

For the safe and optimal use of human proteins



We are an expanding independent, global plasma fractionation specialist and are seeking the following position for the International Clinical R&D Department located in Vienna, Austria:

Medical Writer (f/m)

Responsibilities:

- Preparation of clinical study reports (phase II – IV), Investigator Brochures, regulatory submissions (CTD format), responses to health authorities and manuscripts for publication
- Development and updating of templates for clinical documents in agreement with ICH and electronic submission guidelines
- Assistance in preparation and review of clinical study protocols and statistical analysis plans
- Management of document review and QC process
- Management of outsourcing of medical writing projects
- Review of work of other writers (in-house or contract) for accuracy, quality and adherence to format and style requirements

Requirements:

- University degree in medicine, natural sciences or pharmacy
- 5+ years working experience in the pharmaceutical industry or in a CRO, including 3+ years writing experience
- Ability to evaluate and interpret medical research data
- Knowledge of drug development process
- Knowledge of CFR, ICH and e-CTD guidelines
- Ability to perform several tasks simultaneously without losing sight of overall objectives.
- Advanced word-processing
- Excellent command of written English and a good knowledge of statistics

If you feel qualified please send your application including a CV with a detailed description of your relevant experience:

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