CATHY M. MCCARTHY, RN

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PROFILE

Registered Nurse with 14 years of experience in the healthcare and pharmaceutical industry; currently pursuing a Master's degree in health law. Extensive expertise in drug safety compliance with focus on EU regulations. Ability to interpret and translate legislations, communicates efficiently with legal and regulatory departments, and negotiate contracts. Proficiency in SOP and governance document writing, Part 11 compliance and validation, SPS and DDPS composition, risk assessment, gap analysis, and systems and process improvement. In-depth understanding of HIPAA, the False Claims Act, Fraud and Abuse statutes, the Foreign Corrupt Practices Act, the FDAAA, and Sarbanes-Oxley.

Certifications: Healthcare Compliance; Certified in Compliance & Ethics Professional

EDUCATION

XXXX Name of the University XXXX, Newark, NJ ~ ***M.S. Jurisprudence,*** Expected ~ May 2009
Concentration: Health and Technology Law

XXX Name of the University XXX, Wayne, NJ ~ ***Bachelor of Science***, *cum laude* ~ January 2006
Concentration: Pre-Law Minor

XXX Name of the University XXX, Syracuse, NY ~ ***Associate Degree*** ~ May 1993

EXPERIENCE

XXXX Company Name XXXX, Morristown, NJ
Consultant, XXX November 2008–Present

- Accountable for managing consumer care OTC division of top five pharmaceutical companies.
- Develop and implement pharmacovigilance system ensuring compliance with federal and international health authority regulations.
- Performed gap analysis of the existing PV system which significantly decreased penalty risks cited by health authorities.
- Prepared and implemented documents addressing identified gaps which include SOPs, work processes, and operations manuals; completed a four month project ahead of schedule.

XXXX Company Name XXXX, Parsippany, NJ
Manager, XXX December 2007–November 2008

- Planned and conducted internal inspection and audits; composed and issued audit reports; reviewed and approved corrective action plans following inspections and audits.
- Oversaw composition, review, update, and archiving of departmental and global Standard Operating Procedures.
- Interpreted Good Clinical Practice regulations, guidelines, policies, and procedures, as well as provided sound guidance to global personnel and contracted service providers, both verbally and in writing.
- Offered regulatory and compliance guidance as a representative of Compliance and Safety Intelligence during internal and external meetings both in U.S. and internationally.
- Developed and implemented medical training programs by providing training to Global Pharmacovigilance staff and international affiliates, as required.
- Negotiated and composed safety data exchange agreements between Pharmacovigilance and license partners.
- Managed scheduling and compliance for aggregate reporting to health authorities along with E2B submission compliance for affiliates under EMEA jurisdiction.

Medical Safety Associate, Drug Safety Quality, Training & Compliance October 2006–December 2007

- Managed more than 70 international affiliate sites, ensuring compliance with local and international health authority regulations for adverse event submissions.
- Developed and implemented a global process for investigating root causes and monitoring of corrective actions for late adverse event submissions to health authorities.
- Executed metrics to demonstrate compliance with local and international health authority regulations, as well as increased submission compliance by double digits.
- Compiled and analyzed global submission data to publish monthly and quarterly drug safety compliance reports.
- Identified compliance risks and assisted with composition of pharmacovigilance agreements in response.
- Managed corrective action plans for internal and external audits ensuring closure within established time lines; participated in a MHRA audit and assisted in preparation of the SPS and the response.
- Worked as a member of a global efficiency improvement team and increased efficiency in the department, translating to a cost reduction per case.

EXPERIENCE (CONT'D)

XXXX Company Name XXXX, Branchburg, NJ
Specialist, Drug Safety May–October 2006

- Performed assessment of adverse event reports from assigned international IND studies along with data entry and codes using MedDRA and WHO conventions.
- Composed "Dear Doctor" letters to notify clinical personnel of expedited reports and narrative summaries for expediting FDA submissions.
- Eliminated backlog of adverse events from clinical trials by reducing the excess load prior to the scheduled contract.

XXXX Company Name XXXX, Montville, NJ
Specialist, Medical and Product Services February 2004–May 2006

- Carried out 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.
- Interfaced with internal departments and corporate partners to investigate quality complaints in accordance with federal regulations and cGMPs.
- Supervised four RNs and two PharmD Fellows responsible for the processing of spontaneous adverse events for the female health care, dermatology, imaging, and specialized therapeutics product lines in a call center environment.
- Conducted training for the sales force regarding medical inquiry, adverse event gathering, and product complaint processes for the female healthcare, dermatology, imaging and specialized therapeutics product lines.
- Performed telephonic intake and processing of product inquires and adverse events for the female healthcare, dermatology, imaging and specialized therapeutics product lines.
- Composed medical content letters to gain standardized responses to health care provider inquiries about female healthcare, dermatology, imaging, and specialized therapeutics product lines.
- Composed training program documents for new users of the customer management database, including Siebel, Documentum, and Gx Pharma, as well as executed data testing and validation of customer management database.

XXXX Company Name XXXX, Wayne, NJ
Coordinator, Product Quality Complaints November 2002–February 2004

- 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, as well as internal departments and corporate partners investigating quality complaints in accordance to federal regulations and cGMPs.

XXXX Company Name XXXX, Hackensack, NJ
Director, Case Management April 2000–February 2002

- Coordinated with the discharge planning departments at the hospitals throughout Bergen and Hudson counties.
- Managed staff of four RNs accountable for conducting assessment and admission of patients from hospitals within Bergen and Hudson counties.
- Negotiated facility participating provider contracts with Workman's Compensation Insurance along with managing Care and PPO companies.
- Conducted settlements of rates and length of stay agreements and periodic reassessments on behalf of individuals covered under Workman's Compensation, Managed Care, and PPO plans.
- Performed discharge planning, including arrangement of home care and durable medical equipment for individuals covered under Workman's Compensation, Managed Care, and PPO plans.
- Analyzed pre-admission costs in conjunction with federal guidelines for facility reimbursement under Medicare regulations, as well as composed departmental policies and procedures.

XXXX Company Name XXXX, Fairlawn, NJ
Manager, Clinical Reimbursement April 1998–April 2000

- Negotiated rates, length of stay agreements, and periodic reassessments on behalf of individuals covered under Workman's Compensation, Managed Care, and PPO plans.
- Maintained facility compliance with federal regulations for Medicare and Medicaid via electronic minimum data set submissions.

PROFESSIONAL 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)