattroPro

Intermediate User

- CSS
- Outlook
- Powerpoint
- Visio
- Windows XP

Familiar With

- MS Access
- XML, CDISC
- DreamWeaver
- MS-Project
- SQL, TCL

Education & Training***Hebrew University, Jerusalem, Israel***

- M.S. (cum laude) in Biological Chemistry, 1992
- B.S. in Biology with minors in Mathematics and Computer Science, 1989

Continuing Education

- *Regulatory Affairs Training Course*, DIA, Boston, 2004
- *Supervisory Development Lab*, University of California, Berkeley, 2002
- *ArsDigita Boot Camp*, ArsDigita, Berkeley, 2000
- *Introduction to GCP and Auditing*: DIA, Jerusalem, 2000
- *Introduction to Project Management*, UCSF, San Francisco, 1996
- *Microeconomics course*, Open University, Tel Aviv, 1993
- *Social Psychology course*, Open University, Tel Aviv, 1993