REGDESK

Reinventing Regulatory

Who We Are

Regdesk is the one-stop solution to your company's regulatory challenges. Our platform automates the entire medical device product lifecycle, allowing users to create approval-ready applications in hours rather than months, track registration progress, and receive important resubmission alerts and prepared change notification data. We multiply the efforts of your regulatory affairs team so you can reach new markets ahead of the competition.

RegDesk is a certified Minority Business Enterprise (MBE) and a certified Women's Business Enterprise (WBE).

The Problem

Expanding into new markets is a daunting task, usually requiring endless hours of research, compiling regulatory data, and multiple application rejections before achieving approval. The challenge is rooted in data acquisition and management. Regulatory requirements vary significantly between nations. Guidance released by regulating authorities is often difficult to understand or not provided in English. Traditional solutions include consultants, who are often slow to respond to inquiries due to a high volume of clients or their lack of device or region-specific knowledge, or worse, newsletters and webinars rendered obsolete soon after release. Even when accurate intelligence is obtained, the popular method of compiling data into spreadsheets or rudimentary RIMS platforms makes keeping track of the ever-changing global regulatory landscape nearly impossible. Minor data errors or missed updates can snowball into rejections. Tracking resubmission deadlines and change notification data requires parsing through massive files.

Our Solutions

RegDesk Dash Regulatory Intelligence Database - We provide instant access to comprehensive regulatory requirements for more than 115 countries. Requirements are condensed into concise, easy-to-follow steps and translated to English when necessary. Our analysts continuously monitor the global regulatory landscape to ensure our requirements are updated and accurate.

RegDesk Alerts Notification Module - Receive automated alerts to submission renewal deadlines and important regulatory changes that affect your products.

AI-Powered Application Builder - Our application builder consolidates the medical device submission process into fillable forms. Simply follow the prompts and our AI-powered software automatically generates jurisdiction-specific dossiers based on information provided. Once a product is approved, change assessments data helps Regulatory Affairs team members stay alert to regulatory changes that might affect products. Clients have reported that our Application builder reduced the submission building process from weeks to hours.

RegDesk Peer Regulatory Consulting Network - Our platform provides instant access to a global network of more than 4,000 regulatory consultants. While most companies rely on consultants - who are often slow to respond to regulatory questions due to a high volume of requests or their lack of knowledge regarding