Cathy M. McCarthy, RN

20 Lawson Grove
Morris County, New Jersey
04560
913-657-9299 home
913-555-9355 mobile
Cathym@angelfire.com

Summary

Registered Nurse with 14 years of experience, 6 of those in the pharmaceutical industry. Will graduate from Seton Hall Law School in May 2009 with a Masters degree in Jurisprudence – Health Law.

Current role is Pharmacovigilance Compliance Consultant for a global Top 5 pharmaceutical corporation. Responsible for managing the development and implementation of global and local pharmacovigilance system documents for compliance with local and international Health Authority regulations.

Previous role was Manager of Pharmacovigilance and Compliance for a global Top 10 Pharmaceutical corporation. Responsible for managing compliance with local and international Health Authority regulations for submissions of all adverse event reports. Role was also the compliance liaison for international affiliates. Developed and implemented metrics which resulted in increased submission compliance. Responsible for management and negotiation of safety data exchange agreements between Pharmacovigilance and license partners and / or division partners.

Prior to entering the pharmaceutical industry, was responsible for hospital liaison case management activities performing on site assessment of patients from referring hospitals to physical rehabilitation centers. Experienced in negotiation with insurance companies for length of stay and facility reimbursement rates.

Certified in Healthcare Compliance. Member of the Regulatory Affairs Professionals Society, the Drug Information Association, the Health Care Compliance Association, the Society of Corporate Compliance and Ethics, and the American Health Lawyers Association.

Work Experience

Consultant, XXXX

11/2008 – present *XXXX Company Name XXXX, Morristown, NJ*

- Consultant for the consumer care (OTC) division of a Top five pharmaceutical company.
- Project manager for development and implementation of pharmacovigilance system documents for compliance with Federal and International Health Authority regulations.

Manager, XXXX

12/2007 – 11/2008 *XXXX Company Name XXXX. Parsippany, NJ*

- Develops, plans, and conducts internal inspections and audits; composes and issues audit reports; reviews and approves corrective action plans following inspections and audits.
- Oversees composition, issuing, review, update and archiving of departmental and global Standard Operating Procedures (SOPs).
- Interprets Good Clinical Practice regulations, guidelines, policies and procedures; provides sound guidance to global personnel and contracted service providers, both verbally and in writing.
- Provides regulatory / compliance guidance and interpretation as a representative of Compliance & Safety Intelligence in internal and external meetings both locally and internationally.
- Develops and implements medical training programs; provides training to Global Pharmacovigilance staff and international affiliates as needed.
- Monitors clinical trial safety data and alerts the clinical teams to study related compliance issues.
- Manages negotiation and composition of Safety Data exchange agreements between Pharmacovigilance and license partners and / or division partners.
- Manages scheduling and submission compliance for aggregate reporting to

Health Authorities.

- Manages E2B submission compliance for affiliates under EMEA jurisdiction.

Medical Safety Associate, Drug Safety Quality, Training & Compliance

10/2006 – 12/2007 *XXXX Company Name XXXX*
Parsippany, NJ

- Manages international affiliate sites to ensure compliance with local and international Health Authority regulations for adverse event submissions.
- Developed and implemented a global process for investigation of root causes and monitoring of corrective actions for late adverse event submissions to Health Authorities.
- Increased submission compliance by double digits.
- Developed and implemented metrics to demonstrate compliance with local and international Health Authority regulations.
- Compiles and analyzes global submission data to publish Monthly and Quarterly Global Drug Safety Compliance reports.
- Participates in international committee meetings. Identifies compliance risks and assists with composition of pharmacovigilance agreements in response.
- Implemented improvements to the triage assessment process in response to assessment trends identified through compliance metrics.
- Participated in a recent MHRA audit and assisted in preparation of the SPS and the response.
- Manages corrective action plans (CAP) for internal and external audits and ensures closure within established time lines.

Specialist, Drug Safety

5/2006 - 10/2006 *XXXX Company Name XXXX, Branchburg, NJ*

- Contractor Drug Safety Specialist (Smith Hanley) for a mid-sized biotechnology company.
- Performed assessment of adverse event reports from assigned international IND studies.
- Performed data entry and coding using MedDRA and WHO conventions.
- Composed "Dear Doctor" letters to notify clinical personnel of expedited reports.
- Composed narrative summaries for expedited submissions to FDA.

Specialist, Medical and Product Services

2/2004 - 5/2006 *XXXX Company Name XXXX., Montville, NJ*

- Senior Medical and Product Services Specialist for mid-sized pharmaceutical company.
- Supervised 4 RNs and 2 PharmD Fellows responsible for intake and processing of spontaneous adverse events for the female health care, dermatology, imaging and specialized therapeutics product lines in a call center environment.
- Participated in hiring and performance evaluation of call center staff.
- Participated in creation of training presentations for Sales Force regarding medical inquiry, adverse event gathering and product complaint processes for the female health care, dermatology, imaging and specialized therapeutics product lines.
- Performed telephonic intake and processing of product inquires and adverse events for the female health care, dermatology, imaging and specialized therapeutics product lines.
- Performed quality assurance audits to ensure accurate responses to

consumer inquiries about the products within scope of the published prescribing information.

- Composed medical content letters for standardized responses to health care provider inquiries about female health care, dermatology, imaging and specialized therapeutics product lines.
- Performed data testing and validation of customer management database (Siebel) in a company-wide implementation project.
- Composed training program documents for new users of the customer management database (Siebel, Documentum, and Gx Pharma).

Coordinator, Product Quality Complaints

11/2002 - 2/2004 *XXXX Company Name XXXX., Wayne, NJ*

- Contract Product Quality Complaint Coordinator (Aerotek) for mid-sized pharmaceutical company.
- Performed intake and processing of product quality complaints for the female healthcare transdermal product line.
- Corresponded with consumers and pharmacists to arrange product returns, replacements and credits.
- Corresponded with internal departments and corporate partners for investigations of quality complaints in accordance with federal regulations and cGMPs.

Director, Case Management

4/2000 - 2/2002 *XXXX Company Name XXXX, Hackensack, NJ*

- Director of Case Management for 120 bed sub-acute rehabilitation center.
- Coordinated with the Discharge Planning departments at hospitals throughout Bergen and Hudson counties.
- Managed staff of 4 RNs responsible for assessment and admission of patients from hospitals within Bergen and Hudson counties.
- Negotiated facility participating provider contracts with Workman's Compensation Insurance, and Managed Care / PPO companies.
- Negotiated rates and length of stay agreements and periodic reassessments on behalf of individuals covered under Workman's Compensation and Managed Care / PPO plans.
- Performed discharge planning, including arrangement of home care and durable medical equipment, for individuals covered under Workman's Compensation and Managed Care / PPO plans.
- Analyzed pre-admission costs in conjunction with federal guidelines for facility reimbursement under Medicare regulations.
- Composed departmental policies and procedures.

Manager, Clinical Reimbursement

4/1998 - 4/2000 *XXXX Company Name XXXX, Fairlawn, NJ*

- Clinical Reimbursement Manager for 24 bed Sub Acute rehabilitation unit.
- Negotiated facility participating provider contracts with Workman's Compensation Insurance, and Managed Care / PPO companies.
- Negotiated rates and length of stay agreements and periodic reassessments on behalf of individuals covered under Workman's Compensation and Managed Care / PPO plans.
- Performed discharge planning, including arrangement of home care and durable medical equipment, for individuals covered under Workman's Compensation and Managed Care / PPO plans.
- Analyzed pre-admission costs in conjunction with federal guidelines for facility reimbursement under Medicare regulations.
- Composed departmental policies and procedures
- Maintained facility compliance with federal regulations for Medicare/

Medicaid via electronic Minimum Data Set submissions.

Shift Supervisor, Nursing Services

2/1996 - 2/1998 *XXXX Company Name XXXX, Walpole, MA*

- Nursing Supervisor for MA correctional facility based hospital treating both maximum security and super-maximum security inmates.
- Managed staff of 6 responsible for clinical care, distribution of prescription medications, infirmary patient care, and emergency medical services.
- Chosen to transfer and assist with implementation of policies, procedures and training of transitional staff at correctional facilities in Newark and Rahway, NJ in accordance with new NJ state contract.

Education

5/2006 - 5/2009 (expected) *XXXX name of the University XXXX, Newark, NJ*

- Master's Degree
- M.S. Jurisprudence in Health, Science and Technology
- Concentration: Health Law

9/2002 - 1/2006 *XXXX Name of the University XXXX , Wayne, NJ*

- Bachelor's Degree
- Cum Laude
- Pre-Law Minor

9/1991 - 5/1993 *XXXX Name of the University XXXX, Syracuse, NY*

- Associate Degree

Certifications

Certification in Healthcare Compliance (Mar 2009)

Associations

Regulatory Affairs Professional Society (RAPS)
American Health Lawyers Association (AHLA)
Drug Information Association (DIA)
Health Care Compliance Association (HCCA)
Society of Corporate Compliance and Ethics (SCCE)