



Common Obstacles to Receiving Product Approvals for Global Markets

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Common obstacles and challenges to product approvals

What are the most common hurdles that hinder product approvals?

Driven by social, economic and environmental factors, our world is changing at an unprecedented rate. And so are medical devices - from switches to swipes, hardware to apps, and hospitals to the home environment - healthcare equipment continues to experience a paradigm shift.

This change is bringing complex challenges. Medical device manufacturers need to keep up with the rapid pace of innovations and at the same time, their products need to be safe for use by both professionally trained and inexperienced home users.

Many companies only have experience with single-country access and therefore may lack understanding and expertise of regulatory or technical requirements in other countries. With such a wide array of regulations from country to country, companies can struggle with how to begin the process of meeting the required conformity for their target markets. This issue can be compounded by a lack of internal resources dedicated to compliance issues.

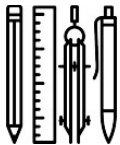
In this constantly changing environment of safety, conformity, and market access requirements, it is even more important to not only respond to the regulatory needs of today but anticipate those of tomorrow.

Key stakeholders in the product approval process

Who are the key stakeholders involved in the product approval process and which players should be considered in a market access strategy?

In order to achieve market access and avoid costly delays to product launches, a multitude of different stakeholders need to be considered.

One key factor for getting medical devices to patients and healthcare professional in a timely manner is early contact with an experienced global testing & certification organization such as CSA Group.



Design engineer who needs to know the applicable standards so they can design the product compliance to the standard;



Testing engineer or **compliance engineer** who knows how to work with the certification agency to test & certify the product and help ensure compliance with product safety requirements;



Regulatory compliance team who can prepare product manual/label/quality management systems in order to help ensure full product compliance with government regulation.

+ **Other key players may include:** R&D, Human Factors Engineering (usability), Risk Management, and Marketing.

Geographical differences in product approval processes

What are the basic differences in the product approval process across North America, Europe, and Asia?



Varying Regional Standards

Technical standards vary across regions. There are overarching standards, such as ISO or IEC standards, as well as national and regional standards that often qualify these international standards. Europe, in addition, has harmonized standards across the European Union.

Different Product Approval Processes

There are different product approval processes for each country or region in order to adhere to specific Ministry regulations (e.g. Health Canada, FDA). Sometimes different countries will adhere to a different version of a standard (e.g. 2nd vs. 3rd edition).

Product Adaption

Sometimes product adaptation must occur in order for the respective device to receive a safety approval and thus be permitted to be sold in another market. For example, nominal voltage or frequencies may affect product design in foreign countries.

The role of a third-party testing agency

What is the role of a third-party testing & certification agency in reducing time to global markets?

To minimize the time from product idea to launch in a foreign market, a third party testing agency must have an ILAC-accredited lab under ISO 17025. The test reports completed in the lab can then be used in any of the countries that participate in the ILAC scheme.

In addition, a global third party testing agency can provide many valuable services, including:

- Thorough and up-to-date knowledge of various country regulations in different industry regulatory sectors;
- Localized single point of contact with streamlined & effective project management;
- Seamless integration with your product development cycle;
- More predictable time to market;
- Multilingual service capability.

What should you look for in a third-party testing agency?

In order to help ensure your projects are delivered within your timelines and launching your product to global patients and healthcare professionals without delays, you should look for a testing & certification agency that offers key advantages such as:

- High level of technical competence to provide you with technical information services early in the development stages of your product;
- Comprehensive lab capabilities including relevant accreditations and recognitions to test your products to applicable standards;
- Experienced multilingual technical experts to support you on a local level;
- Standards Development Organization (SDO) and member of standards committees to anticipate standards updates you can consider in the design of your product.

Note: a certification agency that is accredited under a specific country's regulation can only approve products for that specific market. They can leverage the certificate to access global markets, but it can't be accepted directly in most cases.

Common misconceptions around seeking product approvals

What are some common misconceptions around accessing global markets?

Misconception #1: One report can be accepted by all and one registration can be used by other countries.

- Reality: You can leverage a certificate to access other markets, but cannot transfer it directly.

Misconception #2: That it is overly complicated to access multiple markets.

- Reality: Many people do not realize that the IEC 60601-1 standard for medical devices is widely accepted with limited national deviations.



Do it Right: Having a third-party certification agency with an ILAC-accredited testing facility can help you launch your product on global markets more easily. Early contact with an experienced testing & certification provider is key in receiving quality safety approvals to help get your products to your global customers on time.



Clear common hurdles to product approval and get your devices to your global clients on time

CSA Group can help medical device manufacturers navigate global regulations and help ensure product approvals for timely market access.

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