Dr Robert D'Ambrosio

+1 224-515-0900 pharmdoc77@aol.com NJ

-Physician (BC/BE) with Critical Care and Emergency Medicine Experience and 25+ years experience in the pharmaceutical industry

WORK EXPERIENCE

ICSR Medical Reviewer, Moderna

October 2023 - May 2024

• Provided medical review of clinical trial and post-marketing individual case safety reports (ICSRs) for Moderna vaccine products utilizing mRNA technology

• Executed medical review of clinical study SAEs for clinical content and case coding in MedDRA

• Executive medical triage for appropriate causality assessment and determination of expectedness on ICSRs for regulatory reporting

• Executed ICSR case escalation to GST/Therapeutic Area Safety based on medical judgement

• Acted as a significant point of contact between GSO and GST/Therapeutic Area Safety Teams on medical content and regulatory reporting of ICSRs

ICSR Medical Reviewer, Gilead Sciences

August 2016 - July 2023

• Provided medical review of clinical trial and post-marketing individual case safety reports (ICSRs) for Gilead products assigned to the Hepatitis C, HIV, and Oncology Therapeutic areas

• Executed medical review of clinical study and post-marketing SAEs for clinical content and case coding in MedDRA

• Executed medical triage for appropriate causality assessment and determination of expectedness on ICSRs for regulatory reporting

• Executed ICSR case escalation to GST/Therapeutic Area Safety based on medical judgement

• Acted as a significant point of contact between GSO and GST/Therapeutic Area Safety Teams on medical content and regulatory reporting of ICSRs

ICSR Medical Reviewer, Stemline Therapeutics Inc

January 2019 - June 2023

• Provided medical review of clinical trial and post-marketing individual case safety reports (ICSRs) for Stemline products assigned to the Oncology Therapeutic area

• Executed medical review of clinical study and post-marketing SAEs for clinical content and case coding in MedDRA

• Executed medical triage for appropriate causality assessment and determination of expectedness on ICSRs for regulatory reporting

• Executed ICSR case escalation to Therapeutic Area Safety based on medical judgement

• Acted as a significant point of contact between Stemline Therapeutic Area Safety Teams on medical content and regulatory reporting of ICSRs

ICSR Medical Reviewer, TesaroBio Inc.

June 2017 - September 2018

• Provided medical review of individual case safety reports (ICSRs) for specific Tesaro pharmaceutical products in Argus database

• Executed medical review of clinical study and post-marketing SAEs for clinical content and case coding in MedDRA

• Executed medical triage for appropriate causality assessment and determination of expectedness on ICSRs for regulatory reporting

• Executed ICSR case escalation to Therapeutic Area Safety based on medical judgement

• Acted as a significant point of contact between Tesaro Therapeutic Area Safety Teams on medical content and regulatory reporting of ICSRs

ICSR Medical Reviewer, Allergan, plc

July 2015 - March 2017

• Provided medical review of individual case safety reports (ICSRs) for specific Allergan pharmaceutical products in ARISg and Argus databases and performed PADER Review for Allergan products assigned to the Psychiatric, Women's Health, and Anti-

infective Therapeutic areas

Medical Monitor / Medical Affairs – Consultant, Theorem Clinical Research

November 2014 - July 2015

• Provided medical review of individual case safety reports (ICSRs) for HeartWare Left Ventricular Assist Device

• Executed medical review of clinical study and post-marketing SAEs for clinical content and case coding in MedDRA

• Executed medical triage for appropriate causality assessment and determination of expectedness on ICSRs for regulatory reporting

• Executed ICSR case escalation to Therapeutic Area Safety based on medical judgement

• Acted as a significant point of contact between Theorem Therapeutic Area Safety Teams on medical content and regulatory reporting of ICSRs

Drug Safety Physician Consultant, Hospira Inc.

June 2014 - September 2014

• Provided review of individual case safety reports (ICSRs) for specific Hospira pharmaceutical products with the goal of safety signal detection for specified events of interest under the umbrella of a planned regulatory response

Medical Safety Review Physician – Medical Assessment Safety Team (MAST), Amgen Inc.

July 2009 - January 2014

• Provided medical review of clinical trial and post-marketing individual case safety reports (ICSRs) for Amgen products assigned to the Hematology-Oncology, Inflammation, Bone, Cardio-Renal, and General Medical Therapeutic areas

• Executed medical review of clinical study and post-marketing SAEs for clinical content and case coding in MedDRA

• Executed medical triage for appropriate causality assessment and determination of expectedness on ICSRs for regulatory reporting

• Executed ICSR case escalation to GST/Therapeutic Area Safety based on medical judgement

• Supported creation of follow-up queries per due diligence measures

Senior Medical Director, Clinical Safety and Evaluation, Abbott Laboratories

January 2008 - June 2009

• Lead Medical Reviewer for all Clinical Trial Safety individual case safety reports (ICSRs) for all Abbott products undergoing Clinical Trial Evaluation encompassing Rheumatology, CNS, Cardiovascular, Metabolic, Gastrointestinal, Infectious Disease, and Pulmonary Therapeutic areas

Medical Director, Post Marketing Safety and Surveillance, Abbott Laboratories

September 2006 - December 2007

• Lead Medical Reviewer for Post-Marketing individual case safety reports (ICSRs) in Rheumatology, Cardiovascular, and Metabolic Therapeutic areas

• PSURs – Wrote safety section, including benefit-risk assessment, aggregate event analyses, and provided general PSUR support

Medical Director, Clinical Drug Safety and Pharmacovigilance, NPS Pharmaceuticals

January 2005 - December 2006

• Worked closely with the Vice President and Sr. Director, CDS & PVG, on the creation and sound functioning of the CDS & PVG department as needs of NPS continued to grow and expand

• Led medical review of all serious adverse events which occurred in NPS products in clinical trials, and serious events associated with marketed NPS products post-approval

Global Safety Officer, Amersham Health - GE Healthcare Technologies

January 2002 - December 2005

• Responsible for ensuring that established global policies and procedures were followed in order for the Clinical Safety Department to meet its safety-related obligations to the clinical teams within the Clinical Research Department

• Responsible for all safety aspects of Phase I – III clinical studies (Oncology, CNS, GI, CV, and Pulmonary diagnostic agents)

Director - Sub investigator, Wyeth Research - Clinical Pharmacology Unit

January 1996 - December 2002

• Functioned as Physician/Medical Monitor for 20+ clinical studies performed at the Wyeth Clinical Pharmacology Unit across a wide range of therapeutic areas

EDUCATION

University of New England College of Osteopathic Medicine

1986-1990

Doctor of Osteopathic Medicine - DO, Osteopathic Medicine

Drexel University

1981-1985

Master of Science - MS, Biology

Saint Joseph's University

1977-1981

Bachelor of Science - BS, Biology

SKILLS

-ICSR Medical Review across clinical trial and post-marketing cases

-Extensive experience with the Argus Database platform

CERTIFICATION AND LICENSES

NJ Medical License Active 2023-2025

Board Certified Family Practice 1998-2006

1998