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Device innovation and regulatory bodies

The impact of regulatory requirements on bringing medical devices to market

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When we talk about bringing a new medical device to market, many steps are involved in the process. From our experience of working with medical device OEMs and developing medical adhesives for over 55 years, one of the very first and most important steps in this process is to put together a full-service team of experts. A strong team is built with people of unique skill sets; their varied expertise ranging from quality to regulatory, clinical, laboratory and manufacturing will help build a solid foundation on which your product is built.

Let's take a closer look at what happens when you work with regulatory experts. The regulatory experts work and learn about the regulatory environment in which medical device customers operate. They understand the challenges medical device manufacturers face in the regulatory arena and can help support the go-to-market process. With this in mind, let's examine the overall global regulatory environment for medical devices.

If you're looking to get approval to market for your medical device, there are a lot of tasks to complete. Depending on your device, in it's indications or the presence of drug or biologic components, submissions to the U.S. FDA, EU Notified Bodies or Competent Authorities, and other regulatory bodies are not out of the question. Many medical devices are brought to market with global teams. New products may be designed in one country, manufactured in another country, while being supported operationally around the world. While a medical device may be produced with the intent to sell in the United States, many companies have ambitions to help patients globally. An FDA approval may be the first of many steps to get a new product out the door.

As a global leader in the health care industry, 3M supplies the medical device manufacturing, design, and supply industries with a carefully selected line of medical grade tapes, coatings and adhesive technologies and semi-finished components. We offer a wide variety of adhesive, backing and tape construction options for different manufacturing processes and patient populations. As a product designer, know there is a difference between using a 3M component as a layer between other components and using a 3M component as a stick to skin solution.

If you're using a component as a layer between other components of your medical device, little more than a 3M product composition report on the component part may be needed for your internal records or submissions.

However, if you're using a component to adhere a device to skin, more may be expected by the FDA or other regulatory agency reviewer. When adhering a device to skin special attention should be given to the final, finished device's composition and biocompatibility, inclusive of the 3M component(s).

Composition and component technical information sheets are helpful for regulatory submissions, and this is something that 3M provides to its customers. Composition information is split between two documents - the first is an Article Information Sheet, which summarizes the raw materials present in the component, and a Regulatory Data Sheet, which provides statements about compliance to various regulations, such as U.S. Proposition 65, EU REACH, Chemicals of Concern status, and more. Transparency of our component construction and its regulatory status across the globe will help the medical device manufacturing team make informed decisions and may give some peace of mind in knowing the products used are compliant. Composition information is available at sds.3m.com.

Enough about composition. What about biocompatibility? Our clinical team can provide essential biocompatibility information for 3M components in the form of clinical summaries. These summaries provide an overview of the cytotoxicity, irritation, and sensitization studies conducted in accordance with ISO standards. These summaries show 3M has done its homework and that the components are safe for use on intact skin. Summaries can be found at: www.3M.com/MedTech > Technical Information > choose 'Biocompatibility Summaries' under 'Select Medical Device Components Bulletin Type'.

Be aware that these clinical summaries and biocompatibility reports on the 3M component alone may not be enough for the regulatory reviewer. Once a 3M component is added to your device, the reviewer may expect biocompatibility be conducted on the final, finished device. Cutting, sterilizing, and other processing of the component could prompt the regulatory reviewer to ask for biocompatibility on the final, finished device inclusive of the 3M component you are purchasing. The US FDA especially recommends that biocompatibility be conducted on the final, finished device - bridging 3M biocompatibility data will likely not be acceptable to many reviewers.

Your speed to market is top of mind, especially in a market as dynamic as healthcare. 3M recommends that customers should conduct their own biocompatibility tests to ensure that the finished device is safe and to avoid regulatory submission issues or delays. Worldwide, 3M Healthcare has global operations in over 70 countries and has delivered over 10,000 products across diverse regulatory environments; we invite you to trust us with yours.

The process of bringing a medical device to market can be a challenging journey, but an exciting one. Expanding your team with external experts, particularly in regulatory field, to help you through the obstacles can help alleviate the pressure.