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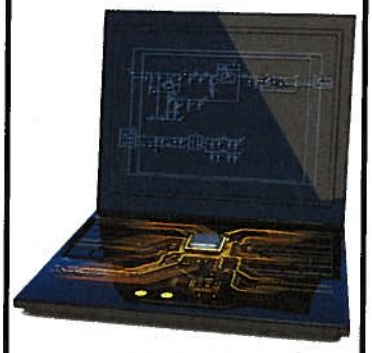

Lack of Global Standardization Directly Impacts Market Access

by Bill Holz, TÜV Rheinland of North America

Bring Your Regulatory Compliance Staff into the Process Early to Achieve Success

A great number of companies define themselves as global, yet their scope for "global" varies and therefore so does their global compliance needs. One company might market its products in the U.S., Canada and European Union, while another might be introducing new products to 150-plus countries. No matter the company's definition of "global," there are several critical areas they should address to ensure they are truly ready to place products on markets worldwide.

Most companies will have some standard development process that deals with the product lifecycle – from new product conception through the end of the product's life cycle. This article deals with new product conception through market introduction phases, as well as the compliance staff's specific contributions.

NEW PRODUCT CONCEPTION

Normally, at this stage of development, only the basic product functions are identified, including the product features, revenue opportunities and market opportunities (where and when the product needs to be introduced). This is the key stage in the standard development process. The chances of a successful project are increased significantly if:

- Opportunities have been identified at the country level, and
- The right team members have evaluated the product opportunity.

This is probably the most common shortcoming for many companies – where the product opportunity is developed and evaluated by a single organization or does not include all the key organizations. Companies must properly address a new opportunity by involving all of the key staff members from:

- Marketing
- R&D (Engineering)
- Regulatory Compliance
- Finance

The involvement of these organizations will ensure that all key aspects pertaining to a successful product development and launch will be addressed. The role the regulatory compliance staff plays during this phase is considerable. Many times these contributions are overlooked until it is too late in the game to overcome an incorrect product introduction assumption. This is especially true with respect to each country's regulatory and technical requirements.

COUNTRY REGULATORY AND TECHNICAL REQUIREMENTS

From this point, we can assume that the product conception document lists each country (where the product introduction will occur), the product launch date and the anticipated revenue. The compliance staff should then be able to provide information on the following:

- **Regulated Products.** Depending on the product, certain certifications must be obtained before a product can be legally placed on a specific country's market. Some products may not have any requirements, while others need a variety of certifications such as:
  - Product safety
  - EMC
  - Energy
  - Telecom/radio
  - Medical

The ramifications of not knowing, or knowing yet not complying, are significant. Not every country is set up to maintain high surveillance on mandatory certifications, but the risk remains if compliance is not met with legal regulations and fines, and in some cases worse can be imposed.

- **Technical Requirements.** Is the envisioned product designed to meet the technical requirements for each country on the list? Have you identified a technology that may only be acceptable to certain countries?

This situation is quite common. A company takes a product – designed for North American standards – and wants to place it on global markets. The problem is not so much that one fails to gain regulatory certifications, but rather, it is often not possible to even use these products in other global markets.

- **Testing Requirements.** Depending on the product and country, there may be specific requirements as to where the testing must be performed or which test reports will be accepted in lieu of in-country testing. In countries where the product is regulated, it is necessary to either perform in-country testing or submit test reports to the correct standard from an accredited lab.

This is a cost concern. First, know the number of samples required for testing in each country. Second, learn which existing test reports will be accepted in which countries. In most cases, accepted test reports come from an accredited laboratory.

In addition, the U.S. has a Mutual Recognition Agreement (MRA) with several countries regarding test reports. The contracted laboratories must be accredited for the appropriate standards, and maximum coverage under available MRA's must be obtained.

- **Language Requirements.** To submit a product for mandatory certifications, each authority must dictate the language of the application and user documentation to be accepted.

This is a cost concern. It only makes sense that a product placed in a foreign country must have user documentation written in the intended users' language. In many cases, it is required that the application and user documents be in the prescribed language for the application to be submitted. In others, it can be submitted in English to gain the certification, but must also be in the local language prior to placing on the market. Still, others will allow everything to be in English. Translation is expensive and can further delay certifications if it is incomplete.

- **Local Residence Requirements.** Each authority has requirements regarding the applicants' legal establishment (residence). In many cases, the formal application must be signed by a legal entity located within that country. These requirements, and how to fulfill them, varies considerably.

This is a cost concern. In many cases, the legal applicant must be an established resident of the country where the application is being made. An established resident can be a locally based company, distributor or licensed agent. Not knowing these legal requirements can cause serious delays,

and significant costs can be incurred if the company does not have a legal solution.

- **Lead Time for Certification.** How long it takes to attain certification is not only dependent on each country's process, but also the time of year the product introduction is planned. Holidays and heavy vacation periods must be taken into account.

This is a cost concern. Revenue planning for a given country should assume that all required certifications have been attained. It is not a simple case of estimating the time (usually overly optimistic) but rather the actual time for these efforts. The same product can take 2 weeks in one country and 12 weeks in another. To properly plan revenue, companies need to know the actual timeline.

- **Documentation Requirements.** To submit an application in any country, you must provide specific product and company information. The application process will not start until all documentation has been made available.

This is a cost concern primarily from the perspective of delayed revenue. An application can be submitted to an authority without all required documents, but the application will not be processed. Even worse, many incomplete applications are just set to the side and lost.

The time to gain a certification, as discussed above, is based on a start date when all samples and/or required documents are available. Providing anything less will not start the clock for the approval. All requested documents must be provided.

If submitting these highly technical documents is not a concern and if one does not or cannot provide them, then no certifications will be granted. Therefore, if information cannot be provided to specific countries, then those markets should be removed from the list.

- **Cost for Certifications.** Once again, the cost to attain a certification will vary significantly from country to country.

There is no way to avoid the cost required to pay for certifications, but it is important to know the cost associated with each country. There may be many cases where the certification cost for a particular country may far outweigh the potential revenue margins. It is better to cross off these revenue-loss situations before investing in the process and know the full cost beforehand.

There is another aspect regarding the cost of certifications: the loss of revenue due to certification delays. This is a far bigger number than actual certification costs. Just consider that there is only a maximum of 260 selling days per year (actually less). Any lost planned revenue days cannot be recovered; they are gone. This can be figured out quite easily. Divide that country's annual planned revenue by 260 days to calculate the revenue per day. For example, planned revenue of $2.6 million can be estimated at $10,000 per day revenue. The daily loss typically is considerably higher than certification costs. This is where a good partner in global certifications will end up making money by getting products certified on time.

SUMMARY

Unlike the European Union, there is very little, if any, standardization of any of the above items or process harmonization for the rest of the world. Therefore, the compliance staff will need to investigate each of the above aspects for each country on the list. The dynamics are such that the regulations vary considerably from country to country, but they also change frequently. Old information cannot be reused; the task must be done frequently.

Each one of the listed items has a direct impact on a company's ability to develop the correct product as well as legally place it on the market. For each item, there is also a cost impact – not only direct costs, but costs associated with:

- Time to place it on the market
- Lost revenue from improperly planned certification time
- Time for planned market introduction

Far too often regulatory compliance staff members are brought into the picture too late in the new product conception phase. As a result, products may be improperly defined to meet the intended market, or applicable regulations and associated costs may not be taken into account – resulting in less then acceptable profitability for the product. The issues presented seem to be amplified in today's economy, but no matter what the economic situation, use the compliance staff to the fullest to bring products to a successful and profitable launch. ■

Bill Holz, Senior Specialist at TÜVRheinland's International Approvals Division since 2008, has 25 years of experience in international regulatory services. Holz is considered one of the foremost experts on the rules and pitfalls of navigating complex international regulatory procedures. He moderates the company's popular roundtable series, "Global Regulatory Approval of Products."