

Associate Director, Benefit-Risk Management. Quintiles Lifecycle Safety dept.

REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

- Extensive experience in preparing end-to-end PBRERs and EU-RMPs including benefit-risk evaluations
- Signal detection and management experience is highly desirable
- Experience with labelling reviews and updates is also welcomed. Ability to strategically identify and implement optimal risk management solutions.
- Good knowledge of current guidelines with respect to risk management during drug development and post-marketing.
- Thorough knowledge of global risk management requirements with an emphasis on US and EU regulations and developing trends.
- Good understanding of peri- and post-approval risk management needs.
- Good overview knowledge of many of the new and cutting-edge design and analytical approaches that can beneficially be applied to all phases of clinical trials and risk management strategies.
- Ability to quickly learn risk management and signal detection electronic tools.
- Excellent written and oral communication skills
- Strong negotiating skills
- Ability to operate simultaneously across numerous projects
- Ability to establish and maintain effective working relationships with coworkers, managers and clients

MINIMUM REQUIRED EDUCATION AND EXPERIENCE

Bachelor's degree in Epidemiology, Biostatistics or other related scientific discipline with 10 years' experience in pharmacovigilance or pharmacoepidemiology in a consulting, industry, or Federal setting or MSc in Epidemiology or closely-related discipline with 3 yrs' CRO/consulting, pharmaceutical, risk management and registry experience.; or equivalent combination of education, training and experience

PHYSICAL REQUIREMENTS

- Extensive use of keyboard requiring repetitive motion of fingers.
- Extensive use of telephone and face-to-face communication requiring accurate perception of speech.
- Regular sitting for extended periods of time.
- Some travel within the US, EU, and other global regions.

**Interested applicants can contact Deirdre McCarthy at
Deirdre.mccarthy@quintiles.com**