CSA Group and BSI open international markets to manufacturers

German manufacturers of medical devices are enjoying a booming business and have a good reputation. But global competition is heating up. Offering outstanding products in established markets is no longer enough. Germany and Europe have become too small. To continue to play in the top league in the future, companies will have to target markets on a broader front. At the Medica trade fair last November in Düsseldorf, CSA Group and the British BSI Group announced their alliance centred around a joint service concept aimed at manufacturers of medical devices who want to introduce their products quickly and successfully in international markets.

CSA Group is a leading testing and certification organization based in Canada and maintains test laboratories throughout the world. CSA Group originally focussed on product testing to North American standards in order to facilitate entry into the North American market. In the process, CSA Group, which operates its own test laboratories, has been accredited by numerous certification agencies. The CSA certificate is also helpful, for example, with regard to the certification of high-risk products by the FDA.

BSI is an internationally active standards organization. As a Notified Body, BSI helps its customers to achieve an excellence status in all corporate processes and supports them in matters regarding country-specific testing and certification requirements. In addition, BSI is a Notified Body in Great Britain and Germany.

At the end of 2013, CSA Group and BSI combined their competencies in order to offer customers wide-ranging services relating to complex, country-specific product tests and certification procedures. At Medica, the MTD editors spoke with Hans-Werner Zeller, Manager Electro-Medical & Technology Europe, CSA Group, and Jan van Lochem, BSI Vice President Medical Devices, EMEA.

Mr Zeller, medical device manufacturers among our MTD readers are already familiar with the CSA Group through an interview with you (see MTD 11/2012) and through advertisements. You are a specialist in matters pertaining to product testing and certification. So far your services have concentrated on successful product introductions in North America. You have now expanded your radius of action. For what other countries do you test products of export-orientated manufacturers?

Hans-Werner Zeller: Basically, we offer our customers global market access. In concrete terms, this means that, we offer access to the Chinese, South Korean and other Asian markets, among others. We also facilitate access to eastern Europe and South America, especially Argentina and Brazil.

With your tests you certify the safety of products. What safety aspects are relevant?

Zeller: Safety requirements have fundamentally changed as a result of the introduction of the new safety standard 60601-1, 3rd Edition. The risk-management process and product usability now account for a large portion of safety requirements. Moreover, other requirements regarding software safety have been added, so that today all equipment has to meet those standards. These are additional points that we consider apart from well-known safety aspects such as electrical, mechanical and thermal characteristics.

That sounds like specialization in specific product categories. What products are at the focus of the CSA mark?

Zeller: The requirements I just mentioned apply to nearly all powered products. We therefore have no product specialization as such. The only product group that we don't certify are active and non-active implants and non-active medical devices. Of course we have more experience in some product categories and somewhat less in others, but our engineers are so well trained that they can cover virtually the entire spectrum of medical devices, thanks not least to a close cooperation with manufacturers.

Mr van Lochem, BSI is a Notified Body in the conformity assessment procedure for obtaining the CE Mark. That means that you are a contact for companies that want to sell their products on the European market. Conversely, you also offer your services to European companies that want to open up new markets. Have you concentrated on specific countries?

Jan van Lochem: We focus strongly on manufacturers in Germany, Switzerland, France, the Netherlands and Great Britain. With our Notified Body in Frankfurt we are in a good position to support German companies. Outside the European regulatory zone, we also provide certifications for Canada (CMDCAS), the USA (510(k)), Australia (MRA), Taiwan (TCP II) and Japan (J-PAL).

Threshold countries are becoming increasingly interesting. Are they developing their own certification procedures, or are they adopting European or US certification procedures?

van Lochem: Most threshold countries are developing their own certification procedures for medical devices or have already done so. They are usually based on a globally recognized model of the Global Harmonization Task Force (GHTF) or on a European model. Consequently, those countries have their own certification procedures, all of which, however, are based on a common model. We at BSI can therefore combine audits and product tests for various certifications, insofar as this is allowed. In addition, we are accredited as a Conformity Assessment Body (CAB) in most threshold countries. This permits us to carry out audits according to specific country regulations (e.g. those of Japan, Malaysia, Taiwan, Canada, etc.). Some countries, e.g. Australia and Saudi Arabia, even recognize our CE certificates for Europe, which of course facilitates certification in those countries.

Mr Zeller, are your product certificates accepted in certification procedures outside North America?

Zeller: Yes, our certificates are recognized internationally and are also used for certification procedures in other countries. In addition, CSA Group is an active member in the CB scheme, so that recognition is guaranteed in well over 70 countries that participate in this scheme.

Harmonization processes with the competent authorities are required. Wouldn't it make more sense to be present on site?

Zeller: CSA Group has offices and laboratories in all key countries. We're represented, for example, in China, Japan, South Korea, India and Europe. In Toronto we also have a special department concerned exclusively with certifications for the global market. It is staffed by specialists who are fluent in the respective national language, which makes the harmonization process with authorities as straightforward as possible.

You can't have your own people everywhere. How do you deal with the formalities in such countries?

Zeller: Unfortunately, we don't have an office in South America at present. As I mentioned earlier, it is therefore very important to have a team of specialists, who speak

the national language so that they are able to communicate directly with the authorities. Regular on-site visits are also helpful in maintaining contact with authorities and harmonizing any new regulations or changes directly. In addition, our partner BSI has offices in over 50 countries, which can also be involved in the process.

Let's talk about the joint service concept of CSA Group and BSI. Your cooperation includes product tests for compliance with national and international standards by CSA Group. However, as partners, you want to take care of the entire certification procedure for your customers. Mr van Lochem, we've addressed the subject of product tests by CSA Group. However, I believe two other elements handled by BSI are important for exporting companies seeking access to new national markets?

van Lochem: That's right. Beside the product tests and certifications for various countries carried out by CSA Group, BSI has to conduct audits and review technical dossiers – in each case in accordance with country-specific requirements. During an audit and during the review of a technical dossier we try to combine various certification requirements. Based on these two reports, we can then certify medical devices for a wide range of markets (CE for the European Union, J-PAL for Japan, etc.).

A detailed explanation of auditing the QM system is probably not necessary. However, the question arises as to whether your audits are recognized by the certification and supervisory authorities concerned?

van Lochem: As soon as we are CAB-accredited by a country, we can conduct tests in our audit pursuant to that country's requirements. Usually the ISO 13485 standard is applied. Our auditors must also be qualified for the countries in question. Provided that these requirements are met, the countries recognize the audit. At the moment this applies to Japan, Canada, Taiwan and Australia, though more and more countries are moving in the same direction. For example, in 2013 BSI became the first CAB-accredited company in Malaysia.

In addition, an interesting pilot project called MDSAP will be launched in 2014. This is a program, according to which BSA, once accredited, can carry out audits for the USA, Canada, Brazil and Australia. This concerns primarily supervisory audits, which BSI would then carry out instead of the FDA (USA) or ANVISA (Brazil). Other countries such as China and Japan are watching this programme carefully and are also planning to participate. The pilot project will be launched in June 2014.

Your services consist of several elements. One of them includes, among other things, documentation, supply chain, instructions for use and risk management. Can you explain this in more detail?

van Lochem: The third element consists of the review of technical documentations. This must always be carried out in a specific manner depending on the requirements of the country in question. However, there is a generally accepted format, the STED (Standard Technical Dossier), that specifies the structure of the documentation. The product design, labelling and documents as well as the supply chain must be described in detail. In addition, applicable tests must have been performed.

At the heart of the STED, however, is the risk management report. All risks in the supply chain and during manufacture and technical assembly as well as clinical risks must be identified and minimized by means of tests, a redesign or a warning in the instructions for use.

BSI reviews this technical report for CE certification in Europe. We can also do this for class II devices in Japan. The USA accepts 510(k) reports from BSI, while Australia,

Malaysia and Saudi Arabia accept the verification of documents regarding CE certification. Nevertheless, there are also countries, such as Canada, in which the national authorities check the technical dossier themselves.

Your assessments, reviews and documentations are comprehensive. Together with CSA Group you offer a well-rounded package for the certification of products in national markets. How do you implement your certifications into certification processes of countries in which you are not accredited?

van Lochem: As far as BSI is concerned, we can only be active if the local country-specific specifications permit certification by an outside CAB. CSA Group has a somewhat more comprehensive approach in this respect: its Global Market Access (GMA) department works together with local authorities and takes care of the entire certification process. Whenever possible, CSA Group's GMA team submits reports prepared by BSI to the local authorities as part of the certification process.

Mr Zeller, CSA Group specializes in powered active medical devices. Is my assumption correct that your joint service concept also focusses on this product sector?

Zeller: Yes, at the moment our alliance focusses specifically on those medical devices. However, that doesn't mean to say that CSA Group and BSI won't be able to work together along a broader front in the future.

Let's talk about the practical procedure. Let's say a German manufacturer of electromedical equipment comes to you in order to sell its products in a South American country. How would you proceed?

van Lochem: If the country in question were Brazil, for example, BSI and CSA Group can offer joint solutions. BSI Brazil is accredited for the certification of products in accordance with INMETRO and can certify products based on product tests conducted in laboratories of CSA Group in Germany or Switzerland. Because Brazil will be participating in the MDSAP pilot project, BSI will be able to carry out audits to Brazilian specifications instead of ANVISA in the future. An account manager of CSA Group or BSI coordinates this on behalf of both organizations. With regard to other countries in South America, we still do not possess accreditation in some circumstances. In that case, CSA Group's GMA department helps to find solutions.

In any case, you draw up a country-specific project plan, followed by the implementation of that plan. Can you give a timeframe of how long it then takes for a product to be certified?

van Lochem: Unfortunately, that's very difficult to say because the time to final certification depends on various factors, such as the country itself, its legal regulations and the individual risk associated with the product. It can take a few months to several years, depending on the case.

Based on our experience with the product in question and the specifications it has to meet, we draw up individual schedules together with the manufacturer as part of the initial project plan. To ensure scheduling that is as accurate as possible, we try to be as transparent as possible with regard to expectations. Nevertheless, the time required always depends on the case at hand.

And how much does that cost the manufacturer?

Zeller: That depends very much on the product. When you add up everything, the costs can range from ten thousand to hundreds of thousands. In our opinion, the fact that our

alliance and integrated project management enable the customer to save time and money in gaining market access is much more important.

To save money, manufacturers presumably also try to obtain certifications on their own. A lot of mistakes can be made along the way that can ultimately prove very expensive or even thwart plans to gain market access for good or for a long time. Once the horse has bolted, can those companies still turn to you for help? Do CSA Group and BSI act as a crisis team, as it were, to save what can be saved?

van Lochem: I wouldn't want to raise false expectations. Of course we will look at every case in detail and see how far the project has already advanced. We can then assess whether it makes sense to pursue the project or whether it might be better to withdraw the application and start anew.

However, CSA Group and BSI have a reputation to uphold. Our credibility vis à vis authorities in various countries is of enormous value to our customers and is key to our success rate. For an efficient certification process it's important that the authorities can trust that we are competent and that we ensure compliance with the applicable specifications. For this reason we would not want to jeopardize our reputation. It's great to be able to help manufacturers who encounter obstacles in their certification projects, but only if we can ensure conformity with regulations in the process.

Mr van Lochem, Mr Zeller, thank you for this interview. Given the large number of factors that have to be considered when seeking access to foreign markets, it's obviously important to have a competent service partner at your side. This avoids frustration and is probably also more cost-effective in the end.

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