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Device Sponsors Should Be Aware of Variations in EU, US Systems

Sponsors of implantable and Class III medical devices are required to conduct trials in the EU only when existing clinical data is insufficient to verify a device's safety and performance.

Contrary to the U.S. system, which requires clinical trials for all high-risk devices, the EU permits certification based on available clinical data that demonstrates safety and efficacy, Christiana Spontoni, European partner with Squire, Sanders & Dempsey, said at an FDAnews webinar last month.

Also in the EU, clinical evaluation is done continuously for a device, both before and after certification, she said, pointing out the differences between the EU and U.S. systems.

EU Trial Standards

When clinical trials are necessary in the EU, they must be conducted under the harmonized requirements set out in the 2007 revision to the Medical Device Directives (MDD), Spontoni said. Sponsors must get an ethics committee to approve the protocol and then request authorization from a national competent authority (CA) to conduct the study. CAs have 60 days to act on the request, after which the sponsor is free to begin the trial, she said.

Sponsors must look at each EU member state's transposition of the MDD for variations, such as labeling requirements and languages. "This can be very cumbersome … and very much impact on manufacturers that produce in the EU or export to the EU," Spontoni said.

For combination products, the EU will consider the sponsor's claim, but the final decision on how to regulate the product is based on the scientific evidence, Spontoni said. The EU has no clear definition of "ancillary role," leaving the interpretation up to the notified body (NB), she added. However, the NBs are not bound by the decision of the drugs CA and can issue a positive opinion for certification even if the drugs authority claims the product is a drug.

By contrast, combination products in the U.S. are assigned to one of the FDA's three centers — drugs, biologics or devices — with participation from the other centers, Maureen Bennett, another partner in Squire, Sanders & Dempsey, said. "One of the things that we're seeing out of the task force on enhancing the use of scientific process within FDA is … a more organized, streamlined way of really sharing scientific information across centers," she added.

Regulatory Contact Encouraged

Similarities between the EU and U.S. systems include encouraging device sponsors to engage in early dialogue with regulators, using risk-based classification and increasing emphasis on postmarket surveillance.

Some proposed changes could bring the two systems closer together. For example, the FDA's 510(k) working group has suggested dividing Class II devices into Class IIa and IIb, with devices in the latter category going through a more rigorous premarket clearance process, Bennett said. The EU already has a Class IIb category. "That would be a very substantial and significant change, if implemented," she noted.

Efforts by the Global Harmonization Task Force, World Health Organization and others to harmonize device regulations globally continue to improve the playing field for devicemakers, Bennett said.

Areas most likely to see harmonization include coordination of inspections and information exchange about risk issues.

Acknowledging a trend toward international harmonization, Bennett told *CTA*, “Differences in the premarket approval versus certification processes … will [not] go away in the very near future, at least for the vast majority of devices.” — Meg Bryant