



# Negotiating the innovation and regulatory conundrum

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## Introduction (the entrepreneurial environment)

There are many hurdles and issues to overcome when bringing a new medical device product to market in an entrepreneurial environment, particularly for entrepreneurs who have limited exposure to the requirements of the medical device market.

Hundreds of books and papers have been written about product development and innovation that lead one to believe it is just a matter of 'read and succeed'. These books may suggest the process, structure and concepts needed to bring new medical devices to market, but the knowledge they provide is obviously not enough. Success for any entrepreneur requires more than just having the idea behind the product or service, or having the drive and willingness to take risks.

Entrepreneurs, innovators and independent developers do not have the corporate resources that support development efforts in large organizations. What they lack in this respect they need to make up for in drive and creativity if they are to survive and be successful. From the original concept through to defining a marketable medical device, the demand for expert knowledge, financial resources and time are relentless. Drive alone can help the innovator address temporal demands, but often creativity and a compelling belief in the idea are all that they have to drive their efforts to find the expert knowledge and monetary support that is also required.

First and foremost, the product concept must address an unmet need or address a need in a more clinically or cost-effective way. This means solving problems that have not been solved or solving them in a new way. Secondly, getting that solution to market quickly and efficiently is critical. However, in the world of medical device development there is an interesting conflict between the rapid deployment of a new concept and the structure imposed by the regulated medical development process.

## Must innovation be chaotic? - The value of structure

That structure is a result of the fact that the medical industry is highly regulated. In order to prevent the restrictions imposed by regulations from being too burdensome, it is critical to understand not only what the regulations say but, more importantly, what they are trying to achieve and the value they can add. In fact, achieving commercialization and success is virtually impossible without this level of understanding. By intelligently applying the concepts embodied by regulations it is possible to proceed toward the market not just confident of regulatory approval, but getting there by the most efficient and effective path. While larger organizations typically have in-house resources to help them achieve this level of understanding, entrepreneurs will probably need to partner with regulatory and compliance consultants.

Too often entrepreneurs dismiss the structured approach called for by regulations as unnecessarily costly, time-consuming and a hindrance to the creative process. However, the common mistakes of proceeding with bad, untested assumptions, repeating previous mistakes and failing to address poor communication between collaborators are not efficient. The definition of success is the assurance that, as each new phase of development is embarked upon, the design team hasn't overlooked something that could jeopardize commercial success, or, worse yet, lead to injury or death.

From a fiscal point of view, the fundamental goal of venture capitalists, investment bankers and other potential sources of funding is to put their resources behind projects that have the highest possible chance of success. Be assured that poorly organized concepts and innovators who cannot show they have tested the assumptions their design is based on, who have not analyzed the market, or who have simply not documented their ideas thoroughly, will have serious investors looking for better investment opportunities.

If the entrepreneur's goal is to develop a concept or product in order to sell the design to an existing device manufacturer, rather than taking the product to market his or herself, it is even more important that they have used a controlled and documented process when developing the product. If you intend to be compensated for the effort you have put into developing the concept, that effort must be documented in a form that is accessible to the organization that buys the design. This should include concept documentation and much or most of the documentation as listed in Table 1.

**Table 1** – Typical types of documentation

Documentation	Definition (Explanation)
Product (Design) Specification (Separate Hardware and Software for Capital equipment)	A living document that describes the product requirements and becomes the Inputs that will need to be verified.
Quality Plan	A living document that defines the Design Verification (test) strategy from component parts to the final package validation.
Project Schedule	A document that defines the required steps and deliverables throughout the development phases.
Risk Management File	Documented through FMEA's (application, design, and process) that capture the risk profile.
Regulatory Strategy	A document that defines the Regulatory strategy (domestic and International)
Marketing Strategy	A document that defines the Target Market and general launch strategy.
Trace Matrix (Verification and Validation Matrix)	A document that captures the testing (outputs) required to comply with the Product Specification (Inputs).
Packaging and Sterilization Requirements	A document that defines the packaging and sterilization strategy for the product.
Usability requirements	Capture the voice of the customer

For the major markets of the world, regulations include FDA 21CFR part 820 (USA), ISO 13485 (EU), MDD 2007/47/EC (IVD and AIMD), CMDR (Canada), PMDA (now updated to PMD(Act)) (Japan). The elements of these regulations that are most critical for the independent innovator to understand are those related to the device development process: design controls (e.g. FDA 820.30). Design controls provide a tested and successful method to keep the development effort focused while allowing alternative paths to be explored. They help prevent basing endeavours on bad and untested assumptions and help ensure that the development team is headed in the same direction. Most importantly, they are an extremely effective tool in ensuring that aspects of the device that could result in harm to the patient or the user are identified as early as possible so they can be eliminated, guarded against, or at least weighed against the clinical benefits the device will provide. In short, design controls have one purpose: *to make sure there are no unpleasant surprises!*

The first thing we need to focus on solving is the product concept problem via unique solutions. The furthest thing from the minds of most entrepreneurs is structure. Their attitude towards it tends to be, 'at some point we will need to add structure'; but for right now, the solution must be found. In short, they believe that structure will conflict with creativity. However, this attitude is based on two fundamental misunderstandings:

1. The creative process must be fundamentally completely unstructured (chaotic).
2. The structure imposed by regulations is an 'all-or-nothing' barrier. By understanding the rationale behind each regulation you can apply the ones that are most applicable to the product at each design stage.

The reality of the creative process is that if some level of structure is not imposed, bad assumptions will result in wasted time, lack of coordination between team members, which can result in them going in conflicting directions, and lack of documenting failed alternatives, which can lead to repeating errors and losing successful elements of discarded alternatives. Worse yet, when a successful approach to solving the problem is found, much of that effort

can be lost because the minimum level of process structure and documentation (necessary for regulatory approval) was disregarded. In other words, you need to capture, through detailed documentation, the rationale behind the solution with supporting test data. However it must be kept in mind that regulations do not guarantee market success and acceptance as they are focused and written around safety and compliance.

In fact, regulations and standards that require a degree of structure and documentation be applied to the design process give a reasonable degree of latitude and improve the odds of success.

Structure ensures that the assumptions upon which the design will be based are evaluated before a commitment to a given direction is selected. It ensures that discoveries made as the design evolves are checked against those original assumptions to ensure they are still valid. As the development process continues, the level of structure increases as much as is necessary to ensure success without unnecessary detours or the repetition of mistakes. Progress is counterproductive when a team is rapidly heading down the wrong road or does not consider the barriers (standards and regulations) they will face later.

The level of documentation created should always be in proportion to the number of individuals involved and the complexity of the design.

When you have a team of horses, the harnesses are intended to make sure they are all pulling in one direction. In the design process, documentation assures that each member is aware of the progress and direction of fellow team member's efforts and keeps everyone focused on the next goal. Of course, this also means that the level of documentation needs to increase as the design becomes better and better defined, ensuring that no one is basing decisions on outdated information.

Even when there are only one or two individuals working on a concept, the number of alternatives explored quickly increases and the design itself evolves and becomes more complex. This means that it can become difficult for each individual to keep track, not just of what the other person is doing, but even of their own work. As the development process continues and by necessity new team members join the effort, documentation that shows where the design stands and where it has come from is crucial to bringing them on board quickly and coordinating their efforts.

Throughout the process, from the moment the 'light bulb' comes on and the concept is born to the first unit coming off the production line, the level of structure and documentation should increase in proportion to what is required to ensure that the team (regardless of numbers) stays on track and that there are no unpleasant surprises.

## The hurdles and issues of new product development for the entrepreneur

So you have the idea, you think you have the market opportunity defined, and you have consulted the regulations and have some structure in place. There are other hurdles that must be considered and dealt with from both a general business and regulatory perspective.

**Product definition:** Product definition can be a hurdle in the entrepreneurial environment as it is a bit counter to the creative process. You need to create a Design Specification, which is a living document that defines the inputs and becomes the specifications and drawings that the produced device must be verified against. Not only does the Design Specification define the product, it becomes the basis for the verifications that will be required. Aspects to consider include those in Table 2.

**Funding:** Numerous sources of funding can be considered, such as government grants, independent financing and local or state incubators.

Regardless of the source of funding, one of the first expectations of those providing financing will be that you demonstrate a solid understanding of your concept and that there are no unforeseen 'landmines'. The Design Specification can be your tool of communication that defines your product.

**Table 2** – Things to consider for a Design Specification

Requirement	Definition (Explanation)
Product Purpose and Description	A statement that defines the specific purpose of the Product along with a brief description that should include the Indication for Use and any other relevant clinical and technical application information.
Product Scope	A statement that defines the product(s) that will be characterized by the product specification.
Functional Requirements (Software and Hardware if applicable)	Specify what the device does, focusing on operational characteristics (inputs).
Interface Requirements	Specify external characteristics of the device including equipment, user and patient interfaces.
Performance Requirements and effectiveness	Specify how the device will perform (speed, accuracy, environmental...) and the acceptance criteria.
Safety Testing	Define the testing that will be required to meet both internal and external safety requirements
Product Appearance	Define the visual exterior elements (e.g. colour) of the product and how the product will be packaged and shipped, including the requirements for external labeling.
Sterilization Requirements	If the product needs to be sterile prior to use, define the sterilization method and exposure limits and stability requirements.
Biocompatibility Requirements	If the product will be in patient contact, define how the product will be characterized (Ref. ISO 10993-1).
Product Life	Define the Product Life Profile which will be needed to define reliability testing protocols.
Applicable Regulations and Standards	Reference regulations and external standard that require product compliance and testing including such items as quality systems, electrical testing, biocompatibility, sterilization, Aging...

Government grant applications and business incubator investment both require extensive descriptions of the concept and the basis on which it was developed. The concept must be clear, the environment in which the device will operate and the principals of operation must be logically presented, and next steps, right up to commercialization, need to be described.

In the case of independent finance sources; in addition to a firm understanding of the concept, they want to have confidence that your assumptions and conclusions have been vetted and that you have anticipated issues that could slow or stop progress to market.

Applying an escalating level of control throughout the design process and generating the appropriate amount of documentation will be of significant value when seeking funding, whether you are writing a grant application or business justification for incubators. When approaching independent financiers, the documented controls that have been applied will demonstrate insight into the demands of a successful endeavor.

In addition you must consider your long term plans for the product. Are you planning on maintaining the production of the product, selling and marketing it yourself, or through distributors? Commercialization plans are key, not only to understanding your financial needs, but also your regulatory path and needs.

**Human resources:** You must also consider your needs for Human Resources and finding the technical, regulatory, administrative and marketing expertise you do not have. Before you are ready to take on the financial burden of a direct staff you can utilize past work associates who are willing to moonlight or consultants. Adequate and clear design criteria and understanding of the market will help you find the resources you need.

Don't be afraid of listening to the experts, as a good advisor has practical experience to avoid the pitfalls.

**Facilities:** It is not uncommon to start your venture from your home or small office, but soon you must decide where the staff will reside and how the product will be manufactured. Again, a key understanding of the regulations is critical, especially if the device is going to be sold sterile and therefore require unique environmental controls. You can get assistance from local medical business incubators, outside suppliers with medical experience and certified facilities. You can always lease space or consider businesses with extra internal space to lease.

You will also need equipment to test and build devices. This equipment can be located through an internet search, contacting suppliers directly for used or refurbished equipment or a lease-to-buy agreement, and of course you can utilize outside suppliers (for capabilities that you need but can't provide internally). Keep in mind that all equipment used for device or process verification must be calibrated.

You will most likely need the services of outside labs that will be able not only to verify the performance of your device to industry standards, but that will have the certifications and equipment needed to be documented for future submissions. Keep in mind that outside test labs see a lot of devices but do not know your product, so your presence during the testing is strongly suggested.

Doctor examining a brain CT scan on a digital tablet



**Intellectual property:** You need to protect your idea through intellectual property, which requires an understanding of patent structure and law. It can be quite expensive if you lack these skills. The best way to proceed is to consult with a patent attorney and file early. One of the key elements of assuring intellectual property ownership is the documentation of the fundamental principles of operation and how those principals are implemented in the design. A structured process and evolving level of documentation can significantly decrease the effort associated with establishing ownership of the concept and obtaining rights. Most important is to remember to file early as the laws have changed over the years and ownership is no longer based on the invention date.

The ownership of the intellectual property behind your product can be the key barrier to prevent others entering your market space, and can also be your most valuable asset.

**Markets and regulations:** Decide what geographical markets you intend for the product and keep in mind that there is one rule when it comes to regulation: finding out later is always expensive and time consuming. Regulatory requirements are fundamentally similar in today's global environment. Having a solid understanding of the basics as early as possible is crucial. Understanding 'why' regulations require what they do is most important so that they can be applied appropriately for the phase of the design.

Market potential for new concepts can be extremely difficult to determine but offer the best opportunity for risk reward. What was the market potential for automobiles during the horse and buggy era?

One of the most common causes for the failure of 'start-ups' is ignoring regulatory requirements until a relatively mature design has been achieved only to find out that most of the work cannot be used in a final design that will meet regulatory minimums. This can necessitate repeating significant amounts of work and time taken to redesign and retest the product. This also can be very costly in financial terms as well as in terms of time (unanticipated delays to market).

Regulation ultimately attempts to ensure that the device is as safe as possible within the context of its clinical function. Regulations pursue this goal by ensuring that potential harms are understood (by controlling the development process) and that those harms are prevented.

Understand the value of risk management and document this early, since regulation is fundamentally a matter of controlling risks to an acceptable level. Risk management is the 'backbone' of all regulatory related activities. Risk management should be at the core of all design control activities and is the basis for scaling the design process from concept through development.

Risk management can also allow significant flexibility when applying product or design standards, so it is critical that you read the standards and take advantage of consultants and advisors with expertise in this area. Misinterpretation can lead to wasted efforts, as well as uncomfortable regulatory and quality system audits.

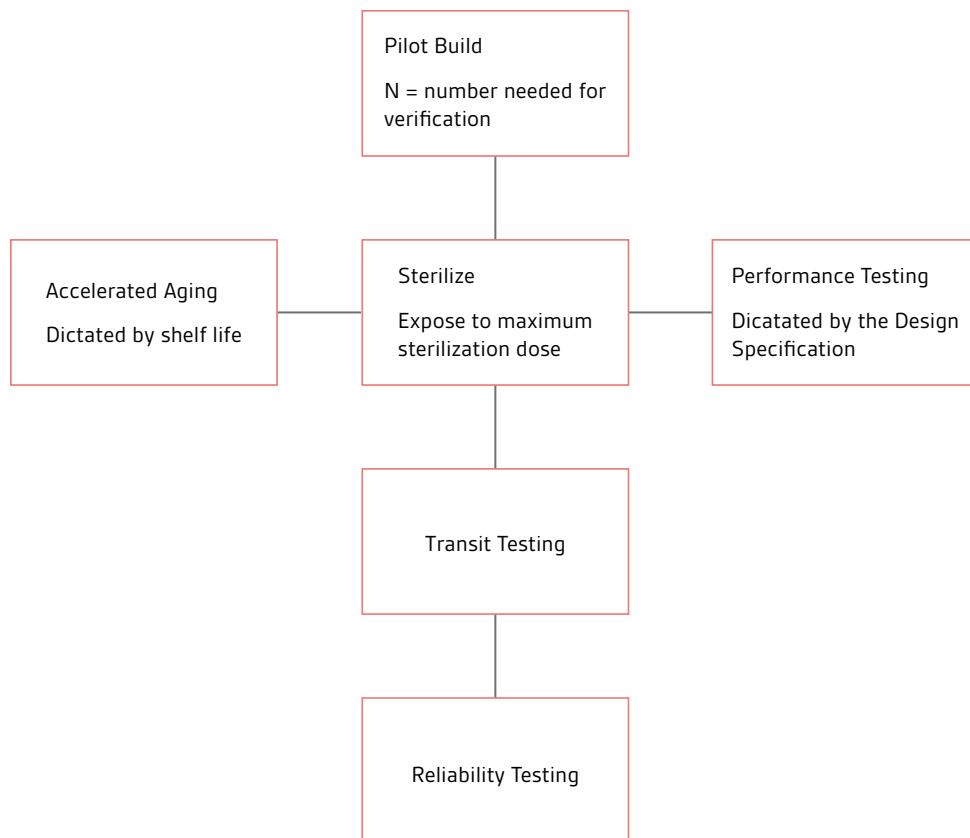
You must be able to show that you thoroughly understand the environment of use, the clinical and physiological processes involved and technologies being employed, as well as how these factors interact.

You must also demonstrate that you have identified all potential sources of harm associated with these characteristics and have either applied recognized means of controlling the risks (such as product standards) or have developed and validated your own unique means of controlling them.

It is strongly suggested, if you do not have this expertise, to involve someone with a solid understanding of regulations and engage with regulators as early as possible. Even if you intend to handle the regulatory submission yourself, consider collaboration with one or more regulators as soon as the concept has evolved enough to allow it to be presented coherently. Contrary to the view taken by most entrepreneurs and even many manufacturers, regulators do not want to see you fail; they want you to succeed and are glad to help guide you toward success. Yet again, the value of appropriate levels of documentation is inestimable.

**Verification:** Verification is another hurdle you will need to overcome. The product definition or specification needs to be verified through product testing. These tests may involve accelerated aging/stability, reliability, and transit testing, and must show how the initial requirements (design inputs) became specifications and drawings, and that the device produced based on those drawings achieves the initial requirements. This test data may be pertinent to obtaining funding and will be critical to your regulatory submission(s) as mentioned earlier. An excellent way to capture and understand the verification requirements is through the use of a Quality Plan that defines the requirements for each verification test and maps (see Figure 1) the verifications required. Building the incorrect number of pilot devices or not utilizing statistically significant sample sizes can cost time and money.

**Figure 1** – Typical design verification flow chart



Each test is an issue and hurdle within itself as each is an individual requirement that you must pass. In the end, be able to show how the original concept developed and evolved into the device that was created.

This is only practicably achievable when the process has some appropriate level of structure and where documentation shows the assumptions made and how they were evaluated, and the resulting conclusions evolved within that structure.

**Regulatory filing:** Early on you should have decided not only where the device will be marketed, but also how it will be classed, as this is critical in determining the applicable standards and regulations so that they can be addressed throughout the design process. They are now needed for the regulatory filing(s). Having experience in this area or contracting someone with regulatory expertise is critical to successful approval(s). Poor documentation, questionable results, report deviations, or poorly structured clinical trials or evaluations can create huge delays as they often cause the approval clock to start over with each set of regulatory responses.



## Release it to the market

If you have done your homework you will have developed a product that meets all of the regulatory and design requirements. This includes completing all of the design verification tests and documenting how the original concept developed and evolved into the final device. Finally, there will be evidence that the performance of the product has been validated against the original design inputs and that it meets the safety, clinical and market requirements that were the foundation of the concept.

This is only practicably achievable when the development process had an appropriate level of structure, where there is documentation of the assumptions made and how they were evaluated and the resulting conclusions that evolved within that structure.

In the end, if you treat the structure and documentation called for by regulations and standards as an unnecessary burden that serves no purpose, you guarantee that it will be just that (it will become a self-fulfilling prophecy). If you recognize it as a tool for efficient and effective development and deployment of that 'gem' you have in the back of your mind, then you will have increased your chances of success significantly.

And finally, all of the documentation created throughout the development process will be utilized through the life of the product as a starting point that can be used in the event of field inquiries, part or material obsolescence, or manufacturing changes.

It's all up to you...

Wrist watch with interface



## Useful resources

International Medical Device Regulatory Forum <http://www.imdrf.org/index.asp>

FDA Guidance Documents <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

FDA Recognized Standards List <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/simplesearch.cfm>

EU New Approach Directives list with links to list of harmonized standards <http://www.newapproach.org/Directives/Default.asp>

MDD Guidance Documents [http://ec.europa.eu/health/medical-devices/documents/guidelines/index\\_en.htm](http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm)

Health Canada Recognized Standards <http://www.hc-sc.gc.ca/dhp-mps/md-im/standards-normes/index-eng.php>

Chinese Regulatory Information <http://www.cmdi.gov.cn>

CENELEC Home Page <http://www.cenelec.eu>

CEN Home Page <http://www.cenorm.be/cenorm/index.htm>

IEC/SC 62A Dashboard (IEC 60601-1 and IEC 60601-1 Collateral Standards) [http://www.iec.ch/dyn/www/f?p=103:7:0:::FSP\\_ORG\\_ID:1359](http://www.iec.ch/dyn/www/f?p=103:7:0:::FSP_ORG_ID:1359)

IEC/SC 62D Dashboard (IEC 60601-1 Device Particular Standards) [http://www.iec.ch/dyn/www/f?p=103:7:0:::FSP\\_ORG\\_ID:1365](http://www.iec.ch/dyn/www/f?p=103:7:0:::FSP_ORG_ID:1365)

ISO Home Page <http://www.iso.org/iso/en/ISOOnline.frontpage>

BSI is grateful for the help of the following people in the development of the white paper series.

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## Published white papers

*The Proposed EU Regulations for Medical and In Vitro Diagnostic Devices – An Overview of the Likely Outcomes and the Consequences for the Market*, Gert Bos and Erik Vollebregt

*Generating Clinical Evaluation Reports – A Guide to Effectively Analysing Medical Device Safety and Performance*, Hassan Achakri, Peter Fennema and Ito Udofia

*Effective Post-market surveillance – Understanding and conducting vigilance and post-market clinical follow-up*, Ibim Tariah and Rebecca Pine

*What You Need to Know About the FDA's UDI System Final Rule*, Jay Crowley and Amy Fowler

*Engaging Stakeholders in the Home Medical Device Market – Delivering Personalized and Integrated Care*, Kristin Bayer, Laura Mitchell, Sharmila Gardner and Rebecca Pine

## Forthcoming papers

*The Growing Role of Usability and Human Factors Engineering for Medical Devices: What is Required in the New Regulatory Landscape?*, Robert North (February, 2015)

*The Proposed Changes to ISO 13485*, Bill Enos (March, 2015)

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