Regulatory 101 Questions When Designing a Stick to Skin Wearable Device

The greatest way to reduce cost and time-to-market when designing a stick to skin wearable device is to prioritize regulatory compliance and quality standards from the very beginning of product development.

From materials selection to prototype manufacturing, it's advantageous and imperative to collaborate with suppliers who are **ISO 13485** certified and compliant. The designation should be considered with material science companies (adhesive manufacturers), converters manufacturing the adhesive tapes into usable parts for assembly, and the contract manufacturers assembling and packaging your final device. This means their facilities' quality management system meets rigorous standards for the design and manufacturing of medical devices. ISO 13485 demands a thorough documentation process for all quality documentation record keeping as well as manufacturing and quality procedures in a manufacturing environment.

There are other quality and safety-related criteria to seek in the wearables supply chain. Some basic questions that companies new to the wearable patient monitoring space should be asking potential material and manufacturing suppliers are:

- Does a supplier have clean room processing capability at both pilot-line and high-speed production levels?

- What level of clean room does the manufacturer use?

- Are sterilization services available?

While such questions may seem low on the priority list when compared with issues around data compatibility and wearable signal accuracy, they may need to be addressed later on to document patient safety.

In addition, when suppliers' operations are registered with the appropriate regulatory agencies in the United States and globally, this will help streamline the path to regulatory approvals for the wearable down the road in the product launch process. When any major considerations affecting product quality and safety are addressed sooner rather than later, the OEM stands to streamline wearable development.

Reference: 1. Prakash, Deepak. Reduce Cost and Time to Market for Medical Wearables. 29 Aug. 2016, www.mddionline.com/digital-health/reduce-cost-and-time-market-medical-wearables.

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