Case Evaluator

Kontakt:

Andrea Nagy
Senior Sourcer
Email: andrea.nagy@cpl.com
Mobil: +36 70 477 1103
Web: https://www.cpl.com/hu

Case Evaluator

Your responsibilities will be:

- Utilize clinical information in safety database to provide company causality assessment and comment.
- Confirm determination of seriousness, assess drug product causal association, and assign global labeling status (expected or unexpected) to achieve the appropriate case reporting status for global distribution for regulatory agency reporting.
- Evaluate and assess complex reports from clinical development projects as well as post-marketing cases.
- Review case reports for medical accuracy, including validation of adverse event listedness and coding consistency.
- Request follow-up information for robust case causality assessment.
- Adhere to global and local procedural documents.

Your skills and qualifications:

- A Medical or Physician Degree.
- Good knowledge of US and EU pharmacovigilance regulatory requirements.
- Experience in pharmacovigilance practices concerning signal detection and evaluation is an advantage.
- Knowledge of drug safety and clinical development and ICH/GCP principles.
- The ability to evaluate, interpret and synthesize scientific data.
- The ability to present and critically discuss clinical data in both internal and external discussions.
- User-level IT skills.

Some of the benefits you will enjoy:

- Hybrid working environment (3-day Home Office)
- We provide a wide range of benefits, including a market-leading **comprehensive private health care package.**
- We offer extensive s**elf-development opportunities**: our colleagues have many training possibilities for personal and professional growth.
- There are both vertical and horizontal **career options** for those who like to challenge themselves and try out different areas and positions.

- You will be part of a **global and diverse working environment** with relaxation areas, terraces, and a friendly atmosphere.
- You can **seize the day** with us at our company events, hobby clubs, and sporting initiatives.