

### Introduction

No matter the medical device or product, no matter how brilliant you know your idea may be, applications of medical devices are specialized, and therefore, the chain of events that bring that product or device to market usually follow a well-thought out course of action. Awareness of what needs to get done is the first big step in getting a medical device from concept to completion. This is where experts are brought on board to successfully navigate the process. After all, the goal is not just to create a masterpiece; the goal is to have others actually use the device and monetize a brilliant concept. Spend significant time at the front end of the process discovering what the marketplace needs, rather than creating a glossy marketing campaign to sell something no one may want. Next, find experts to assist in each process phase. Last, but certainly not least, keep your arms and legs in at all times and enjoy the ride.

[http://www.mpo-mag.com/issues/2017-03-01/view\\_features/navigating-the-12-steps-of-medtech-development-264519/26679](http://www.mpo-mag.com/issues/2017-03-01/view_features/navigating-the-12-steps-of-medtech-development-264519/26679)

### 1. Identify Worthy Ideas Innovations & Inventions

It's important to have an understanding of the differences between creativity, invention, and innovation. Creativity is the ability to come up with new ideas or concepts. It has nothing to do with value or monetizing the idea. Innovation is the process where value is created in the form of a new solution to a problem, and occurs when a need is identified and a product is developed to meet that need. Innovators use existing technology in new ways. Invention, on the other hand, involves a filed patent. It results in a better mousetrap and new way of doing something, and is an improvement or new idea that must be proven to be different and often superior. Paramount to moving the idea, innovation, or invention toward success is remembering that it will not be worth much if nobody wants to buy it. Identifying consumer wants and needs, and subsequently developing the product or service to meet them, is an initial step that must be completed before moving onto other steps in the process..

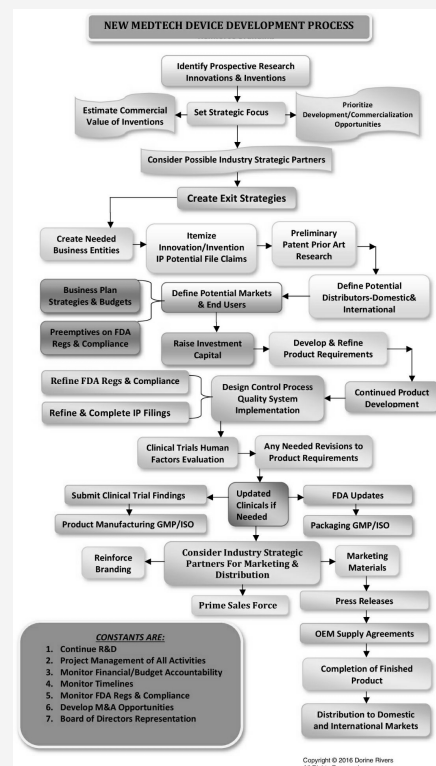
### 2. Patent Research, IP & Development

This includes researching existing and/or potential competition, as well as patent defense mitigation. The protection of intellectual property (IP) is essential to your project. In return, it stimulates medical advances, economic growth, and the introduction of new medical devices. You will be better positioned for compensation for your contribution to the field when the necessary and cautionary steps are taken to secure the concept. Unless you are a knowledgeable patent attorney that is able to complete these tasks, it is advisable to find one to advise and help legally and properly bring the concept to fruition. A reputable project developer will have worked with competent patent attorneys and can suggest one if so desired.

### 3. Develop Business Formations

What business name and what type of business entity will you select for your project? Entity options may include a C Corporation, S Corporation, or Limited Liability Corporation (LLC). Both legal and tax advice will help you decide which entity will serve you best.

### Medtech Development Process



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### 12. Taking the Lead

Leadership throughout the development process, including research and development, executive and general management of operations, intellectual property, regulatory affairs, quality assurance, process engineering, and domestic and international manufacturing operations for GMP/ISO medical device manufacturers are some of the qualities needed to keep the process afloat. The project developer and project managers will assist in this complexity of organizational and management skills, leaving you time to think of your next great idea..

### 4. Strategic Alliances for Investment Capital

Finding money is almost always one of the first problems that arises. Many investment avenues are available including, but not limited to, angel, private placement, venture capital, bridge, initial secondary public offerings, and family and friends. As in all other aspects of this process, a knowledgeable, competent investment advisor may save you time, money, and even the viability of your project.

### 5. Asset Growth

Create asset growth through identification, development, and execution of innovative technology-based products via business plans and strategies, and then continually monitor progress.

### 6. Oversight of Financials

Implement and oversee financial activities, including budgets, accounting systems, and financial reporting. Engaging competent advisors, conducting periodic reviews of the financial status of your company, and maintaining proper records will aid you in presenting your company accurately and completely each step of the way.

### 7. FDA Registration, Regulatory & Compliance

This segment of the process will end your project quickly if you do not dot all of your i's and cross all of your t's. It is ongoing throughout your device development and is an intricate part of every step you take. The first item the FDA looks for in a submission is how the product was developed. Did the developer follow a formal Design Control Process and do they have evidence of compliance with the process? Generally, design controls for medical devices are part of a broader Quality Management System (QMS) for the developing company.. When a U.S. Food and Drug Administration (FDA) investigator reviews your design control requirements, they will evaluate the control process, not determine if the design is appropriate, safe, or effective.

### 7. FDA Registration, Regulatory & Compliance (cont)

The challenges of incorporating the design and development process into your QMS can be daunting. Since a significant number of medical device recalls are due to design problems, it is advisable for design controls to be in place prior to approval of the system-level requirements document and after completion of the feasibility phase..

### 8. Clinical Trials/Studies Project Management

#### Clinical Trials/Studies Project Management, Execution, and Compliance

Managing clinical trials of any size and complexity requires an expert in this particular field. This portion of the device development process will have five inherent process stages: initiating, planning, executing, monitoring and controlling, and analysis and reporting. Select a trial manager who knows how to include the details of the arrangements for developing and monitoring all aspects of the clinical trial, and also possesses the communication skills to keep you up to date.

To select a trial manager that will properly serve you and the specific clinical trial your device or product requires, take care to discover the following attributes.

1. Qualify the contract research organization (CRO) by visiting the facility and checking out the range of expertise within the CRO. Hold meetings with management, scientists, and quality assurance personnel who would be involved in your trial.
2. Ensure the proposed CRO and selected professionals within that company are capable of doing the kind of work required (device vs. product vs. procedure) and they work well as a team.
3. Conduct an investigator meeting where all investigators and site staff are informed of the particularities of your clinical trial. During this meeting, be sure to provide background information for the clinical trial, why it is being conducted, and its clinical endpoints. This meeting is interactive in nature, and gives the participants a chance to ask questions.
4. Since the clinical trial must be supervised by a qualified person, confirm qualifications specific to your applicable regulations and guidelines.

### 9. Sales, Marketing & Branding

The market for medical devices is not a single channel, but rather a plethora of buyers in various audiences, such as doctors, hospitals, clinics, and consumers. Regardless of the product, it is imperative to get doctors on board with the device. If the medical professionals in your intended marketing space don't believe the device is effective and/or it is too difficult to use, they won't use it. And word will spread.

### 9. Sales, Marketing & Branding (cont)

It's also important to implement a consumer campaign because consumers are going to investigate what procedure is right for them, and then ask their doctor about it. If you are lucky enough to find a marketing partner who is well-versed in digital marketing and knowledgeable about virtual product tours, you may benefit from their advanced expertise.

### 10. Design for Manufacturability

Paramount to a successful end product is the importance of your device engineer working closely with the manufacturer in the design phase. This collaboration builds value into the product. For example, if design changes can be made to increase production efficiency while meeting the end-use requirements, it's a win-win for all involved. At the end of the day, the product needs to be able to be manufactured in a cost-effective manner, so design with the end in mind. Some of the many additional considerations in this development stage include the enterprise license, reproduction, territory, term, termination rights, fees, warranty and disclaimer, infringement indemnity, limitation of liability, assignability, and miscellaneous contract provisions..

### 11. Thinking Ahead

Transactional activities—business sales, mergers, acquisitions, due diligence, negotiations, and implementation—should initially be considered at the beginning of the process in terms of a potential exit strategy, and then revisited throughout the product development process. Sometimes, corporate partnering or strategic alliances are formed at this juncture in order to move the project ahead more efficiently. By way of definition, corporate partnering is not the same as a strategic alliance, in that a strategic alliance may be shorter in duration, less formal, and/or contain fewer contractual or transactional elements. Your business sales intermediary, often a financial advisor, should possess the knowledge and skills needed to execute these activities on your behalf..



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