Proclinical
Part of Acacium Group

The medical devices development process

In general terms, a medical device is any product or equipment that is intended for health purposes. These devices help to diagnose and treat conditions, allowing patients to prevent, overcome and manage diseases, prolonging and improving quality of life. Medical devices range from digital thermometers and adhesive bandages to complex programmable pacemakers, and implanted cardiac defibrillators.

The medical device development process turns an inventive idea into a safe and effective product fit for medical use. This innovation is usually prompted by the longing to create better clinical outcomes, less invasive procedures, or a shorter recovery time for patients.

3-7 years
for a medical device to make it from planning to market

Classes of medical devices:

Class I Devices

These are the quickest devices to gain approval for as they involve the lowest risk.

Examples:
Oxygen masks, electric toothbrushes and bandages

Class II Devices

Class II devices have a moderate risk associated with them. Around 40% of devices fall under this category and the manufacturer needs to be able to prove device safety and efficacy through substantial comparison to another approved device.

Examples:
Contact lenses, catheters and syringes

Class III Devices

These devices are the most invasive and pose the highest risk to patients. Class III devices account for around 10% of devices. They also require the most rigorous checks during the development process in order to attain approval.

Examples:
Defibrillators, implanted prosthetics and cochlear implants

Research & planning

Regulatory process

The regulatory process involves demonstrating to relevant health bodies, such as the FDA or EMA, that the medical device in question is fit for purpose. The regulatory team will provide advice at all stages of the process. As product developers work to bring the concept to reality, the regulatory affairs team advise on appropriate regulatory strategies to ensure the product can be approved and legally marketed. Once the device design is ready, the regulatory affairs team need to draft a successful marketing submission. If the device gets approved, the regulatory team is involved in post-market surveillance, ensuring that any adverse events or malfunctions are appropriately reported to the relevant bodies.

Discovery

The development process usually begins when researchers see an unmet medical need or the prospect to improve an existing medical process. Once an opportunity has been pinpointed, they will create a concept or come up with an idea for a new medical device. At this stage the marketing requirements of the new product will also be outlined, defining who the user would be, the intended use of the product, what the regulatory requirements would be, and what legal requirements the device would need to meet.

Concept

Once an idea has been decided on, researchers will put together *"proof of concept"*. This document aims to demonstrate the viability of an idea by identifying any logistical or technical issues that might affect the device's success. Many concepts will not succeed past this stage but ones that are feasible will move on to the latter phases of development.

Design and development

Prototype

Engineers and researchers build an early version of a medical device. At this stage, the device prototype is not for human use.

Preclinical research

Researchers test the prototypes in controlled laboratory settings. A prototype device will undergo a cycle from preclinical testing to redesigning, to preclinical testing of the redesign, and so forth. Once the design has been refined and tested, it is then ready to be tested on humans.

Risk management

Every medical device must go through a rigorous risk management process that is compliant with ISO 14971, the internationally recognised risk management standard for the medical device industry. The ISO 14971 allows manufacturers to identify hazards associated with medical devices, estimate and evaluate associated risks, control identified risks, and monitor the effectiveness of risk-management controls.

Verification and validation

While verification and validation are both elements of the medical device testing process, they serve two very different but equally essential functions. Verification determines whether the right product was built and checks whether it meets the needs of the user. Validation is the process of ensuring that the medical device being manufactured will function safely and appropriately.

Clinical

Clinical trials

The clinical trials process for medical devices is similar to process of testing new drugs – there are strict regulations, safety and ethical requirements, and the process is split up into a series of phases. The clinical trials process will depend on the classification of the device. In some markets, Class I devices are considered to involve such low risk that they do not require clinical trials. Most clinical trials for medical devices will be outsourced to clinical research organizations (CROs). A clinical evaluation report (CER) will be filled out to document the conclusions of the clinical evaluation of the medical device.

CRO

Medical affairs

The medical affairs department will communicate information about the medical device to the wider community so it is important they have an input in the clinical trials phase. Their learnings in this stage will help them to formulate the provision of information that is used in subsequent publications.

Clinical operations & safety monitoring

The clinical operations team are responsible for overseeing clinical trials and ensuring they are running on time, within budget, and are compliant with regulations and procedures. During clinical trials the medical device is assessed for any risks. Throughout the development process safety is paramount, and monitoring continues even after the medical device has been approved.

Market Access

Once the initial clinical trials are complete, the market access team will gather real-world evidence to plan how the device will be positioned. They will ensure the device is marketed at a reasonable price in line with its effectiveness.

Biometrics

The biometrics team will check the data and findings from the clinical trials process and uncover any critical insights that may be hiding within the data.

Production

Manufacturing

Medical device manufacturing includes all aspects of the fabrication of fabrication of the product, from designing a manufacturing process to scale-up, to ongoing process improvements. It also includes the sterilization and packaging of a device's element. The way in a medical device is produced will depend on its design, but will usually involve processes such as 3D imaging, additive manufacturing/3D printing, and laser manufacturing.

ISO 13485

Quality assurance

Throughout the production process, quality assurance specialists will make sure products are safe, fit for purpose, and consistently of a high standard, in line with the ISO 13485. The QA team aim to prevent flaws in the way a medical device is manufactured and look for problems in processes that might result in nonconforming products. If any problems are identified, they will aim to fix processes that would otherwise cause defects.

Quality control

Throughout the production process, there is a critical need for consistent quality to ensure every device meets the correct standards. Quality control tests products of devices to see whether they conform to product specifications. The goal is to catch defective products before they reach the patient.

Commercial

Sales and marketing

Once the medical device has been approved by regulatory bodies and has the correct marketing licence for that country or region, it is ready to be marketed and distributed to healthcare providers. Sales reps will work strategically to increase the awareness and use of the device. They will travel around to sell the device to a variety of healthcare professionals, including general practitioners, hospital doctors, surgeons and pharmacists. The marketing department will ensure the product and brand are represented effectively.

Sales support

Application specialists, clinical/surgical trainers, and field service engineers will also be heavily involved in this part of the cycle to ensure the sales team have the knowledge and materials they need to sell the device safely and effectively.

Post-market surveillance

Once the device is available, manufacturers will continue to collect and evaluate data to identify if they need to take any action. Post-market surveillance helps ensure that the medical device continues to be safe and effective. The evaluation of post-market surveillance experiences can also highlight opportunities to improve.

It is important to note this is just an average timeline of device development and the specifics of each company's path to market will vary based on their unique products and set of circumstances. The development process will also differ depending on the device's classification.