

PRESS RELEASE

Tekniker, a strategic partner to develop healthcare products

- *The technology centre has been awarded the ISO 13485:2016 certificate to design and develop medical devices according to harmonised quality standards.*
- *Quality management systems are linked to specific regulations that must be applied throughout the entire life cycle of healthcare products, covering design, manufacturing and post-marketing actions.*

[Eibar, 16 June 2021] – Companies and start-ups that intend to manufacture healthcare products, also known as medical devices, must first meet a number of strict requirements. Generally speaking, companies must comply with EU regulations 2017/745 and implement a demanding quality management system that has to be applied throughout the entire life cycle of a product, from the moment it is designed and manufactured, launched into the market and subsequently monitored.

In view of the major effort involved for companies and start-ups that want to develop and make products of this kind, the Basque technology centre **Tekniker**, a member of the Basque Research and Technology Alliance (BRTA), has been awarded the **ISO 13485:2016** certificate this year to offer companies support in designing and developing R&D&I projects for the healthcare industry. It is, in fact, the first centre of the aforementioned alliance to be awarded this certificate that will enhance its contribution towards the 2030 Science and Technology plan of the Basque Government.

According to Tekniker sources, “the Regulations do not oblige companies to have a certified quality management system for healthcare products, although the ISO 13485 standard is a reference that facilitates the process and provides guidance for companies in terms of implementing a quality management system that is robust, reliable and internationally recognised”.

As a fully certified organisation, Tekniker can guarantee that it has a specific quality management system to develop healthcare products covered by the regulations such as, among others, prostheses, orthoses, diagnostic devices or surgical materials. In this way, any companies or start-ups that want to develop healthcare products will not only be backed by Tekniker as a technological partner, but also receive the support required to meet market access requirements efficiently and efficaciously and speed up marketing actions.

Tekniker has received counselling from the firm [A3Z Advanced](#), prior to being certified by SGS during the process carried out to implement the standard.

In an ever-changing environment characterised by many uncertainties, playing the role of an agile and collaborative firm focused on management excellence offers a major competitive advantage. This certificate can be added on to the list of those obtained recently related to environmental management ([ISO 14001:2015](#)) health management and occupational safety ([ISO 45001:2018](#)). It must be stressed that the technology centre has also been awarded other certificates.

Mercedes Aja, the person in charge of the management system at Tekniker, explains that “the technology centre is the first organisation of the Basque Network to be awarded these certificates”. She also explains that “the development of a management system that embraces quality, efficiency in terms of R&D&I management, health and environmental management is the end result of a commitment based on the centre’s sustainability model seen from an economic, social or environmental perspective”.

Concerning Tekniker

Tekniker is a technology centre specialised in Advanced Manufacturing, Surface & Product Engineering, and ICTs for manufacturing. Its mission is geared towards fostering growth and wellbeing through R&D&I actions aimed at society and enhancing competitiveness in the business fabric in a sustainable manner. Tekniker is a member of the Basque Research and Technology Alliance (BRTA).

Further information:

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