This way please

In May 2019, the European Medicines Agency (EMA) presented a draft of a new directive for quality standards of drug-device combinations (DDCs). It poses major challenges, in particular for medical device manufacturers.

Strict requirements for development documentation for the approval of drugs are a matter of course for drug manufacturers. Until recently, manufacturers of medical devices, in contrast, were subject to rather vague requirements under the Medical Devices Directive. This changed in May 2017 when the EU Medical Device Regulation (MDR) replaced the old directive and regulated the requirements for the documentation of medical devices in much more detail. The draft of the European Medicines Agency (EMA) with its regulation on quality standards for drug device combinations goes one step further.

What is at issue?

Drug device combinations (DDCs) consist of a device and a drug to be administered with it. A distinction is made between integral and non-integral DDCs. We speak of an integral DDC when a device – a syringe, a pen or an inhaler – is already filled with a drug during production. A non-integral DDC consists of an unfilled device that has been specifically designed for a particular drug and is packaged with the drug. For both variants, only the proof of efficacy of the drug had to be provided so far. Manufacturers did not have to submit any development documentation for the approval of the device.

This is now changing: For the first time, the EMA directive demands that medical device manufacturers must specify how a device influences the quality of the entire product. In the future, they will have to submit complete and precise development documentation for the device as well, including proof of integrated risk management. Over the next few months, this will create some bustle and the occasional outbreak of sweat, especially among medical device manufacturers. In contrast to pharmaceutical products, where the new requirements only apply to new approvals, medical device manufacturers also have to re-document products that have already been approved and register them anew. It's a Herculean task, with the clock ticking on top of everything else: The new directive is to take effect as early as 2020. An application for an extension of the deadline was rejected by the responsible EU authority.

Backed by experience through the thicket of regulations

Since the beginning of the year, Harro Höfliger has also been supporting customers in the development of new devices and medical products or in the optimization of existing ones with its "Device Services" offering. And although the company is neither a pharmaceutical manufacturer within the meaning of the German Medicines Act (Arzneimittelgesetz) nor a manufacturer of medical devices within the meaning of MDR, the service offering also includes preparing and providing detailed development documentation for the device. As a basis serves Harro Höfliger's compliance with the European ISO 13385 standard and the US Federal Food and Drug Administration (FDA) 21 CFR820 guideline. In recent years, both directives have converged to such an extent that they are almost identical.

In addition, Harro Höfliger incorporates the requirements of the ICHQ9 guideline into the device documentation and thus covers information on quality and risk management that must be documented. The three guidelines together meet all the requirements of the new EMA specifications. Consequently, Harro Höfliger customers receive detailed and EMA-compliant development documentation for their device, which they can use for their product approval.

Targeted support

There are already initial inquiries from customers, who in view of the structured device development documentation of Harro Höfliger also desire support with the documentation for their complete product. This shows the degree of uncertainty regarding the new EMA Directive. With our experience in the field of machine and device documentation as well as the ALL YOU NEED service philosophy, Harro Höfliger can provide extensive support in this area. ■

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