Who should perform clinical evaluations?

Revised European guidance for medical devices has taken comprehensive considerations relating to risk management, post-market surveillance and has introduced many pre and post-market clinical investigation requirements.

The objective of the revised guidance is to facilitate the medical device manufacturers in the planning and the implementation of robust and systemic clinical evaluation process and the compilation of technically valid Clinical Evaluation Reports (CERs) (Vegher, 2015). The guidance also includes the necessary qualification requirements for the authors and evaluators to perform clinical evaluations.

Experts in this specialized field recognize that many medical device manufacturers receive nonconformities mainly because the concerned evaluators are not adequately qualified or their qualifications were not supported with necessary documentation.

The clause 6.4 of the revised MEDDEV 2.7.1 Rev 4 European Commission (2016) prescribes the stricter eligibility requirements for the report authors and clinical evaluators. It contains details of the essential qualifications and the supporting documentation procedures needed for the medical device companies to perform clinical evaluations.

Important Qualification requirements of a Clinical Evaluator

As per the revised guidelines, each evaluator involved in the clinical evaluation process needs to be a qualified individual with sufficient knowledge of clinical study design, biostatistics, current regulatory requirements, information technology management and medical writing skills. The evaluator team and each evaluator need to have adequate technical and functional knowledge specific to the medical device under evaluation, technological know-how and operational proficiency.

The device manufacturer needs to document all the qualifications set by the company properly, and the concerned manufacturer also needs to submit a declaration of interest for each evaluator involved in the clinical investigation (Achakri, 2017).

CER and Post market phase

In the post-market phase, clinical evaluation of the device is continued with the maintenance of surveillance programs to monitor device safety and performance. The updated CER can include adverse incident reports, results from published literature reviews on the actual device or similar products, and clinical investigations.

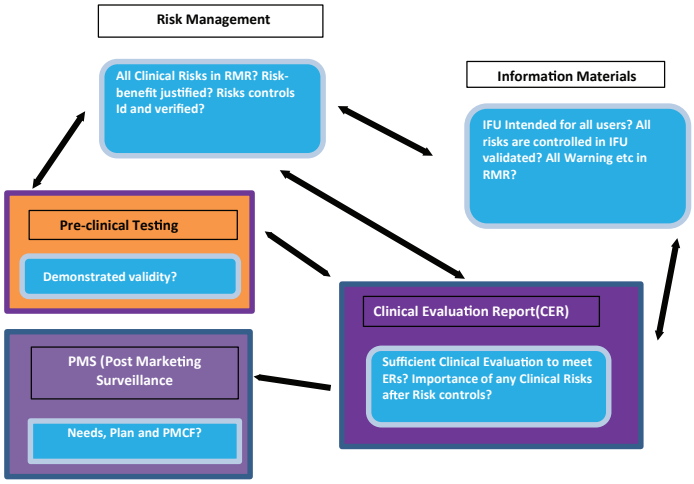
Revised European guidance requires the clinical evaluators to possess the following training and experience in their area of specialization

- A higher education degree in their respective field and five years of documented professional experience in the relevant field; or
- Ten years of documented professional experience in case if the higher education degree is not be taken into consideration for the proposed clinical evaluation of the medical device.

The manufacturer needs to take into account the following considerations to maximize the conformity to the prescribed qualification requirements of the revised European guidance related to medical devices.

- The quantity and quality of the evaluators are in line with the nature, clinical performance and the associated risks of the medical device under evaluation.
- Proper justification from the manufacturer regarding the choice of evaluators for the clinical evaluation based on the training qualifications and documented professional experience
- Declaration of interest from the evaluators needs to have sufficient clarification relating to their individual financial interests and conflict of interest in undertaking the clinical evaluation (Vegher, 2015). In circumstances where the expertise level of the evaluators may be less or vary from the prescribed guidance, the manufacturers need to be appropriately documented and have to present proper justifications for such deviations.

Clinical Evaluation for initial CE Marketing



Professional scientific service providers with a network of renowned medical specialists and biostatisticians meet the high requirements of the revised European guidance on authors and evaluators of clinical evaluation. Their experience and expertise in research techniques can be of great assistance to the medical device manufacturers in conducting a well-documented clinical evaluation and in the creation of comprehensive clinical evaluation report (Achakri, 2017).

Eliminating Clinical Evaluation Pitfalls:

"Understanding the crucial steps to preparing a successful clinical evaluation report (CER) for submission of a technical file is significant role for the clinical Evaluator for medical device CE Marking as well as its helps to eliminate the pitfalls at each stages of CER process".

Pepgra CRO assist you in Preparing Pre-Market Phase and Post Market Clinical Follow Up for Clinical Evaluation(CE)

Steeped in experience, Pepgra offers you top quality service in the preparation of CERs. As the very mission of your requirement, we extend our expertise to ensure the need and utility of the clinical trial. For this, extensive research is carried out with the addendum of referring to relevant guidelines such as the MEDDEV 2.7.1 Rev. 4.

Pepgra can thus help you achieve,

- Regulatory assistance and approval for your CER
- Preparation of clinical trial protocol and comprehensive literature search;
- CERs both for review or full products for approval
- Extensive support in regulatory affairs and approval;
- Extended service through post marketing surveillance and adding to the CER if necessary.

About Pepgra

Pepgra are aspirers of the best in quality clinical research and are collaborators for the best in kind research service. Our commitment towards providing the world with quality and safety assessed medicines, medicinal products and devices are indomitable. We aim for our insights into the field of clinical research can optimize your desire to produce quality medicine and other diagnostics. Pepgra offers customised services in the broadened arenas of research that are inclusive of clinical data services with the addendum of post-marketing surveillances.

Pepgra Healthcare Pvt. Ltd. is headquartered in Chennai, India with centres in Dallas, Texas, UK, India, China, and Malaysia and is committed to the utmost in clinical research services evidenced in being a leading CRO.

We began as medical writing service providers and have since forayed into the clinical research domain since the year 2011. Our company has not only grown over the years but has also proved its excellence in the exemplary services we have provided thus far.

References

Achakri, H. (2017). Generating clinical evaluation reports A guide to effectively analysing medical device safety and performance. Retrieved June 15, 2017, from https://www.bsig-roup.com/meddev/LocalFiles/en-US/Whitepa-pers/Generating-clinical-evaluation.pdf

European Commission. (2016). Clinical Evaluation: A Guide for Manufacturers and Notified Bodies.

Vegher, H. (2015). Clinical Evaluation Report Overview and the Literature Review Process. Retrieved from https://ww-w.sla.org/wp-content/uploads/2015/06/1547_ClinicalE-valRptsMedDevice-Vegher-Hana-Vegher.pdf

Note: All clinical data in the possession of the manufacturer will be considered for the overall analysis and preparation of any requirement put forth.

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