



**Product
Realization
Group®**

MedTech Regulatory Services

FROM PRODUCT IDEA TO COMPLIANCE

Compliance failure is a leading cause of delays to new product launches. Noncompliant products can impede long-term product profitability and lead to outright rejection from customers. PRG helps MedTech companies navigate critical regulatory hurdles and drive product success.

Combining information from government agencies, industry trade groups and standards organizations, we provide you with a regulatory compliance strategy to help you to meet specific requirements. The strategy includes classification of your device, regulatory paths, providing guided interaction with FDA reviewers, and determining applicable predicate technologies. We also help identify relevant international standards, scope performance data requirements and work with you on your product's submission documentation.

Our Team of hands-on experts will help you to:

- Understand the requirements and certifications that you need to meet
- Develop the regulatory plan and provide help with regulatory submissions, such as FDA (United States) or internationally (e.g. CE marking for the EU)
- Manage and minimize compliance costs
- Design your product to get through certification more quickly

By accurately interpreting requirements and carefully managing test labs, PRG allows you to avoid these key challenges:

- Products rejected by customs during importation
- Customers disqualifying or rejecting your product
- Lawsuits brought by competitors, as well as criminal or civil fines and penalties
- Liability for harm caused by non-compliant or insufficiently tested product
- Poor product competitiveness
- Failed quality system inspections/audits
- Product recalls and field corrective actions

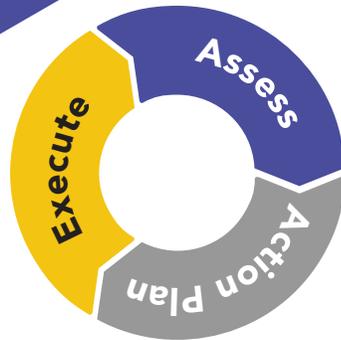
"PRG helped us make sure that our product was tested to the correct standards and received all the necessary certifications"

-- VP Engineering, robotic guided medical system



“The action plan that PRG developed was the critical component in getting our product compliant”

— CEO, surgical medical device company



HOW IT WORKS

PRG offers a streamlined process for product regulatory compliance:

1. **Assess:** First, we conduct an assessment of your product to determine required government and industry standards, test and certifications, as well as recommended voluntary actions.
2. **Action Plan:** We then design a specific plan for your product and a cost effective strategy for meeting the requirements
3. **Execute:** PRG can manage your entire compliance process, including:
 - Working with your engineering and product management teams to align the necessary technical and business resources
 - Interpreting how complex requirements affect your product
 - Navigating gray areas and new product categories
 - Helping to select the best test labs for your product
 - Managing test labs and guiding the test & certification process
 - Assisting your engineering team to overcome regulatory challenges

KEY BENEFITS

Compliance standards can drastically affect the industrial design, materials, electrical and mechanical design of the product. With PRG you can minimize the costs of failed tests and product redesigns and:

- Avoid regulatory delays to your product, getting it to market faster
- Meet product safety goals
- Reduce overall cost and compliance risk
- Improve product competitiveness and customer satisfaction
- Drive channel sales success through high product reputation