

Medical Writing Services

PAREXEL Medical Writing Services provide a range of high-quality documents for all phases of product life cycles, from pre-clinical development to post-marketing literature.



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PAREXEL has supported nearly all of the top fifty drugs on the market

PAREXEL Medical Writing Services

From Pre-clinical Development to Post-marketing Literature



PAREXEL Medical Writing Services provide a range of high-quality documents for all phases of product life cycles, from pre-clinical development to post-marketing literature. Our worldwide team of accomplished writers is highly qualified, many at the doctorate level, with a background in the biological sciences, and is able to cover a broad range of therapeutic areas. With an extensive pool of dedicated, experienced writers, we are able to meet your medical writing needs, whether large or small. In contrast to freelance writers, multiple resources can be provided to enable the completion of a series of documents within a short time frame. There are over 30 writers distributed throughout Europe and the United States.

PAREXEL medical writers prepare documents according to client specified formats, styles and word-processing environments. Alternatively, if needed, PAREXEL has its own default standard document formats and styles which have been developed to ensure consistency with ICH and the appropriate regulatory guidelines.

PAREXEL Medical Writing Services are available for both stand-alone medical writing projects and as part of comprehensive clinical trials management programs. We can also train your staff in-house on all aspects of medical writing.

Our breadth of services includes:

- Clinical study reports, phase I – IV
- Preclinical study reports
- Clinical study protocols
- Investigator brochures
- Patient narratives
- Clinical and preclinical CTD sections
- Clinical sections of IND, NDA
- Annual safety reports (e.g., per EU Clinical Trials Directive)
- Periodic safety update reports
- Medical and scientific literature reviews
- Abstracts and manuscripts

All PAREXEL Medical Writing staff participate in regular training either led by senior staff or through courses offered by the American and European Medical Writers Associations. This ensures the entire team adheres to consistent internal Medical Writing processes and to quality and regulatory standards.

PAREXEL Medical Writing Services work closely with our dedicated medical communications division as an integrated team of writers with therapeutic area expertise and specialist knowledge in their writing field. This complement can assist your clinical and marketing teams to develop the complete scope of documents, reports, and internal and external communication editorials. This approach helps to optimize the product's impact on regulators and other audiences and ensures a consistent message.

accomplished

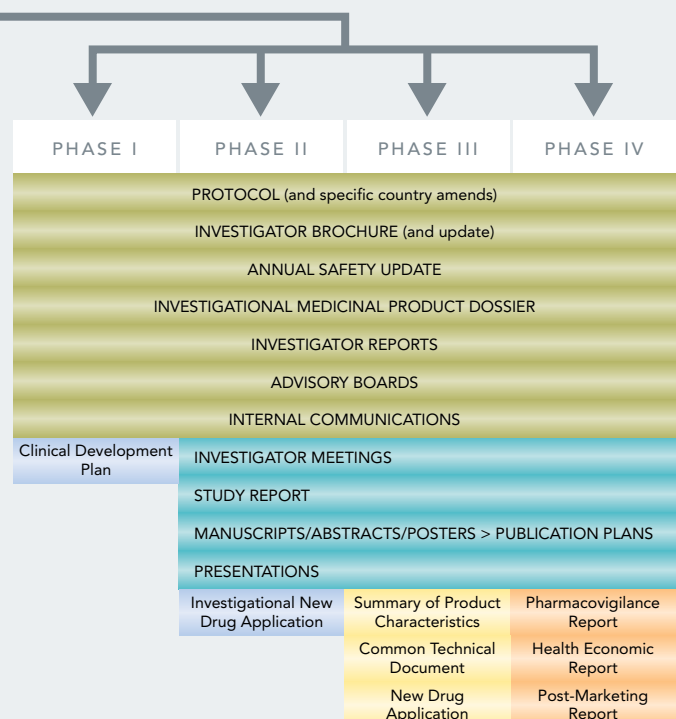
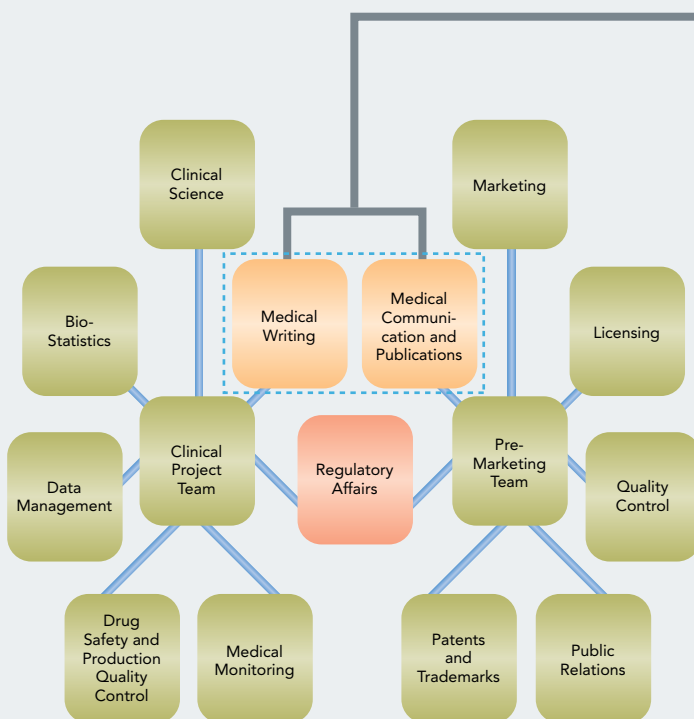
Tailor-made Training Courses

PAREXEL can provide in-house medical writing training for 2 to 20 people tailored to your individual company needs. This can cover anything from a half-day training session on patient information leaflets to 3 days training on CTD and NDA documentation. All training is provided by experienced, practising medical writers and can be arranged as straightforward lectures or to include practical exercises in a workshop style.

Courses cover all areas of medical writing, including the following:

- Structure and clinical documentation requirements for CTD/NDA
- User-friendly submissions
- Clinical Overview/Summary
- Clinical study reports to ICH guidelines
- Clinical study protocols
- Investigator brochures
- Periodic safety update reports
- Medical information: published biomedical reference tools, CD-ROMs, on-line databases and Internet sources.

Harmonizing Scientific Communications and Medical Writing



Pharmacovigilance

Although PAREXEL Medical Writing has wide expertise in a broad range of medical writing deliverables, the focus on pharmacovigilance is increasing throughout product development and marketing. Working closely with pharmacovigilance experts within PAREXEL, PAREXEL Medical Writing Services can support your team by preparing documents for all stages of the pharmacovigilance life cycle. We have the resources and expertise to meet all pharmacovigilance requirements, including preparation of periodic safety update reports in both PSUR and FDA formats, annual safety update reports, literature searching and reviews, and pharmacovigilance SOPs.

PAREXEL has developed its own narrative formats and styles consistent with ICH E3 requirements. PAREXEL medical writers also prepare narratives according to client specified styles and word-processing environments.

Periodic Safety Update Reports

PAREXEL has developed systems to streamline the process of PSUR production, including data checklists, templates and quality control procedures tailored to PSUR specifications. We use these tools, or your own company SOPs and templates, to ensure all your requirements are met. Our experience includes a series of 14 PSURs across a range of therapeutic areas, completed for a major pharmaceutical company within a 5 month period.

Annual Safety Reports

Since implementation of the EU Clinical Trial Directive 2001/20/EC in May 2004, an Annual Safety Report (ASR) must be prepared for all long-term clinical trials (longer than 6 months) conducted within the European Union. All PAREXEL writers have been fully trained in the requirements of the CT directive, and have the experience to produce ASRs of the highest quality. Our experience includes almost 30 ASRs across a range of therapeutic indications.



flexible

PAREXEL

*Expertise
that makes the Difference®*

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