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Roadmap to bringing your medical device to market: 5 stops to consider

By Brian Ochs, Quality Manager

The path to bringing a medical device to market is usually winding, but working with an experienced partner that will guide you through the process can make it much more navigable and efficient.

We generally encounter five main phases when working with OEMs to launch a new medical device. The following is an overview of what your journey could look like with tips and best practices to consider.

1. Assemble a full-service team of experts

One thing is for sure, step one is always to assemble a full-service team of experts. A strong team is built with people of unique skill sets; the varied backgrounds of experts from quality, regulatory, clinical, laboratory and manufacturing should be the foundation on which your product is built.

- Quality: These folks make sure the product requirements are understood and then translate them into specifications. It's their job to set the project up for long-term success by ensuring product stability and repeatability.
- Regulatory: This team makes sure the i's are dotted and the t's are crossed by getting the documentation in place and ensuring compliance with specific regulations in the countries in which the device will be sold. The regulatory team also provides input on technical and clinical summaries to support device registration.
- Clinical: The clinical team conducts testing to ensure proper product function and safety. The test results are used to support any claims made in documents needed for submission to regulatory bodies in the countries in which the device will be sold.

5 stops to consider along the roadmap to success

1. Assemble a full-service team of experts
2. Establish product requirements
3. Prototyping
4. Commercialization
5. Product support

- Laboratory: The lab team can also be thought of as the experimentation team. They help you transition from a concept to a fully-functional device that is ready to scale. They also typically provide input on technical documents necessary to support device registration.
- Manufacturing: When the prototype is ready to have trials run for scale-up during commercialization, the manufacturing team gets involved to make sure the correct equipment and processes are in place.

2. Establish product requirements

Once your team is built, it's time to learn about your device's needs. This is where the details start to get ironed out and take shape.

During this phase, the intended application and material requirements are discussed (e.g. the device's intended duration of use, the materials the device might be made from, what type of substrate it's intended to stick to, etc.). To understand material requirements, different adhesive and backing options, among others, should be discussed.

From there, a confidential disclosure agreement and/or a quality agreement may be drafted to ensure expectations are understood and parties are protected.

3. Prototyping

Now that the product requirements are established, it is time for your device to take shape and come to life. Let the prototyping begin!

Not all components are meant for all applications — and keep in mind that there are some incompatible combinations. Different combinations of materials and adhesives should be extensively tested to determine the best option for your device.

The prototyping phase can take a few days to a few months, depending on the complexity of the device and experimental results.

4. Commercialization

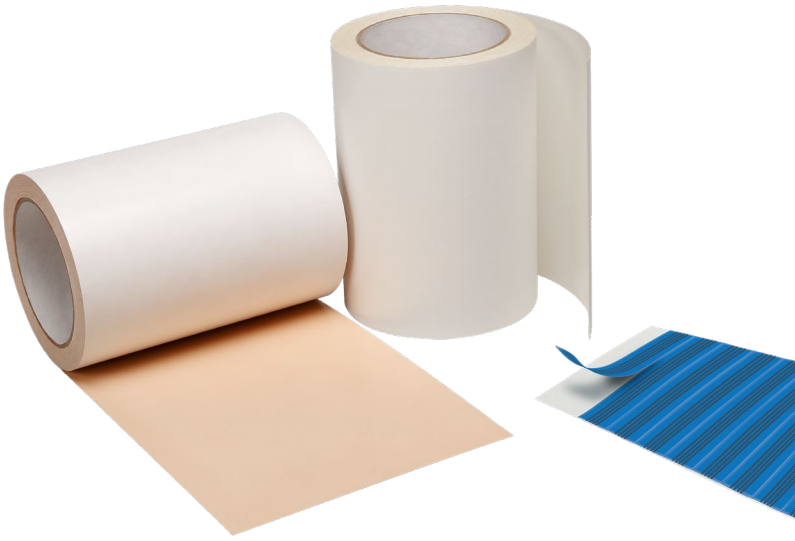
Before your device is ready to hit the market, it will be put through a variety of tests to ensure safety, functionality and reliability. While not a comprehensive list, below are the main tests your device may go through.

- Product stability testing: The materials are exposed to different temperatures and varying levels of humidity to simulate accelerated and/or real-time aging.
- Design verification/validation: The product is tested to ensure it is meeting requirements consistently and feedback is provided.
- Process validation: This protocol relates to the manufacturing process. It challenges the equipment and processes to make sure they're able to produce the product dependably.
- Regulatory and safety reviews: Be sure all documentation is in place for each country in which the product will be sold.

5. Product support

Your product is officially launched and available for purchase — congratulations! Once sales start flowing, product issues could be a serious threat to your company. It is critical that your partner checks in about how your device is performing. If an issue arises, you need to feel confident that it will be resolved quickly — responsiveness and dependability are crucial.

The process of bringing a medical device to market cannot only be a challenging journey, but an exciting one. Expanding your team with external experts to help you through the obstacles can help alleviate the pressure.



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