PATRICIA A. HAMILTON, RN, MS

Ms. Hamilton can be reached via
Clinical Device Group Inc.
Please click here.

[CDG NOTE: Ms. Hamilton has a unique expertise in Latin and South American regulations.]

Objective

To ensure FDA compliance and early regulatory approval by offering customized pre-clinical, clinical, regulatory and quality support to pharmaceutical, biomedical and device companies.

Summary

Extensive senior level management and team leader experience. Deliverables include:

- managed international and domestic clinical project teams
- managed international and domestic clinical research studies supporting FDA submissions
- managed all projects on time and within budget for various Fortune 100 global corporations
- coordinated international teams of clinicians and researchers during multi-site clinical trials
- managed Quality Review Board and Health Hazard Reporting

Management and team leader experience with all phases of drug and device clinical trials. I am results-driven, self-motivated, and an innovative leader with excellent interpersonal and team building skills.

Professional Consulting Experience

ClinStat Consulting LLC, Cardiff by the Sea, CA 1999-Pres
President

Scope of Services

Acquisition Due Diligence
Auditing
Case Report Form Design
Clinical Study Design
Clinical Protocol Development
Clinical Quality and Risk Management
Clinical Training
Corporate Training and Presentations
Data Entry and Data Analysis
Expert Witness
FDA Guidance and Interface
FDA remediation
Health Hazard Advisories and Safety Reporting
Human Factors Design, Testing and Evaluation
Identification and Qualification of Investigators
Informed Consent Form Preparation
Investigator Brochure Preparation
Investigator Meetings, Plan, Organize, Conduct
IRB/EC Submission Preparation
Management Multi-center **Domestic** Clinical Studies
Management Multi-center **International** Clinical Studies
Medical Writing
Monitoring, Clinical Site
Patient Safety/Data Safety Monitoring Board
Post Market Surveillance Studies Management
Preparation of FDA Submissions and Interim Reports
Project Management
Product Validation Studies
Quality Auditor
Quality Oversight Monitoring
Quality Systems Review Board
Standard Operating Procedure (SOP) Development
User Study Design and Management

Professional Corporate Experience

The Gillette Company, San Diego, CA and Boston, MA 1997-1999
Director of Clinical Studies, Medical Devices

- Worldwide responsibility for Braun medical device clinical and marketing studies coordinating research teams and clinicians in Germany and the US

- Hosted weekly international project team videoconference sessions
- Coordinated all FDA/CE activities and submissions with VP Regulatory Affairs
- Member new product identification team resulting in acquisition of two new businesses
- Responsible for cost containment of business transfer overseas and local facility closure

Baxter Healthcare Corporation, Irvine, CA 1995-1997
Manager Clinical Affairs, Cardiovascular Group, Vascular Division

- Managed Class II and Class III implantable medical device clinical studies
- Managed US and German clinical device teams
- Managed endovascular drug/device studies for reclassification
- Directed all multinational clinical programs (heart valve and stent) resulting in decreased costs and decreased time to market
- Successfully interfaced with FDA on long term surveillance programs

Telectronics Pacing Systems, Englewood, CO 1994-1995
Clinical Manager, Tachycardia

- Managed international project teams in US, Europe, Australia forming one cohesive workgroup
- Managed new implantable cardioverter defibrillator project resulting in shortest product to market timeline
- Managed implantable drug/device product lines

Pfizer Incorporated, Irvine, CA 1980-1994
Manager Department of Medical Affairs
Shiley Heart Valve Research Center

- Managed heart valve strut fracture epidemiology study resulting in evaluation of 30,000 patients worldwide as part of recall effort
- Managed European international long term surveillance IDE heart valve study to satisfy FDA requirements
- Directed product labeling

Education

University of La Verne, La Verne, CA
B.S., Business Administration
M.S., Business Organizational Management
Graduated all studies with honors

Chaffey College, Alta Loma, CA
R.N. State of California (Active)

Professional Memberships

Association of Clinical Research Professionals (ACRP)
Biocom San Diego
California Nurses' Association
Regulatory Affairs Professionals Society (RAPS)

INVITED LECTURER

Clinical Concerns and Human Factors.
San Diego State University Masters Program in Regulatory Affairs course November 2010.

Overview of Regulatory Affairs for Medical Device Professionals.
University of California, San Diego
Summer 2011

PUBLICATIONS

Available upon request