PROPHARMA GROUP®

Improving Patient Health and Safety

Navigate Complex Global Requirements for Medical Device Approval

From concept development through Food and Drug Administration (FDA) and European Union (EU) approval, our team of specialists is highly qualified to assist you in all aspects of medical device regulation throughout the product lifecycle.

- Medical Device Regulatory Strategies
- Stand-alone Medical Devices or Combination Products
- Meeting and Submission Support
- Quality Management and Compliance
- Risk Management and Human Factors Engineering
- Medical Device Vigilance

US MEDICAL DEVICE DEVELOPMENT

We provide regulatory strategies and support services to assist you with all aspects of gaining and maintaining FDA approvals for your medical device. Our emphasis on quality, risk management, and science helps you effectively communicate with the agency on their wavelength in support of your product.

EU MEDICAL DEVICE DEVELOPMENT

We support medical device companies from device concept development through CE mark approval. Working with companies that have medical devices and *in vitro* diagnostic medical devices, we are adept at navigating the complexities and gaining approvals in the EU.

Comprehensive Medical Device Consulting Capabilities

At ProPharma Group, our worldwide network of experts has unparalleled experience and knowledge in every aspect of medical device development and approval in the EU, US, and other regions of the world. We can bring your device to market and keep it there, with a focus on efficiency in timelines and cost to help ensure an excellent return on investment.

Whether you have a stand-alone medical device or a combination product (integrated or not integrated), we can partner with you to bring your product to market and ensure its ongoing success by building and maintaining an effective quality management system (QMS) and managing regulatory affairs throughout the product lifecycle.

ProPharma Group: Supporting Medical Device Development and Approval At Every Stage in the Product Lifecycle.

ProPharma Group has a full range of medical device consulting capabilities, including all regulatory and compliance aspects of device and combination product development. We have experience with medical devices across all classes spanning a diverse range of indications.

Our experts are scientists with extensive backgrounds in the development of medical devices, pharmaceuticals, and biotechnology products. We are highly qualified to assist you during all product development phases, from device concept development through the approval process and post-marketing requirements, we support companies that have medical devices and *in vitro* diagnostic medical devices at every stage of the product lifecycle.

Improving Patient Health and Safety. At Every Step.

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory expectations are met, business goals are achieved, and patient health and safety is improved.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

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