Clinical Evaluation Services for Medical Devices

Your partner for literature search and clinical evaluations

YOUR CHALLENGE – OUR EXPERTISE

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SCC
WE CARE FOR YOUR SUCCESS

If you are manufacturing or supplying a medical device to be placed on the European market, you should meet the obligations set out in the Medical Devices Regulation MDR (EU) 2017/745. One of those obligations is the need for clinical evaluations (Article 61 and Annex XIV of the MDR).

CONFORMITY ASSESSMENTS

In the EU, technical documentation and clinical evaluation form the central part of any medical device conformity assessment. With the introduction of the MDR (EU) 2017/745, the rules for planning and preparing of clinical evaluations have been tightened.

To prepare a clinical evaluation in accordance with the MDR, the MEDDEV 2.7/1 guideline revision 4 and the latest guidelines relating to clinical evaluations issued by the Medical Device Coordination Group (MDCG) need to be followed.

However, due to the increasing number of guidelines, a literature search or clinical evaluation can become a complex and tough task. For that reason, it is advisable to let experienced experts carry out a clinical evaluation to ensure conformity with all requirements.

LITERATURE RESEARCH

Conducting scientific literature searches in line with the requirements of the MDR and applicable guidelines forms the basis for any clinical evaluation.

CLINICAL EVALUATION SUPPORT

The required information, including evaluations, should be provided in a targeted manner, using the "clinical evaluation assessment report template" also applied by notified bodies. If available, data of technically, biologically and clinically similar products should be considered to avoid gaps in the proof of safety and performance of your product with respect to its intended uses.

OUR SOLUTION

We provide tailor-made services, designed to meet the individual needs of our customers:

- Preparing or updating literature searches and clinical evaluation plans and reports, based on the data available for your medical device
- Providing expert support for your inhouse literature search and clinical evaluation process
- Supporting you in processing deviations identified by your notified body

YOUR BENEFITS

- We ensure your clinical evaluation is carried out in accordance with the requirements of the MDR.
- We use professional databases for literature searches to avoid missing important results.
- With suitable literature evidence and the professional evaluation of all data, you can save costs by avoiding unnecessary clinical investigations or PMCF studies.
- We follow all requirements and guidelines for literature search reporting and the clinical evaluation in order to save time and speed up the conformity assessment procedure with your notified body.

Please visit our website
for more information or
contact one of our experts at
https://www.scc-gmbh.de/clinical-evaluation-meddev-2-7-1

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