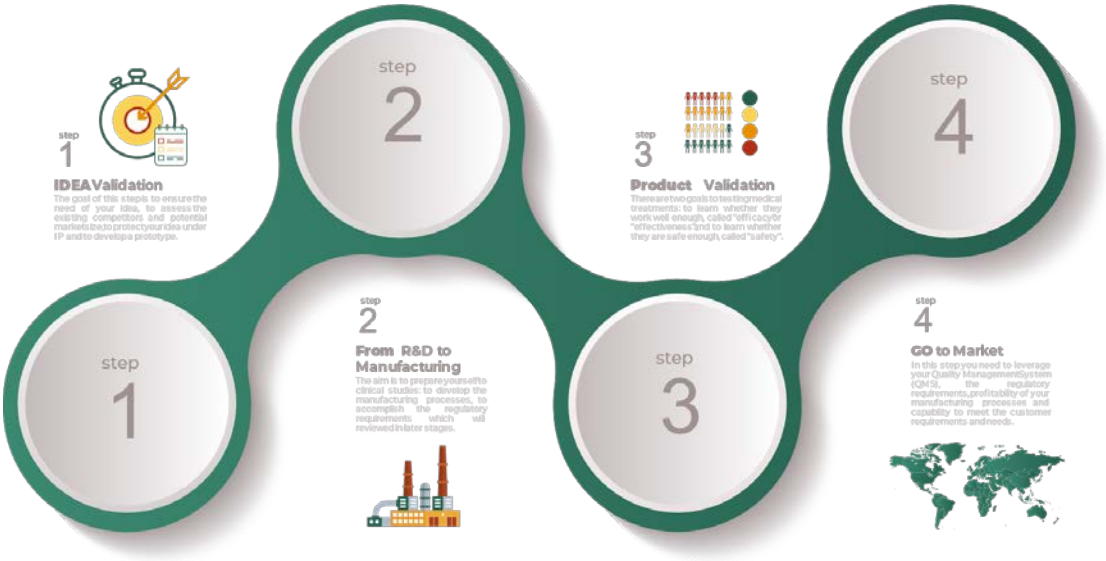
Medical Device Roadmap from Idea to Market

Commercializing medical technology is challenging, often requiring 10 – 20 years just to bring new ideas to market. There is an essential need for better understanding of the overall process to the market. Challenges arising from time delays, misalignment with regulatory requirements and resource constraints potentially amount to substantial losses in value, for both companies and patients.

The aim of this short guide is to assist in the understanding of how commercialization and adoption of medical technology innovations in ecosystems can be achieved.

To simplify the understanding of the overall journey to the market we divided it into 4 phases: prod



1. IDEA VALIDATION

The goal of this step is to ensure the need for your idea, to assess the existing competitors and potential market size, to protect your idea under IP and to develop a prototype.

2. FROM R&D TO MANUFACTURING

The aim is to prepare yourself for clinical studies: to develop the manufacturing processes, to accomplish the regulatory requirements which will be reviewed in later stages.

3. PRODUCT VALIDATION

There are two goals to testing medical treatments: to learn whether they work well enough, called “efficacy” or “effectiveness”; and to learn whether they are safe enough, called “safety”

4. GO TO MARKET

In this step, you need to leverage your Quality Management System (QMS), the regulatory requirements, profitability of your manufacturing processes and capability to meet the customer requirements and needs.

1. IDEA VALIDATION

The goal of this step is to ensure the need of your idea, to assess the existing competitors and potential market size, to protect your idea under (Intellectual Property) IP and to develop a prototype.

1.1. Clinical need

So, you have an idea for an amazing product, which you believe will make the world better and healthier. Before you begin the Research and Development (R&D), make sure there is a clear clinical need for your product, and specifically if it could be a “game-changer”. Establish the medical segment and claims you will be addressing. This due diligence will prevent you from wasting time and money on an idea that may not be needed.

1.2. Market research & assessment

Conduct market research in order to understand and assess how the existing companies target the same clinical need and how your new device will add value to what is already available on the market. In addition, market research will assess the potential size of the market for your medical device. This assessment is crucial for when you present your business proposition to potential investors. There are a number of methods to conduct market research and assessment, including professionals who specialize in this type of research.

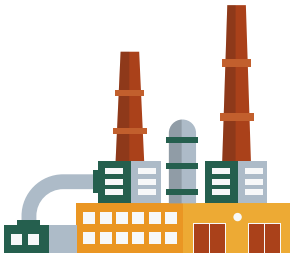
1.3. Intellectual Property

Law firms specializing in Intellectual Property conduct an assessment of the patents in this area and determine your Freedom to Operate (FTO)- the ability of your Company to develop, make, and market products without legal liabilities to third parties (e.g., other patent holders). In the Biological and Biotechnology space, the IP is an integral part of your submission package.

2. PROOF OF CONCEPT

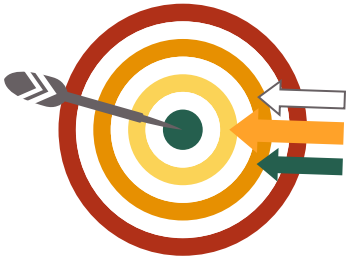
Besides dedication, your team is the most important factor for success. This team will help you determine the functional and operational volume you require in order to develop the prototype. Your initial development phase will include the need to "choose" between the alternatives for the prototypes you would like to take to the final stages of concept review and decide upon the winning concept – this will be your proof of concept.

2.1. From R&D to Manufacturing



Now, you know that your idea meets the customer need, you know your competitors and potential market size, it is protected by IP and you have a proof of concept. The next goal is to reach the Clinical trials. The following steps shall be achieved prior to these trials (The order of tasks is only for demonstration- you can perform them consequently or in parallel).

2.2. Regulatory strategy establishment



The initial regulatory strategy should be created early in the development phase, prior to progressing into testing or even establishing a Quality Management System (QMS). It is essential for a company to have an understanding of the regulatory roadmap in order to provide the guideline and requirements for almost all of the activities concerning the product development and manufacturing, as well as enabling early interactions with health authorities.

Having a regulatory expert can help you to define the requirements of your application dossier (FDA, EU-MDR Vs MDD, ROW). These requirements vary depending on device classification. You will also need to appoint a Notified Body to assess your device and an Authorized Representative to overlook this process for marketing in the EU, given your company is based outside the EU.

2.3. Establishment of selected chapters of a Quality Management System

For medical device companies (per relevant class), the expectations from the quality system are that you have all parts and pieces written and implemented by the time you market the device (or perform design transfer).

Many of the requirements (both FDA QSR regulations and ISO13485) also apply to you even prior to marketing, as they enable the organization to establish the desired design controls required to hold an inclusive Design History File (DHF).

If you are undergoing development, there are, at minimum, 5 parts of a quality system that you should have in place:

- Design Controls
- Risk Management
- Document & Record Control
- Supplier Management
- Basic Quality Management System elements (i.e., Changes, nonconformances, complaints etc.)

Early on (during the concept phase), you don't need to spend too much time establishing and implementing all parts of quality systems, since it is important you focus on the product development, however it is recommended to realize that the medical industry will require the working environment governed by Quality Management System.

2.4. Manufacturing process development

Now you are planning to move to production of pre-clinical and clinical products. This usually will introduce modifications to the manufacturing process done under the development umbrella. If this is done, a change management process will modify the existing production process and will include a project to build a suitable manufacturing plan (the plan should include pre-clinical and clinical products where you will have to manufacture a certain amount of product).

The main keys to success in manufacturing processes & compliance with regulatory requirements are correct characterization and planning of the processes, equipment, utility and facility, as well as integrating Quality Assurance into the process as early as feasibly possible. All these will ensure an easier, safer and less expensive downstream outcome.

2.5. Manufacturing process qualification

The pre-clinical and clinical trials are expensive and complicated processes, you want to be ready for them and prevent the risk of the device malfunctions due to the poor quality of the product.

Producing devices for clinical testing does not require a validated manufacturing process, but it is reasonable to expect the equipment used in production to have been properly installed and capable of operating as intended.

Upon design freeze (the step of design control, where the manufacturing processes are finalized, as well as suppliers and raw materials, are approved, to ensure reproducibility of the manufactured device) the following shall be achieved (from the regulatory aspect and to ensure robustness and reliability):

- Facility, Systems & Equipment qualifications- (Installation & Operational Qualification)
- Test Method Validation (TMV)- the processes for the release tests shall be validated
- Packaging and Shipment Validation– since the product shall be transferred to Pre-Clinical and Clinical sites, it is necessary to validate these processes prior to these studies
- Sterilization process Validation- For the sterile devices, shall be validated prior to Clinical studies

3. PRODUCT VALIDATION

You have your regulatory strategy in place, as well as selected chapters of QMS are implemented. You also have the required amount of devices manufactured for Pre-Clinical & Clinical trials. Now is the time to initiate the studies. There are two goals in testing medical treatment: to learn whether they work well enough, this is known as “efficacy” or “effectiveness”; and to learn whether they are safe enough, known as “safety”. Neither is an absolute criterion; both safety and efficacy are evaluated relative to how the treatment is intended to be used, what other treatments are available, and the severity of the disease or condition. All these elements are also covered in the company’s risk management program.

3.1. Preclinical Studies

Deciding whether a device is ready for clinical trials. The ultimate goals of pre-clinical studies are to asses with the highest potential accurately model, in animals, the desired biological effect of a product in order to predict treatment outcome in patients

(efficacy) and to identify and characterize all toxicities associated with a product in order to predict adverse events in people (safety). Pre-clinical tests include animal testing, toxicology, sterility and biocompatibility testing. To accommodate this, you will have to manufacture a certain amount of product, which is also amongst the reasons for implementing your manufacturing quality system before conducting pre-clinical studies.

3.2. Product registration

Clinical trials generate data on safety and efficacy. They are conducted only after they have received health authority and/ or ethics committee approval in the country where approval of the therapy is sought. These authorities are responsible for vetting the risk/benefit ratio of the trial—their approval does not mean the therapy is 'safe' or effective, only that the trial may be conducted in their region.

3.3. Clinical Trials

You've reached the huge goal where it's time to initiate the clinical trials. To do so you will need to have the following in place:

- Receive approval from your target country's health authority and relevant institutional review board/independent ethics committee (IRB/IEC);
- Successful preclinical results;
- Successful design verification results (design inputs meet the design outputs);
- Risk Management Report (including benefits outweighing risks);
- Relevant parts of the quality management system implemented.

Clinical trials are experiments or observations done in clinical research. Such prospective biomedical or behavioral research studies on human participants are designed to answer specific questions about biomedical or behavioral interventions, including new treatments and known interventions that warrant further study and comparison. Clinical trials generate data on safety and efficacy. Clinical trials are usually a heavy burden on the company's budget, therefore having a clinical expert guiding and/ or managing the clinical efforts can reduce expenses at a very effective percentage.

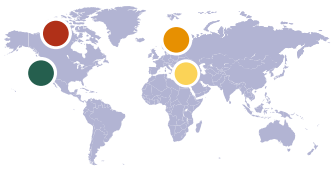
3.4. Gaining reimbursement and clearance for marketing

Here is where your reimbursement strategy is put into practice. Once your reimbursement consultant has helped you gather all the necessary documentation for each target country you are ready to start complying with their respective reimbursement procedures. The health authorities will now decide if your device should have a reimbursement price or if it should be integrated into a healthcare plan.

Your consultant will also help you negotiate the pricing of your device with the health authorities.

At the same time, you will need to gain authority approval to get your device registered in your chosen markets.

4. GO TO MARKET



Congratulation, you passed all the obstacles on the way to the market!!! In this step, you need to leverage your Quality Management System (QMS), the regulatory requirements, profitability of your manufacturing processes and capability to meet the customer requirements and needs.

4.1. QMS compliance

In this step, the full Quality Management System needs to be in place, in accordance with ISO and/or FDA requirements (depended on the market you intend to access).

4.2. Moving to routine manufacturing process

Now you are planning to take the small capacity manufacturing process to the next phase of routine manufacturing. This may require modifying an existing production process (which may also include scaling-up).

The product profitability is depended on the manufacturing product efficiency.

4.3. Manufacturing process validation

Prior to commercialized step the following shall be achieved in term of Manufacturing Process Validation:

- Facility, Systems & Equipment qualification (IQ, OQ, PQ)
- Test Method Validation (TMV)- for all tests and verifications during the production and tests for Equipment Qualification
- Computerized system validation (CSV)
- Process Validation: Sterilization, Cleaning, Manufacturing,
- Shipping & Packaging Validation
- Cleaning Validation

4.4. Initial commercialization/ Limited introduction

Bring in your commercial team, it's time to start the seeding trials. This is the first market where you will commercialize your device so you should have your commercial strategy set in place. Based on your first market feedback, determine whether your

device is ready for commercial expansion. Set up distribution contracts in your different markets and monitor product delivery.

CONCLUSION

To shorten the process from idea to market, it is necessary to become familiarized with the regulatory requirements at each and every stage. This will allow you to save money and time during your journey to market, and increase the quality of life or even save patients' lives when you are in the market.

It is mandatory that you involve experts from various disciplines during the different lifecycle stages of the company, such as Regulatory Affairs (RA), Quality Assurance (QA), Engineering, Validation personnel, Process Development personnel, Clinical Affairs (CA). It is also suggested to use outsource resources to provide your company with the maximum benefits which will allow you, on the one hand, to focus on the product development, and on the other to shorten time to launch your product while preventing mistakes and unnecessary delays.

If you have any questions, or if you need professional support, please contact us: info@rs-ness.com

RS NESS provides an umbrella of services to the Life Science industry at different lifecycle stages incorporating end-to-end project activities while adhering to the regulatory requirements. Knowledge, professionalism, and dedication lead our highly qualified team to your success.

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