Medical writing

Expert reports and documentation

We prepare clinical, pharmacological and toxicological expert reports for marketing authorisation dossiers and borderline projects. Diapharm's medical writing is perfectly tailored to regulatory and clinical processes. We design the preclinical and clinical development of your products and analyse the gaps.

Further information:
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Our services include:

- Evaluation of existing documents and literature research
- Medical statements
- Documents for clinical trials
  (such as IMPD, investigator's brochures and final reports)
- Preclinical and clinical expert reports,
  CTD modules 2.4 to 2.7
- Support with deficiency letters
- Summary of product characteristics (SmPC)
- Patient information leaflet (PIL)

We prepare required expert reports (CTD modules 2.4 to 2.7) for your marketing authorisation dossier on the basis of the data provided.

We can evaluate how well suited existing dossiers are for the marketing authorisation process and for special instances, such as well-established use (WEU) authorisation.

We also can provide thorough literature research for our clients and process scientific findings to enable their use in dossiers.

Get in touch with us!

Your benefits:

- **Sound documentation of clinical projects**
- **Compilation of all relevant medical and scientific information**
- **Medical writing for regulatory and clinical requirements**

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