Sharon Bianco

Product Analyst II - Post Market Surveillance

Arlington, MA
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Industry professional with a strong scientific and analytical background. Experience includes the medical device, pharmaceutical and biotech industries. Skills involve creating, writing and editing narratives, standard operating procedures, training manuals and regulatory documents. Additional skills include medical adverse event writing within the healthcare sector. Strong ability to effectively convey technical information to a general reader and to the industry professional.

WORK EXPERIENCE

Regulatory Affairs Associate

Beaver-Visitec International, Inc. - Waltham, MA - June 2014 to Present

Responsibilities
Completing International regulatory registrations in markets including the United Kingdom, Latin America, Asia Pacific and the European Union.

Product Analyst II - Post Market Surveillance

Boston Scientific Corporation - Marlborough, MA - August 2009 to May 2013

Analyzyed information related to surgery outcomes in support of the HydroThermAblation (HTA) women's health device. Determined the reportability status of adverse events to the Food and Drug Administration (FDA) to regulate patient safety.

• Technical writing of Medical Device Reports (MDR's) to the FDA, related to adverse events during surgeries.
• Completed supplemental MedWatch technical reports to the FDA through the Trackwise, GCS2 database.
• Through direct contact with physicians and other health professionals, obtained post-surgical information related to patient safety.
• Technical writing of a high volume of Medical Device Reports in support of the Mesh Sling class action lawsuit.
• Collaborated with Medical Safety, Research and Development (R&D), Marketing and Quality Engineering and served as the Subject Matter Expert during group meetings.

Regulatory Associate

Vertex Pharmaceuticals - Cambridge, MA - December 2007 to January 2009

Tracked, audited and archived clinical documentation. Collaborated with groups in commercial development, drug development and discovery. Assisted with the transition of legacy clinical documentation into the OmniRim database.

Regulatory Documentation Coordinator

Wyeth - Cambridge, MA - November 2005 to September 2006

Performed audit of documents in support of the clinical study for Mylotarg (a drug used in the treatment of lymphoma) and other investigative oncology drugs.

• Review and tracked of investigative site, protocol, and drug level documentation.
• Provided documentation to the Clinical Study Team to assist in the collection of clinical data from the investigative sites.

Regulatory Affairs Specialist

Cytyc Corporation - Marlborough, MA - April 2004 to June 2005

Collaborated with marketing to obtain approval for medical devices worldwide.
• Obtained marketing approval for the ThinPrep® Imaging System in South Korea - class III medical device.
• Obtained marketing approval for the ThinPrep® 2000 System in Canada- class II medical device application.
• Served as regulatory support for the company's women's health products used in the detection and treatment of oncology and related diseases.
• Provided International technical product information to government health administrations in areas such as Australia, Canada, Latin America, and Asia Pacific. The information was provided to obtain approval to market medical devices in these countries.
• Served as the Regulatory Affairs representative to various group projects to ensure compliance with FDA standards.

Regulatory Affairs Associate I

Genzyme Corporation - Cambridge, MA - January 2003 to April 2004

Wrote design dossiers for class III medical devices: Synvisc, Hylaform, Sepragel Sinus, and Hylashield. Submitted the design dossiers to the European Union (EU) Notified Body and received CE Mark approval Certification for all four products.
• Wrote and designed a Standard Operating Procedure (SOP) on how to create a technical file and/or design dossier. The SOP was implemented as a department-wide template for future SOP's related to technical files and design dossiers.
• Wrote and submitted the Annual Report to the United States Food and Drug Administration for Synvisc.
• Worked with the marketing, legal, medical, and regulatory groups to review U.S. advertisement and promotional materials for Synvisc. Responsible for directing the regulatory aspects of the advertisements to ensure accuracy, consistency and compliance.
• Obtained International product registrations in markets including Latin America, Australia (TGA), Canada (Health Canada) and Asia Pacific. Provided technical product information to various government health administrations in support of product registration approval.

Medical Information Coordinator

Genzyme Corporation - Cambridge, MA - February 2001 to January 2003

Provided product information (via telephone) to health care providers and patients.
• Collected data on adverse events and product malfunctions related to pharmaceuticals and therapeutics.
• Wrote a training manual for the medical literature database.
• Designed the data format for an electronic library database.

Quality Control Analyst I

Wyeth - Andover, MA - February 1997 to September 2000

Performed various quality control tests including stability testing, ELISA assays, and Gas Chromatography.

EDUCATION

Bachelor of Arts in Chemistry

University Of North Carolina At Wilmington - Wilmington, NC