The Critical Task of Selecting a Notified Body, Part Two

Since the dawn of the European medical device directives more than 20 years ago, the process of selecting a Notified Body has been an important undertaking. In the current regulatory environment, this process is even more critical. Part one of this article discussed Notified Body regulatory requirements and the Notified Body Operations Group. Part two covers important criteria to consider in selecting a Notified Body.

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As discussed in part one of this series[1], Notified Bodies play a vital role in the CE marking process of devices where Notified Body involvement is required. A Notified Body is designated by its European Competent Authority to conduct conformity assessments in accordance with various procedures in the medical device directives. The certifications that result from these assessments allow manufacturers to affix the CE mark to their devices and place them on the European market.

A critical criterion when identifying potential Notified Bodies is whether the Notified Body has been designated for the services required by the manufacturer. Not all Notified Bodies can certify compliance with all conformity assessment procedures in all medical device directives, nor are all device types necessarily covered. For example, relatively few Notified Bodies are designated to cover *in vitro* diagnostic medical devices. Not all Notified Bodies can certify conformity with quality system standards used to provide a presumption of conformity with the quality system requirements of the directives. Some Notified Bodies can provide services related to European requirements only, while others can provide quality system certification or audits useful in covering other regions of the world. In some cases, the location of Notified Bodies and their affiliate offices also may be an important consideration. The cost of services should never be the sole criterion for selection of a Notified Body; however, this can vary widely. Some Notified Bodies provide a high quality of service, including the conduct of effective quality system and technical file audits, while others leave much to be desired. These and other factors, tailored to the specific needs of the manufacturer, should be considered.

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Notified Body notification scope and location

Once a manufacturer has identified the applicable medical device directive and chosen a CE marking conformity assessment route, the scope of services of potential Notified Bodies can be used to begin the Notified Body selection process. The Nando website,[2] which is published and maintained by the European Commission, is an electronic register that allows users to search lists of Notified Bodies, including their location, the directives under which they may operate, the tasks for which they have been notified and other information. The Nando website's left-hand menu includes the following items: Country, Legislation, Body, Mutual recognition agreements, Notifying authority – Notification procedures, and Accreditation Body, among other categories. For example, a manufacturer interested in locating potential Notified Bodies in a particular country would click on Country, which opens a list of European countries where Notified Bodies operate. Clicking on a

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particular country opens a list of Notified Bodies operating under all legislation within that country. It is therefore necessary to filter for the desired medical device legislation, such as 93/42/EEC – medical device, which results in a list of Notified Bodies operating under that specific legislation. Clicking on the name of a Notified Body opens a page with its address and contact information, together with a list of the various legislations under which it has been designated to operate. Each legislation links to information on the Notified Body scope, including the products covered (described as product family, product intended use or product range), the directive conformity assessment procedures covered, and the corresponding annexes of the directives listed. It is also possible to begin a search for Notified Bodies by clicking on Legislation in the left-hand menu of the Nando site. This opens a list of European legislation, including the three medical device directives. Clicking on a particular directive opens a page with a list of the Notified Bodies operating in various countries that provide services related to that directive. Regardless of the information obtained on the Nando website, it is important to confirm the information found with the particular Notified Body of interest.

Quality system certification services

Under the European medical device directives, a manufacturer is provided with a presumption of conformity with the quality system requirements of the directives by complying with and being certified to harmonised standard EN ISO 13485:2012, Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003). Although quality system certification is not mandatory, most manufacturers use this method for demonstrating quality system compliance.

Some Notified Bodies, notably governmental Notified Bodies, are not accredited to certify quality systems to this standard and are only able to certify compliance to the quality system–related annexes of the directives. This means that a manufacturer choosing to use one of these particular Notified Bodies and also wishing to certify its quality system to the standard will need the services of two organisations, one for certifying compliance with the conformity assessment annex and the other for certifying the quality system to the standard. For this reason, companies should carefully consider whether or not the benefits of contracting the services of a Notified Body that can only certify compliance with the directives' annexes is beneficial.

Service coverage of other regions

The capability of a Notified Body to provide services that apply to regulatory jurisdictions outside Europe is another important consideration for some manufacturers.

For example, in Canada, medical devices are grouped into four risk-based classes with Class I devices presenting the lowest potential risk and Class IV devices presenting the highest potential risk. Before selling a device in Canada, manufacturers of Class II, III and IV devices must obtain a Medical Device Licence.

Health Canada requires medical device manufacturers to use a quality system certificate as evidence of compliance with the quality system requirements under Canadian law. Health Canada will only accept quality system certificates that have been issued by third-party certification organisations, called Canadian Medical Devices Conformity Assessment System (CMDCAS) recognised registrars. The Canadian Medical Devices Regulations require Class II, III and IV medical devices to be manufactured (Class II) or designed and manufactured (Class III and IV) under a quality system certified to CAN/CSA ISO 13485:2003. Manufacturers wanting to market their devices in Canada, therefore, may wish to select a Notified Body that is also a CMDCAS-recognised registrar.

In addition, some Notified Bodies have been designated by US FDA to be conformity assessment bodies (CABs), able to provide selected services, such as third-party regulatory review, under US regulations. Manufacturers considering the use of such services may wish to select a CAB-designated Notified Body.

Audit method and stringency

Unfortunately, some Notified Bodies have been known to conduct quality system audits that consist of little more than checking the existence of selected standard operating procedures, without adequately assessing whether the quality system requirements are being appropriately met or if the procedures have been properly implemented. The failure to provide effective quality system auditing services can have far-reaching effects for manufacturers, ranging from increased risks to patients and users of medical devices not adequately meeting quality requirements to increased risks to manufacturers with regard to product liability, reputation or the cost of product recalls. Ineffective quality system audits against European requirements also can affect a company's ability to meet quality system requirements of other regulatory jurisdictions. For example, manufacturers certified by a Notified Body for many years may have serious problems in meeting US quality system requirements, not primarily because of differences in the requirements, but because of differences in the depth of some Notified Body audits compared with US FDA inspections. It is recognised that a Notified Body's audit effectiveness is difficult to assess during the selection process; however, manufacturers should attempt to gain an understanding of how a Notified Body performs this critical task. At a minimum, manufacturers should discuss the Notified Body's audit methods to determine how they are conducted.

Team-NB and code of conduct

The European Association of Notified Bodies for Medical devices (Team-NB) is a not-for-profit association consisting of Notified Bodies operating under any of the three medical device directives: 90/385/EEC, 93/42/EEC or 98/79/EC. The stated purpose of the organisation is to improve communications with the European Commission, industry, Competent Authorities and user groups by acting as a focal point and the single voice of Notified Bodies; to promote high technical and ethical standards in the functioning of

Notified Bodies; and to protect the legal and commercial interests of Notified Bodies. According to the Team-NB website (www.team-nb.org), the organisation has 32 members. Although, manufacturers may not consider Team-NB membership to be a criterion for selecting a Notified Body, it does indicate that the Notified Body has the opportunity to share and exchange views with other Notified Bodies and that it endeavours to adhere to the Team-NB Code of Conduct, which currently applies to Notified Bodies operating under Directives 90/385/EEC and 93/42/EEC.

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Timing and the right decision

Manufacturers should not wait until the last minute to select a Notified Body. If a clinical investigation is being planned, potential Notified Bodies should be identified, where possible, before initiation of the study. The Notified Body's procedures for reviewing clinical data and its expertise should be discussed. Early involvement of the selected Notified Body in the clinical investigation strategy should help avoid costly problems that could occur if the Notified Body does not agree with the strategy for generating clinical data for the CE mark. Early contact is equally important if the medical device is complex or if its regulatory status is not straightforward, which can occur with drug-device combination or borderline products.

Careful contract review

Although discussion of all the steps in the Notified Body selection process is beyond the scope of this article, one of the most important activities is a careful review of the contract between the Notified Body and the manufacturer. Some Notified Bodies may interpret their roles in the conformity assessment process in a way that exceeds the requirements of the directives. For example, how the Notified Body approaches design changes may prove to be of critical importance once a device is available on the European market. Contracts that appear to overreach the requirements of the directives in this and other respects should be questioned and either amended or avoided.

References

1. M.E. Donawa, "The Critical Task of Selecting a Notified Body, Part One," *European Medical Device Technology*, 4, no. 4 (2013); www.emdt.co.uk/article/critical-task-selecting-notified-body-part-one
2. Nando (New Approach Notified and Designated Organisations) Information System; http://ec.europa.eu/enterprise/newapproach/nando/index.cfm

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