

## Professional Experience

In the area of diagnostic imaging for the following modalities: X-ray including computed tomography, magnetic resonance imaging, ultrasound, and radiopharmaceutical imaging. Responsibilities assumed (chronologically):

### Drug Safety Scientist, Pharmacovigilance.

#### April 2007

##### Database reconciliation

Reconciliation of adverse event data in the Pharmacovigilance DB with safety information from subsidiaries in the Americas and product complaint information in Quality Assurance.

#### March 2007

##### Pharmacovigilance System Administration

Approval, implementation, and documentation of case deletions and data change requests in ARISg.

#### July 2006

##### FDA Inspection of Pharmacovigilance

Interviewed with FDA inspector providing explanation of Pharmacovigilance system and controls. Received award in recognition of outstanding performance and exemplifying company values.

#### March 2003

##### Case quality and compliance review

Reviewing AERs and SAEs for accuracy and compliance with data entry conventions and SOPs.

#### June 2002

##### Expedited Reporting Compliance

Analyzing latency of serious reports to global health authorities and subsidiaries; ensuring compliance with SOPs and health authority reporting requirements.

#### March 2002

##### Serious Adverse Events (SAEs)

Request case report forms (CRFs) from investigational site or CRA. Review CRFs for completeness and accuracy and request corrections. Enter SAE data in ARISg data base. Maintain detailed documentation of communications.

#### January 2002

##### Periodic Safety Update Reports (PSUR)

Writing presentation of data on individual case histories, safety studies, overall safety evaluation, and conclusion and generating summary and cumulative tabulation of reactions, and line listings.

##### MedDRA

Coding reaction and medical history terms to MedDRA.

### Professional Services Associate, Medical Affairs.

#### February 2001

##### ARISg (Global Adverse Reaction Information System)

Case processing, periodic safety report generation, and querying of SAEs (Clinical) and spontaneous AEs.

##### Narrative writing

Writing narratives for spontaneous and clinical trial adverse event reports, including medical histories, concomitant medications, laboratory test results, treatment, and chronological event descriptions.

##### Labeling assessment

Determining if the reported reactions are expected as described in the product's prescribing information.

##### Annual reports to FDA

Preparing published literature for Drug Regulatory Affairs. Clinical and non-clinical published literature searches and making initial decision for inclusion or exclusion of the literature in the Annual report. Designed database to help associates track results (abstracts) of literature searches.

**System validation and user testing**

Review and execution of test scripts for operational qualification (OQ) and performance verification (PQ) of ARISg and Impromptu applications.

**Product Complaints**

Collect, assess, and request investigation of complaint from QA at manufacturing site. Prepare letter to customer with QA's findings in response to the complaint.

**Product Information**

Provide technical, prescribing, and safety information for x-ray and nuclear imaging products and oncology devices, both on and off label, to doctors, nurses, technologist, and physicists.

**Professional History**

January 2002 – Present	GE Healthcare Drug Safety Scientist, Pharmacovigilance.
February 2001 – January 2002	Amersham Health Professional Services Associate, Medical Affairs. (Drug Safety, Product Complaints, and Product Information)
March 1999 – February 2001	Amersham Health Nuclear Medicine Logistics Analyst.

**Education**

BS Business/E-Business - University of Phoenix Online.

This program combines business and information technology to address the emerging field of e-Business. The program courses provide fundamental knowledge and application in both business and information technology.