ROBERT P. D'AMBROSIO, MS, DO

Mobile 224-515-0900

PROFESSIONAL SUMMARY

Physician (BC/BE) with Critical Care and Emergency Medicine experience and 25+ years in Pharmaceutical Industry, with the last 15 years specializing in Individual Case Safety Report (ICSR) review

PROFESSIONAL EXPERIENCE

Safety Physician
Medical Review Consultant **Nov 2024 – Present**
Ivigee Pharmacovigilance Solutions

- Medical review of pharmacovigilance documents prepared by PV associate as per applicable procedures
- Comprehensive medical review of narratives, CIOMS/MedWatch reports, and MedDRA coding in safety databases
- Assessment of expectedness, seriousness, and causality of ICSRs, ensuring alignment with safety standards

ICSR Medical Reviewer **Oct 2023 – May 2024**
Moderna

- Provides medical review of clinical trial and post-marketing individual case safety reports (ICSRs) for Moderna vaccine products utilizing mRNA technology
- Execute medical review of clinical study SAEs for clinical content and case coding in MedDRA
- Execute medical triage for appropriate causality assessment and determination of expectedness on ICSRs for regulatory reporting
- Execute ICSR case escalation to GST/Therapeutic Area Safety based on medical judgment
- Act 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 **Aug 2016 – Jul 2023**
Gilead Sciences

- Provides medical review of clinical trial and post-marketing individual case safety reports (ICSRs) for Gilead products assigned to the Hepatitis C, HIV, Oncology Therapeutic areas
- Execute medical review of clinical study and post-marketing SAEs for clinical content and case coding in MedDRA
- Execute medical triage for appropriate causality assessment and determination of expectedness on ICSRs for regulatory reporting
- Execute ICSR case escalation to GST/Therapeutic Area Safety based on medical judgment
- Act 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 **Jan 2019 – Jun 2023**
Stemline Therapeutics Inc.

- Provides medical review of clinical trial and post-marketing individual case safety reports (ICSRs) for Stemline products assigned to the Oncology Therapeutic area
- Execute medical review of clinical study and post-marketing SAEs for clinical content and case coding in MedDRA
- Execute medical triage for appropriate causality assessment and determination of expectedness on ICSRs for regulatory reporting
- Execute ICSR case escalation to Therapeutic Area Safety based on medical judgment
- Act as a significant point of contact between Stemline Therapeutics Area Safety Teams on medical content and regulatory reporting of ICSRs

ICSR Medical Reviewer **Jun 2017 – Sep 2018**
TesaroBio Inc.

- Provide medical review of individual case safety reports (ICSRs) for specific Tesaro pharmaceutical products in Argus database
- Execute medical review of clinical study and post-marketing SAEs for clinical content and case coding in MedDRA
- Execute medical triage for appropriate causality assessment and determination of expectedness on ICSRs for regulatory reporting
- Execute ICSR case escalation to Therapeutic Area Safety based on medical judgment
- Act as a significant point of contact between TesaroBio Area Safety Teams on medical content and regulatory reporting of ICSRs

ICSR Medical Reviewer **Jul 2015 – Mar 2017**
Allergan, plc

- Provide medical review of individual case safety reports (ICSRs) for specific Allergan pharmaceutical products in ARISg and Argus databases, perform PADER Review for Allergan products assigned to the Psychiatric, Women's health, Anti-infective Therapeutic areas

Medical Monitor / Medical Affairs – Consultant **Nov 2014 – Jul 2015**
Theorem Clinical Research

- Provide medical review of individual case safety reports (ICSRs) for HeartWare Left Ventricular Assist Device
- Execute medical review of clinical study and post-marketing SAEs for clinical content and case coding in MedDRA
- Execute medical triage for appropriate causality assessment and determination of expectedness on ICSRs for regulatory reporting
- Execute ICSR case escalation to Therapeutic Area Safety based on medical judgment

Drug Safety Physician Consultant **Jun 2014 – Sep 2014**
Hospira Inc.

- Provide 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) **Jul 2009 – Jan 2014**
Amgen Inc.

- Provides 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
- Execute medical review of clinical study and post-marketing SAEs for clinical content and case coding in MedDRA
- Execute medical triage for appropriate causality assessment and determination of expectedness on ICSRs for regulatory reporting
- Execute ICSR case escalation to GST/Therapeutic Area Safety based on medical judgment
- Support creation of follow up queries per due diligence measures

Senior Medical Director, Clinical Safety and Evaluation **Jan 2008 – Jun 2009**
Abbott Laboratories

- 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 **Sep 2006 – Dec 2007**
Abbott Laboratories

- Lead Medical Reviewer for Post Marketing individual case safety reports (ICSRs) in Rheumatology, Cardiovascular and Metabolic Therapeutic Areas
- PSURs – Write safety section, including benefit-risk assessment, aggregate event analyses and provide general PSUR support

Medical Director, Clinical Drug Safety and Pharmacovigilance **Jan 2005 – Dec 2006**
NPS Pharmaceuticals

- Works closely with the Vice President and Sr. Director, CDS & PVG in the creation and sound functioning of the CDS & PVG department as needs of NPS continue to grow and expand
- Lead medical review of all serious adverse events that occur in NPS products in clinical trials, and also serious events associated with marketed NPS products post-approval

Global Safety Officer **Jan 2002 – Dec 2005**
Amersham Health – GE Healthcare Technologies

- Responsible for ensuring that established global policies and procedures are followed for 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 **Jan 1996 – Dec 2002**
Wyeth Research, Clinical Pharmacology Unit **Philadelphia, Pennsylvania**

- Functioned as Physician/Medical monitor for 20+ clinical studies performed at the Wyeth Clinical Pharmacology Unit
- Involvement in a wide range of therapeutic areas

EDUCATION

- St. Joseph's University
  B.S., Biology, 1981
- Drexel University
  M.S., Biology, 1985
- University of New England College of Osteopathic Medicine
  DO, Doctor of Osteopathic Medicine, 1990

CERTIFICATES

- Board Certified Family Practice, 1998–2006

SKILLS

- ICSR Medical Review across Clinical trial and Post-marketing cases
- Experience in multiple therapeutic areas including Oncology, Hematology, Infectious Diseases, Renal, Bone
- Extensive experience with Argus Database Platform