

Case study - Bringing medical devices to the EU

Avanti Europe had been selected for becoming the EC REP for a medical device manufacturer from Asia. Even though the medical device was sophisticated and well documented, additional work had to be conducted to bring the medical device to the EU market.

The task

The client assigned Avanti Europe as the EC REP for one of their medical device products to be brought to the EU market.

The case

After an initial exchange on basic product details and company setup, Avanti Europe audited the client for compliance to ISO 13485 and MDR. Soon, it was clear that compliance to ISO 13485 was established and sufficient for Avanti Europe to jump in as the EC REP. The product compliance to MDR, however, was insufficient as the client CE-marked the product under MDD.

Avanti Europe assisted the client in not only bringing the product into compliance with the MDR but also reviewed the other products of the client and closed all gaps on these in a second priority as well. This remediation work was conducted in no time as Avanti Europe assigned its experts as an extended team to support the client in updating the product documentation and processes to meet the MDR requirements.

Further, the client used a special way to keep track and store its records and process documentation making it very hard for remote access for the EC REP. Thus, Avanti Europe not only supported in selecting a valuable solution but supported the client in configuring the software to the needs of the client. Further, Avanti Europe implemented automated forms and reporting templates to keep the work load for reporting complaints and customer feedback on a very low level.

Even though the efforts had been higher than initially expected by the client, the result was that compliance of the products and process was re-established in a very short time. Further, Avanti Europe implemented its proprietary standards, regulation and guidelines monitoring system with which the client can be assured that all changes and updates are reported to him in an easy to digest and timely manner.

The learning

1. This case study shows very impressively that the most fundamental factor of success is an experienced team with the ability to understand the situation fast and to embrace the task fully.
2. Very stringent and risk-aware process and compliance review with no shortcuts paid it out in the end, even though major changes in the initial task came up during the initial review of the task scope. Assigning flexible resources to meet the timeline even when tasked with additional work led to a happy client in the end.
3. Passion for the topic and understanding of the environment let to the continuous support and implementation of tools to reduce ongoing work load both at the client as well as at Avanti Europe. With this, the product could be placed on time on the EU market and supported with high quality and expertise ever since.

Avanti Europe is...

...reaching far beyond conventional consultancy as we are supporting companies with "hands-on" expertise. Our experts provide tailored service in order that along to the product, the know-how is delivered as well. We call it the "end-to-end" approach which delivers superior service quality also as an EC REP.