



# Benefits of Early Regulatory Strategy

**Grace Powers, MS, MBA, RAC (US, EU, Global)**

Early Regulatory Strategy is a Must

Most early stage companies are focused on solving the next biggest clinical problem. They are also trying to keep their finances afloat. Does that sound like your company or one you know? There are some important additional considerations that need attention early in development such as regulatory strategy and compliance.

Device makers need to consider their product's regulatory strategy up front so that there are less compliance issues in the long run. Having a formulated strategy will help with business planning and timeline prediction. A well thought out strategy will also help with fund raising and address potential questions from prospective investors.

The regulatory classification in the U.S. determines the amount of design control documents needed. If the product is a Class I device, then less documentation is required to place a device on the market than a Class II or Class III product. The regulatory classification also determines if a pre-market submission to FDA is needed. Many Class II products require a 510(k) and Class III products require a pre-market approval submission (PMA).

The regulatory strategy also needs to consider the marketing plan. For example, is the device a catheter with a coating? What is the purpose of the coating? Is it for manufacturing or lubricity or is it to help reduce infection? The way in which the device is described and marketed can drive the regulatory classification of the device. A higher regulatory classification will likely create additional pre-market requirements and, therefore, can affect the value of the product.

When the regulatory requirements are not a consideration up front, there are often delays with the FDA or notified body submissions. Delays could occur from not completing the correct bench testing. Delays could also occur from having to repeat animal or biocompatibility studies. This can lead to delayed product launch and have significant impact on younger companies. Additionally, post-market delays can occur in the form of warning letters and 483s.

A regulatory strategy is typically a formal document that outlines the regulatory information for a specific medical device or family of devices. It typically contains the intended use, indication for use, device classification, submission pathway, and general regulatory requirements. Some early stage strategies can be very high-level. For products that are farther along in the design process, the strategy may include detail on all the standards, guidance documents, testing, and predicate device(s). The regulatory strategy is a living document that evolves throughout the product development process.

Consulting with a regulatory consultant early will help make a more efficient and predictable product development process. Powers Regulatory Consulting would like to help you with your early regulatory strategy for the U.S. and Europe.