Medical Device Company – LaserX
Foreign Compliance Case Study, May 2017
(Company Name Changed to Protect Confidentiality)

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BACKGROUND

LaserX designs and manufactures laser-based medical devices for medical and veterinary healthcare professionals. Its devic3e uses light therapy to alleviate pain and aid in healing. LaserX has 65 employees and has sold its products in over 40 countries. It has a full time regulatory/compliance manager.

EUROPEAN MARKET

LaserX's distribution partners help with compliance, but their knowledge is insufficient – LaserX must stay on top of the requirements themselves.

In tackling the EU market, LaserX pursued ISO 13485 certification first, to meet the requirement for a quality management system that is necessary to obtain the CE Mark. Companies typically implement ISO 13485 to meet the requirements for a quality management system defined in the Medical Device Directive (MDD). By working toward ISO 13485, and also adding additional MDD (EU Medical Device Directive) requirements into the ISO effort, much of the work needed for CE Mark certification was achieved. LaserX achieved CE compliance in 2009. (In the US, ISO 13485 is not specifically required for FDA approval, but a quality management system is, and ISO 13485:2016 aligns with FDA requirements.)

For certification testing and auditing, LaserX used several organizations with worldwide reach. For electrical testing, the company used Intertek (intertek.com), a Nationally Recognized Testing Laboratory (NRTL). This testing cost on the order of $50,000. BSI (bsigroup.com) is LaserX's Notified Body, which means it conducted the company's conformity assessments for EU Directives and CE marking. The initial audit by BSI had a set fee and then each follow-up to check on corrective actions by LaserX required additional fees. This can be costly.

Finally, Emergo (emergogroup.com) is LaserX's in-country authorized representative in Europe (and Australia). Having a European authorized representative is a requirement under the MDD. This rep coordinates aspects of European compliance. For example, Emergo's name and information is on the LaserX label and it has LaserX's declarations of conformity and its Post-Market Surveillance (PMS) plans.

LaserX is anticipating a new MDR (Medical Device Regulation) to be issued by the European Parliament, which may include major changes to requirements. LaserX keeps tabs on the new MDR through several means. While LaserX does not use Emergo as a consultant (at $290/hour, consultations are pricey), Emergo's "RADAR newsletter" helps LaserX keep up with EU regulatory news. Other resources the company utilizes include: FDA's newsletter, which includes international news; LinkedIn medical device groups; BSI notifications; and free webinars offered by organizations such as Greenlight guru (www.greenlight.guru).

EU compliance is also being impacted by the ISO14971:2012 Risk Management Standard update, which requires all risks to be reduced **as far as possible** (no matter what the cost). Previously, risks could be reduced "as low as reasonably practical" (ALARP) but that is no longer acceptable to be compliant with the European Medical Device Directive. So, "if you took liberties" in your design in the past using this ALARP justification, then design changes may be required to further reduce risk as far as possible.

OTHER MARKETS

Countries differ in their compliance requirements. Some countries will do their own quality system audit, for example, Korea and Japan sent auditors to LaserX. Canada (which is an important market for LaserX) posed a different challenge. The laser at the heart of its product shifts the classification into a higher risk category in Canada as compared to the U.S., which involves more work and compliance costs. The company also wrestled with regulations in Singapore. On the other hand, Thailand simply required a Certificate of Free Sale, and LaserX found that India likes FDA approval, but does not appear to require it. Emergo provides a comparison tool to look at medical device compliance requirements across markets (https://www.emergogroup.com/resources/worldwide/global-regulatory-comparison-tool).

A streamlined method for obtaining electronic device safety certifications in multiple countries is available through the CB (Certification Body) Scheme, an IECEE[1] program. Under the CB Scheme, a manufacturer applies to a National Certification Body (NCB), which works with an approved testing lab (CBTL) to test the product's conformity to the IECEE standard. If in compliance, the NCB will issue a CB Test Certificate, which can then be used to get national certifications in other markets, typically *without re-testing.* Over 40 countries have an NCB and over 50 nations participate in the CB Scheme. (According to IECEE, some countries that do not have an NCB also accept CB Test Reports and Certificates.) LaserX worked with Intertek, which has NCBs in several countries and 38 CBTLs around the world.[2]

Another program on LaserX's radar that has the potential to streamline certification across multiple countries is the MDSAP (Medical Device Single Audit Program), which is a new international effort allowing medical device manufacturers to be audited once for compliance with five markets: Australia, Brazil, Canada, Japan, and the U.S. The company believes this type of program is critical because "the compliance issues we've faced have been big barriers." BSI, Intertek and TÜV SÜD (tuv-sud.com) are auditing organizations for MDSAP. To stay abreast of MDSAP news, LaserX cites the Regulatory Affairs Professional Society (RAPS.org) as a great source. Other resources given for MDSAP news include the FDA, BSI, and Emergo. LaserX wonders whether this single audit program will be effective and truly reduce the number of required audits for different countries.

According to LaserX, "from a documentation point of view, if you have design control compliance per FDA and technical files per CE, you're 99% there with (many) other countries." So FDA and CE compliance – and leveraging the CB certification scheme to avoid redundant testing for multiple markets – meant that LaserX only added minor additional testing (through Intertek) for "country deviations" (e.g. testing related to different voltage or hertz), making it cost efficient to become compliant in additional markets.

OTHER ADVICE

Overall, the cost of becoming compliant is more about testing and documentation than it is changing the product. "If you do your due diligence up front during the design phase, there shouldn't be major changes – otherwise you made a mistake if you are making big changes to get your product registered in a foreign market."

In addition, LaserX suggests drafting a regulatory plan during the initial design phase, and going through the process of classifying the device in different markets to determine if there will be additional requirements that were not in the scope of the original design.

[1] International Electrotechnical Commission assessment schemes for Electrotechnical Equipment and Components.
[2] Source: http://www.intertek.com/marks/cb-scheme/faq/