INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

MEDICAL WRITING

WELL WRITTEN, STAND-ARDS-COMPLIANT DOCUMENTS FOR THE MEDICAL DEVICE INDUSTRY

Medical Writing is gaining more and more importance for the medical device industry. Combining engineering with medico-scientific knowledge is key for creation of meaningful submission documents and publications Integrated Scientific Services (ISS AG) has decades of cumulative technical and scientific experience in providing supportive services to companies. ISS can help drive the writing of scientific documents in a highly efficient manner to maintain deadlines and budget constraints.

Your benefit

ISS AG speaks the language of the medical device world. Understanding the regulatory environment, the technical documentation of devices, submission documents for notified bodies, for clinical investigations and publications takes away the burden from you. Our Services range from required engineering work documents, to fully compliant technical documentation of medical devices, but also to documents related to clinical investigations, clinical evaluation reports and scientific publications.
The proximity of our engineers and scientists to the product provides an understanding of the normative requirements before the commencement of clinical trials and according to ISO 14155.

Our services

Compilation of the submission dossier for approval of a clinical investigation
The standard ISO 14155 as well as the competent authorities and ethics committees specify the content of the dossier. The experts of ISS will assist you to strategically plan drive a clinical study, create the proper supporting documentation or critically review your documentation prior to submission.

Regulatory Medical Writing
ISS AG understands regulatory medical writing as creating the documentation that notified bodies and other regulatory bodies require in the approval process for medical devices. These documents include clinical investigation protocols, clinical investigation reports, patient informed consent forms, investigator brochures and summary documents that summarize and discuss the data a company gathers in the course of developing a medical device. ISS AG has a long track record of successful writing of clinical evaluation reports

Medical Communication
ISS AG may develop for you educational brochures, news articles, web content, books and journal articles for health care professionals. Grant proposals for research scientists and institutions can be drafted. The team of scientist and medical doctors at ISS AG have extensive publishing experience.

Some examples

– Compiling submission dossiers for clinical trials for ophthalmic devices
– Authoring patient information brochures for clinical studies
– Supporting Surgeon in writing publications after a proposal was rejected (several, publications were accepted after revision by ISS)
– Re-arrange and reprocess and re-analyze Data of a publication after it was rejected by the reviewer. Publication was accepted after revision by ISS
– Revise a scientific rational for skipping animal studies
– Etc…

Your Contact

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