PCG Clinical Services QAdvis

Clinical evidence

Is your product ready to meet MDR?

Introduction

New regulations have introduced more extensive and more detailed requirements on medical devices. Medical device manufacturers are now facing even more rigid requirements on clinical evidence, and they need to provide detailed technical documentation of clinical data.

To be able to continue placing products on the market, it will be necessary to review existing clinical evaluations for all products to investigate whether sufficient clinical data is available. For new products, a clinical evaluation should be performed in an early phase of product development to identify the potential need for a clinical investigation.

When a clinical investigation is set up, proficient design, performance and documentation are of outmost importance.

This paper will provide insights in how medical device companies can prepare a strategy to fulfil the requirements on clinical data to meet the Medical Device Regulation (MDR), 2017/745.

Revised requirements

The new Medical Device Regulation, 2017/745, entered into force on 26 May 2017, and will apply from 26 May 2020. Certificates issued for medical devices according to 93/42/EEC are valid until the end of the period indicated on the certificate, but no longer than 27 May 2024.

To comply with MDR, medical device manufacturers have to update their quality management systems. Subsequently, the technical documentation of all products, irrespective of class, needs to be reviewed and updated.

Clinical evidence is one of the areas which will be subject to increasingly strict requirements. All medical devices have to be supported by clinical evidence to demonstrate that it is safe and that it is able to achieve the intended clinical benefits. The clinical evidence is analysed and summarised in the clinical evaluation report. For an increasing number of products, data from clinical investigations are needed to get sufficient clinical evidence for placing a device on the market.

A clinical evaluation is performed during the initial CE marking process, and periodically thereafter as new clinical information becomes available or changes are made to the device. The evaluation investigates whether conformity with the relevant general safety and performance requirements can be demonstrated or if additional clinical data are needed.

Previously, many clinical evaluations were based on clinical data relating to equivalent devices. MDR has clear requirements on access to data for the device considered to be equivalent, which implies that clinical data must be generated for many devices which have been referred to as equivalent.

The manufacturer has to determine if sufficient clinical evidence already exists to support CE marking, or if additional clinical data is required. If devices already on the market have limited clinical data, or if data is based on equivalence, additional data from clinical investigations may be necessary to justify that the device can continue to be on the market.

Streamline clinical efforts

QAdvis and PCG Clinical Services work together to provide a "one-stop shop" for Medical Device companies. Our unique offering blends the regulatory expertise within QAdvis and PCG Clinical Services' comprehensive experience and global reach of a large Clinical Research Organisation (CRO) coupled with the agility, personalised service, and cost-effectiveness of a small CRO. Together,

QAdvis and PCG Clinical Services can provide:

- Overall regulatory guidance for medical devices, including how to handle the transition to MDR.
- In-depth reviews of your current clinical data and clinical evaluations.
- Writing of clinical evaluation reports.
- Design, performance and reporting of clinical investigations.

Clinical evaluation

The creation of the clinical evaluation report and necessary continuous updates according to the new requirements demand experience and knowledge in MDR and MEDDEV 2.7/1. QAdvis experts can help you put together a clear and concise clinical evaluation that reflects your unique needs and identify any need for additional data.

QAdvis is a team of expert professionals in compliance, quality, productivity, and regulatory affairs for the MedTech industry. The in-depth knowledge of the new Medical Device Regulation and participation in EU Commission working groups enables us to provide professional support for MDR interpretation, gap analysis, training and implementation regarding both Quality Management Systems and Technical Documentation.

Clinical investigation

PCG has a dedicated project management team that has performed a very large number of clinical investigations on medical devices, before and after CE labelling. Thus, our experience in the medical device regulations required for clinical investigation, including ISO 14155, is vast.

PCG will guide you through all steps of the clinical investigation and make sure that all quality aspects are fulfilled for all parts and activities; the design of the trial (setting the primary objectives and endpoints, including the calculations of how many patients will be required to reach the endpoints), selecting sites, submitting the essential documents to the ethical and regulatory authorities, performing the risk management and data monitoring by using the electronic data capture using the world class, cutting edge system, Viedoc. As master users of Viedoc, PCG can utilize its full potential and provide cost-efficient data management, biostatistics and medical writing. Regardless of whether you choose to outsource all or just some services, we will be working as a team.

Conclusion

With the present strengthening of the regulatory landscape for medical device manufacturers, it is advantageous to partner with experienced medical device expert consultants and expert clinical investigation organisations. We understand medical device strategies – from initial guidance throughout all stages of clinical investigation.

Avoid the risk of failing to meet with the requirements on clinical evidence as stated in MDR, since you are not allowed to continue selling your product on the EU market after 26 May 2020, or after the end date of your transitional period.

By acting now, you will prepare to continue to provide your products to European customers.

Contact us to discuss your needs or visit our websites for more details about our services: www.qadvis.com, www.pharmaconsultinggroup.com

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