

Betsy Gamlin, MS, RN

EDUCATION

2002-2005- North Park University, Chicago
Master of Science with major in Nursing and Leadership and Management Track
Magna Cum Laude

1989-1993- Andrews University, Berrien Springs , Michigan
Bachelor of Science with Major in Nursing
GPA 3.84/4.0 Magna Cum Laude

1983-1985- Kishwaukee College, Malta, Illinois
Associate Degree of Nursing
GPA3.9/4.0 Sum Cum Laude

1974-1977- Illinois State University, Normal, Illinois
Music Education Major
GPA3.5/4.0 Magna Cum Laude

EXPERIENCE

01/2008- present Clinical Research Manager
Abbott Laboratories, Global Pharmaceuticals R & D, Oncology

3/2007- to 9/2007 -Director, Clinical Operations
ClinSearch

- Business Development Regulatory Affairs
- Financial Oversight
- Training/Teaching of new Sub investigators
- Liaise with FDA
- Liaise with CRO's
- Over view of Research Center

2/2004-to 3/2007- Senior Clinical Safety Specialist
Takeda Global Research and Development
Lincolnshire, Illinois

- Review and expedite serious adverse events to the FDA
- Complete assessment of serious events from beginning to conclusion
- Present/teach at Investigator Meetings, Coordinator Meetings, and CRA Meetings
- Write narratives/code SAE's, write pregnancy narratives
- Develop templates for different compound SAE's, Develop new orientation material for Safety
- Mentor new hires
- Spearhead and execute Lunch and Learn Series mandated by company president
- Competent in Medra coding, ARISg data base system
- Clinical Trial review, narrative review, study report review,
- Attend Safety Working Group

2/2002-to 2/2004- Clinical Program Manager

**Takeda Pharmaceuticals of North America
Lincolnshire, Illinois**

- Participate in strategic planning activities related to clinical studies and design of the clinical protocols
- Operational Execution of Phase II and III studies
- Oversee, coordinate, and contribute to the clinical documents related to the drug development process including Investigator brochures, IND's protocols, final study reports and NDA preparation
- Assist Vice President with the development of the clinical program budget, clinical supply and related material projections
- Manage clinical study activities within budget
- Oversee and manage the Senior Study Manager, Study Managers, and Associate Study Managers in the finalization of protocols, selection of investigators and execution and close out of clinical studies
- Lead, manage, and develop Senior Study Managers
- Lead cross functional study teams and represent study team at the project team level
- Identify and address operational issues, elevate to Vice-President when necessary
- Lead and direct research in South America
- Interface with Europe for Phase II and Phase III studies
- Plan and lead Advisory Board Meetings
- Responsible for Phase III /IV studies guidance and conduct

9/2001-2/2002-Senior Safety Specialist

**Takeda Pharmaceuticals of North America
Lincolnshire, Illinois**

- Review and expedite serious adverse events to the FDA
- Complete assessment of serious events from beginning to conclusion
- Present/teach at Investigator Meetings, Coordinator Meetings, and CRA Meetings
- Weekly Conference calls with Lilly to discuss serious adverse events
- Write narratives/work in Arisg data base system

1/2001-9/2001- Clinical Research Manager/Operations

**Pharmacia
Skokie, Illinois
Clinical Area: Cardiovascular/Metabolic/Oncology**

- Manage multiple Phase II- IV trials
- Manage Regional CRA's
- Site Selection/ Conduct feasibility studies
- Negotiate contracts
- Track payments for Investigators
- Strategies for patient recruitment
- Co-monitor with CRAs
- Train Investigators and CRAs GCP practice
- Strategic planning

9/98 to 1/2001- Senior Clinical Research Associate

**Pharmacia
Skokie, Illinois
Clinical Area: Cardiovascular/Metabolic**

- Assist with close out of Xenilofiban, 9,000 patients
- Review of tables for filing of NDA

- Assist writing protocol/CRF's for Phase I first in man study and Phase II
- Manage, coordinate, and implemented Phase I, and II, clinical research trials
- Monitor Phase I
- Review budgets and evaluated feasibility of Investigator's for Phase I and II (enrollment 86-500+)
- Manage CRO and conduct frequent face to face meetings
- Manage Phase II trial (50 sites)
- Co-Monitor with CRAs
- Manage and supervise junior colleagues
- Coordinate Investigator Meeting for Phase II/ Responsible for speaking and running meeting
- Initiate sites and co-monitor
- Lead weekly meetings with CRA's and CRO
- Track enrollment

1/98-8/98- Consultant to Debra Owens, Owens International
Strategic Management
Antioch, Illinois

- Assist Owens International management with diagnosis, prioritization, and improvement of key business needs enhancing competitive advantage, profitability and clinical outcomes
- Clients included Novartis/Basil Switzerland and Private practice Gastroenterologist
- Train Investigator site on how to conduct Clinical Trials and adhere to GCP guidelines
- Train Investigator site on writing job description for research personnel

8/94-2/98- Clinical Research Associate
TAP Holdings Inc.
Deerfield, Illinois
Clinical Area: Gastroenterology

- Evaluate and assist in CRO selection
- Writing protocols for Phase I-III studies
- Assist in development of CRFs
- Monitor Phase I-III Studies to closeout
- Monitor two Phase I European Studies
- Work closely with Central Laboratory, statisticians, medical directors and project management
- Assist with NDA preparation writing clinical summary
- Preparing Clinical Pharmacology Section of NDA
- Write monthly Newsletter to Investigational Sites
- Assist in preparation of Investigator Meetings
- Present at Investigator Meetings, Coordinator and CRA meetings
- Work on studies instrumental in Prevacid approval

1989-1994- Intensive Care-Coronary Care/Neuro Intensive Care
Hinsdale Hospital
Hinsdale, Illinois

- Charge nurse /Hinsdale Hospital
- Responsible for critically ill patients
- Care plans for patients
- Collaborative effort with physicians, social workers, families

1985-1989- Neurological Rehab, Obstetrics, Pediatrics

Hinsdale Hospital

Hinsdale, Illinois

- Charge Nurse Responsibilities
- Responsible for care, teaching of stroke patients/rehab
- Obstetrics/ mother baby care
- Cross trained to pediatric high risk nursery
- Pediatric nursing

ACTIVITIES AND AWARDS

- Integration Team Member for Takeda (2005-present)
- Appointed leadership position for Lunch and Learn
- Risk Management at Resurrection Hospital (2004-2205) with Lawyers and Claims as part of my Clinical for Masters Program
- Takeda Circle Award (September 2005) for meeting stretch goals
- Takeda Circle Award (September 2003) for flawless execution of Phase II trial
- Takeda Commitment Awards for excellence/team work
- Advanced Cardiac Life Support Prepared
- Basic Life Support Prepared
- Recognized by the American Heart Association for saving a life
- Deans list at NorthPark University Masters Program
- Deans list Andrews University, Kishwaukee College and Illinois State University
- Kathy Moan award for Outstanding Senior Vocalist
- Chairperson for Intensive Care/Cardiac Care Unit
- Nurse Advocacy Committee
- Inducted into honors Sigma Theta Tau International (1992-Present)
- Recipient of Outstanding Nurse Graduate Award (1985)
- President of Christian Nurses Fellowship (1984-1985)
- Vice President of Christian Nurses Fellowship (1983-1984)

PROFESSIONAL ACTIVITIES

- Published article on smoking and Helicobacter pylori
- CPR Instructor
- Helped develop and teaching 2 modules for Clinical Research at Northwestern University, Chicago Fall of 2004
- Taught CRA/CRC Course at Northwestern University
- HOPE Volunteer (Help offer Protective Environment for Abused Women)
- American Red Cross Volunteer
- Nursing and Physician Advocacy committee member pioneering first such efforts in Illinois
- Children's Choir Director
- United Methodist Women Vice-President/President
- AACN (local and national)
- Member of DIA (Drug
- Participate in RAPS (Regulatory Affairs Professional Society)
- Member of American Diabetes Association
- Member of ACRP (Association of Clinical Research Professionals)
- Member of Association of Gastroenterology
- Member of American Heart Association
- Attend European Cardiology meeting
- Attend American Heart Association meeting
- Attend European Endocrinology Meeting

- Speaker on Patient Recruitment Washington DC July 2006
- Round Table speaker at Northwestern CRA/CRC class
- US Airways presentation for Focus on Chattanooga/ ClinSearch August 2007
- Member Chattanooga Chamber of Commerce
- Mentor and teach Physicians/ Nurse Practitioners as Sub-Investigators

Training

- GCP/ICH Guidelines
- Microsoft/Word
- ARISg system
- Medra Coding
- Orient new employees in Research and Development/Safety/Drug Development
- Write job descriptions for Senior Program Managers
- Sit on Leadership committee
- Write SOP's
- Presenter at Orientation Programs
- Global Trainer for Safety
- Develop and chair Lunch and Learns
- CITI Training
- IATA Training
- Fraud and How to Detect
- How to speak in front of a crowd
- How to deal with difficult people
- Managers Training Course

REFERENCES

Furnished upon request

Updated 06/May/2008