Q&A

NAVIGATE THE REGULATIONS FOR IN VITRO DEVICES

In-vitro diagnostic devices (IVDs) are subject to stringent regulation across the EU. Robyn Meurant, executive director for the IVD and medical devices regulatory team at **NSF**, talks to Medical Device Developments about the full import of these rules, and how the product testing company can help original equipment manufacturers deliver fully compliant IVDs.

What are the main points for in-vitro device (IVD) manufacturers to be aware of with regards to IVD Regulation 2017/746?

ROBYN MEURANT: Under the IVD Directive 98/79/EC (IVDD) a majority of IVDs (as many as 80%) were exempt from the requirement to submit to a notified body to obtain CE marking. This did not mean that they were exempt from the regulatory requirements, but rather that they could self-declare that a product was in conformity. With the introduction of a risk-based classification scheme in the IVD Regulation 2017/746 (IVDR), all medium to high-risk IVDs must have assessment of conformity by a notified body. It is now believed that at least 80% of IVDs will need notified body intervention. This requirement will impact not only new products to the market, but also those already CE marked.

Product manufacturers should also be aware that, under the new system, there will be no grand-fathering.

The concept of risk management is strengthened in the new regulations, especially its implementation throughout the life cycle of the IVD. Of note are the requirements to continuously review the risk assessment, as well as the need to eliminate or reduce the risk as far as possible. This later requirement is not new, but a common approach that does not apply is to reduce risk to as far as reasonably possible. Manufacturers who have taken this approach must revisit their risk assessments and associated solutions.

There are also a lot of new requirements for labelling, including the addition of a unique device identification (UDI), as well as additional roles and responsibilities for economic operators within the pre and post- market arena, whether that be the authorised representative, legal manufacturer, importer or distributor. As a result, the performance of the IVD will come under much greater scrutiny than under the previous regime.

What are the clinical evidence requirements for the IVDR?

Manufacturers must demonstrate clinical evidence based on a continuous process of performance evaluation. It means that manufacturers must now include evidence of scientific validity, a term used to describe clinical association of a marker with a disease state. For established IVDs, evidence in peer-reviewed literature can be used to support scientific validity and clinical performance; analytical performance must always be demonstrated by actual studies using the IVD. When evaluating the performance of an IVD, the process must take into consideration favourable and unfavourable data.

What is Eudamed?

Eudamed is an acronym for the European electronic database on medical devices, and is the tool designed for competent authorities primarily to strengthen market surveillance and transparency of IVDs and other medical devices by providing the authorities with fast access to information. It consists of the electronic systems for the registration of devices, the UDI database; the electronic systems for registration of economic operators, notified

bodies and certificates; performance studies; vigilance and post-market surveillance; and electronic systems on market surveillance. Manufacturers, or their authorised representatives, have a number of obligations under the IVDR with respect to registration and data input with Eudamed.

What is a PRRC?

A PRRC is a 'person responsible for regulatory compliance'. This is a new role that must be fulfilled for all manufacturers and is similar to that of a qualified person in pharma. Each manufacturer shall have at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of IVD and medical devices.

Small and micro enterprises do not have to have this person within their organisation but must have one permanently at their disposal. This person, as the name infers, is responsible for regulatory compliance, including ensuring reporting obligations are fulfilled. Authorised representatives are also required to have a PRRC permanently and continuously at their disposal.

What are the time frames for the EU IVDR and how can manufacturers prepare?

The main deadline for the EU IVDR is May 2022. Manufacturers are allowed to maintain their current certifications until they expire but there are a number of new post-market activities they are obliged to incorporate after May 2022 and the end of the certificate.

However, if a manufacturer makes a 'significant change' after May 2022, they have to switch to the new regulation. It goes without saying, therefore, that they have to be prepared. As most IVDs do not have certificates of conformity issued by a notified body, these products will need to meet the new requirements by May 2022.

Preparations among manufacturers should typically start with a gap analysis, which compares the current processes and procedures with what the new regulation requires. From there, they need to march though a very methodical, project-managed time line to start handling some of those gaps.

Many IVD manufacturers think that because they have an FDA 510(k) for their IVD that they will not have many gaps to fill. Worryingly, this is not the case. Equivalence of IVDs is much harder to demonstrate, especially with the emphasis in European law on demonstrating state-of-the-art capabilities in the product.

Indeed, the IVDR impacts on almost all functions of a manufacturing company, not just the regulatory affairs and quality assurance departments. It is imperative that senior management are aware of the extent of the impact and support the transition. Companies may need to rationalise their product range as well as decide whether they are going to hire additional resources to keep manufacturing in-house or if they will use third parties for some of these functions.

How does NSF International help companies implement these procedures?

An impressive offering at NSF International is its regulatory and quality training. We are continually producing e-learning resources and face-to-face training because regulations are constantly changing. If people haven't thought of some of these things, there is a fantastic e-learning module on the new regulation. Our staff includes ex-regulators from the EU, ex-notified body staff and internationally recognised IVD experts. NSF International goes beyond traditional consulting. There are people involved in clinical evaluation reports, technical file remediation and performance evaluation reports. They are now helping companies remediate those files and keep them updated. A call to action is the biggest message. Companies cannot wait for more guidance – they need to act now.

For more information visit **www.nsf.org**.

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