

Magellan is a breakthrough technology for medical device compliance. The software platform automates and archives all the regulatory documents required to bring a device to market, and creates a roadmap so that errors and omissions are eliminated.

Ferdinand Magellan was a Portuguese explorer who embarked on a seemingly impossible voyage: a 1,126-day odyssey around the world. Magellan's expedition was trailblazing in every sense of the word: It was the first to sail from the Atlantic to the Pacific; the first to cross the Pacific; and most importantly, the first to complete a circumnavigation of Earth. It revolutionized exploration and ocean navigation, and positioned Magellan as one of the world's truly great explorers.

Magellan's voyage also proved beyond doubt that the planet was round, which had important implications for astronomy and geography, not to mention science and religion.

Today, medical device companies face their own navigation challenge: making their way successfully through an increasingly complex maze of regulations, an ever-changing landscape of regulatory processes, multiple jurisdictions, and new compliance and documentation requirements. As a result, it can cost millions of dollars to bring innovative products to market. The process has become so complex and onerous to navigate that a new industry has emerged: regulatory consulting.

Medical device companies historically had two options to choose from: rely on internal resources to gather the volumes of information required, which can draw expertise away from other projects; or hire a consultant to guide them through the process, which can be expensive. To date, there has been no way to harness the power of the internet to gather the necessary information and store it in a central location for convenient access.

Magellan's cloud-based backbone scours the web for the most current regulations, forms and any other information pertinent to the companies that are bringing medical devices to market. This information is stored in a separate and secure repository, which subscribers can access through a customized dashboard. This simplifies document management, ensures accuracy, and facilitates timely completion. The platform is supported by experts in the field who are fully versed in guiding companies through the regulatory process.

Magellan offers the only solution for leveraging the internet as a source of compliance information and for staying abreast of the ever-changing criteria for each jurisdiction. The goal of RegIQ Solutions is for Magellan to become a standard part of the process for bringing medical devices to market. The product saves clients from hiring additional staff or external consultants, which in turn saves them time and money – in addition to improving the efficacy and accuracy of the compliance process.

Walk-away concepts

Through a well-known, historic event, the Magellan brand story conveys:

- The ‘expedition’ of bringing a medical device to market
- A breakthrough in ‘navigation’
- Immediate and significant impact for ‘explorers’ (i.e. regulatory managers)
- The opportunity to obtain new knowledge and capabilities
- A ‘voyage’ to significant achievement in the face of overwhelming odds.

Magellan

[muh-jel-uhn]

noun Ferdinand, c1480–1521, Portuguese navigator: discoverer of the Straits of Magellan in 1520 and the Philippines in 1521, and credited as the first to circumnavigate Earth.

Rationale

The process of bringing a medical device to market is much like sailing the uncharted oceans. RegIQ Solutions is introducing Magellan, a tool that greatly enhances regulatory managers’ capabilities in navigating the existing landscape for medical device companies to commercialize their products. Associating the platform with a historic explorer gives the platform a personality, endowing it with the characteristics of bravery, vision, navigation expertise and leadership. It also associates the compliance process with a referenceable story about a navigation breakthrough that will resonate with the desired audience.